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| Access to Genetic Resources and Intellectual Property Rights: Opportunities and Perils for Developing Countries Rich in Biodiversity and the Pharmaceutical Industry |
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A thesis submitted in partial fulfilment of the requirements of Sheffield University for the Degree of MPhil

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This thesis is dedicated to Anita, Daniela, Leo, Nidia, Oscar and Yuri   
who are   
my strength, my life, my family

**Abstract**

This thesis analyses the regulation on access to genetic resources and access to technologies that employ genetic resources for drug development in Colombia. This normative legal analysis is based upon the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPs) and the International Regime on Access to Genetic Resources and Benefit Sharing (ABS or the ABS regime). India and China are also analysed since these countries offer comparator regions and industries’ capacity against which Colombia can be contextualized in the global market. As a result, this thesis analyses the capacity of India, China and Colombia in the drug development process, the global market and the importance of genetic resources for the pharmaceutical industry. To address the question of improving Colombia’s capacity in technologies that employ genetic resources for drug development, this thesis suggests a number policies and legal mechanisms which centre on entitling this country to obtain benefit sharing from the utilisation of genetic resources by allowing access to genetic resources in exchange for access to technology according to the country’s capacity, and the different compromises acquired in TRIPs and the ABS regime.

**Declaration**

I declare that this thesis is my own work and it has not, in whole or in part, previously been presented by me to this or any other university for the conferment of any degree.

**Acknowledgements**

As a school student I was taught that despite the fact that Colombia was not a developed country, it was rich in biodiversity, and that would make it an important country for sectors such as the pharmaceutical and agricultural industries. Thanks to that view of how we perceive our own country, I have been always interested in exploring whether such a conception is true. Then, it is obvious that I should now thank Colombia for being the seed of instigation to write this thesis.

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Of course, any errors or omissions are my own.

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* Kenya the Industrial Property Act 2011
* Uganda Patent Act 1993
* The Zanzibar Industrial Property Act No 4 2008 (Tanzania)

**The Andean Community of Nations**

* Agreement of Andean Sub-Regional Integration Agreement or Cartagena Agreement signed on 26 May 1969 and modified by the Trujillo Protocol of 1996
* Decision 85 of the Andean Community of Nations approved on 27th May of 1974 in Lima, Peru
* Decision 311 of 1991 Common Regime on Industrial Property as signed on November 8, Caracas
* Decision 344 of 1993 Common Regime on Industrial Property as signed on October 21, Bogotá

Decision 391 of 1996 Common Regime on Access to Genetic Resources, as signed in Cartagena (Colombia) July 2

* Decision 523 Regional Biodiversity Strategy for the Tropical Andean Countries as signed in Lima, Peru on 17th of July 2002
* Decision 632 of 2006 on the Clarification of the Second Part of Article 266 of Decision 486 of 2000 as signed on 6 April 2006, Lima, Peru
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**Brazil**

* Brazilian Patent Act (*Lei de Propriedade Industrial, Lei 9.279/96*)

**China**

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* Patent Law of the Peoples Republic of China (Adopted at the Fourth Meeting of the Standing Committee of the Sixth National People’s Congress and Promulgated by Order No. 11 of the President of the People’s Republic of China on March 12, 1984, and effective as of April 1)

Patent Law of the People’s Republic of China Adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on March 12, 1984, Amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 27th Session of the Standing Committee of the Seventh National People's Congress on September 4,1992, Translated by the Patent Office of the People's Republic of China)

**Colombia**

* Act 99 of 1993 or Environmental Act
* Act 100 of 1993 or Social Security Act
* Act 152 of 1994 Colombian Act of the National Development Plan
* Act 165 of 1994 (which Implements the CBD in Colombia)
* Act 1340 of 2009 or Competition Act

Colombian Constitution of 1991

Decree 597 of 1904 on Convention on Industrial Property with France

* Decree 410 of 1971 Colombian Codex of Commerce
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* USA and Colombia Governments- “Understanding Regarding Biodiversity and Traditional Knowledge” (November 22 of 2006)
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**European Union**

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* EMA Good Manufacturing Practice for Active Pharmaceutical Ingredients (CPMP/ICH/4106/00)
* EMA Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Herbal Medicinal Products (Final) (EMA/HMPC/CHMP/CVMP/287539/2005 Rev 1, 2010)
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**India**

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**Central America**

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**United Nations**

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* Stevenson-Wydler Act of 1980 (Public Law 96-480)
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**World Trade Organization**

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Ministerial Declaration, Fourth Season of the Ministerial Conference Adopted in Doha on 14 November 2001

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* *Novartis v. Union of India* [2013] Indian Supreme Court of Justice (Civil Appeal Nos. 2706-2716 of 2013)

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* *Amgen, Inc v. Chugai Pharmaceutical Co, Ltd* [1991] US 927.F.2d 1200
* *Association for Molecular Pathology et al. v USPTO* [2010] 702 F. Supp 2d 181 (SDNY)
* *Association for Molecular Pathology et al. v USPTO* [2011] Fed. Cir., No. 2010-1406

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**Abbreviations**

ABS Regime International Regime on Access to Genetic Resources and Benefit Sharing

ACN Andean Community of Nations

ATJ Andean Tribunal of Justice

BIO Biotechnological Industry Organisation

CBD UN Convention on Biological Diversity

CGIAR Consultative Group on International Agricultural Research

CHM Clearing-House Mechanism

CR Contribution Regime

CROs Clinical Research Organisations

CSIR Council for Scientific and Industrial Research (South Africa)

EMA European Medicine Agency

EBL Enquiry-Based Learning

EPC European Patent Convention

EPO European Patent Office

EU European Union

FAO Food and Agriculture Organization

FDA USA Food and Drug Administration

FDI Foreign Direct Investment

FTAs Free Trade Agreements

GATT General Agreements on Trade and Tariffs

HMPC EMA Committee on Herbal Medicinal Products

ICBG International Cooperative Biodiversity Groups

ICCP Intergovernmental Committee for the Cartagena Protocol on Biosafety

IFPMA International Federation of Pharmaceutical Manufactures and Associations

IGC Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

INBio Costa Rica’s National Biodiversity Institute

IPO United Kingdom Intellectual Property Office

IPRs Intellectual Property Rights

IRCC Internationally Recognized Certificate of Compliance

IUCN International Union for Conservation of Nature and Natural Resources

ITPGRF International Treaty on Plant Genetic Resources for Food and Agriculture

JPO Japanese Patent Office

LDCs Least Developed Countries

MA Marketing Authorisation

MATs Mutually Agreed Terms

MCIC Indian Ministry of Commerce and Industry

NP Nagoya Protocol

NPDS The National Patent Development Strategy (2011-2020) (China)

OP Opposition Division of the EPO

PCT Patent Cooperation Treaty

PIC Prior Informed Consent

PLT Patent Law Treaty

POSPlan Obligatorio de Salud

R&D Research and Development

SAI State Members and the Andean System of Integration or SAI

SICSuper Intendencia de Industria y Comercio (Colombian IPR Office and Antitrust Office)

SIPO Chinese State Intellectual Property Office

SMES Small and Medium Enterprisers

SR Subsidised Regime

TRIPs Agreement on Trade-related Aspects of Intellectual Property Rights 1994

TKDL Indian Traditional Knowledge Digital Library

UN United Nations

UNCTAD UN Conference on Trade and Development

UNIDO UN Industrial Development Organization

UPOV International Union for the Protection of New Varieties of Plants

US United States of America

USPTO US Patent and Trademark Office

WHO World Health Organization

WIPO World Intellectual Property Organization

WTO World Trade Organisation

Introduction

This thesis focuses on the regulation of access to genetic resources and access to technologies that employ genetic resources for drug development, and the impact of this regulation on the pharmaceutical industry in developing countries rich in biodiversity, especially Colombia. Biodiversity is an important source for the drug development process as it supplies components for it, i.e. genetic resources (see Annex I). This normative analysis is important in the context of Colombia because of its genetic resources availability and its actual interest in employing those resources for drug development. Indeed, since Colombia is a country with high biodiversity (Annexes II and III), Colombia’s authorities have pointed out that biodiversity is a key asset to increase capacity in Colombia’s pharmaceutical industry. [[1]](#footnote-2)

However, this thesis identifies that the drug development process involves different sets of skills and abilities from discovery to clinical trials and the manufacturing of medicines, as well as a range of stakeholders (e.g. generic companies, originators, publicly funded organisations, etc.) that give shape to the global pharmaceutical market. This means that a normative analysis of Colombia regulations on access both to genetic resources and technology should not only be centred on the availability of those resources and Colombia’s interest in employing them, but also in assessing Colombia’s capacity in the drug development process, the global market and the importance of genetic resources for the pharmaceutical industry.

As a result, the normative analysis carried out by this thesis, is based upon the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPs)[[2]](#footnote-3) and the International Regime on Access to Genetic Resources and Benefit Sharing (ABS or the ABS regime); to carry out this normative analysis, three important elements are studied in detail throughout the thesis: capacity, global markets in the pharmaceutical industry, and genetic resources. Therefore, before the research question, the methodological approach, theoretical framework, scope and road map of the thesis are explained, it is important to analyse these three elements.

**Capacity**

This thesis focuses on developing countries’ capacity in technologies that employ genetic resources for drug development. The term ‘capacity’ has been employed in economic and social development, particularly related to skills and abilities for development. Programmes and mechanisms that aim to increase countries’ capacity are known as capacity building initiatives or programmes. Therefore, capacity involves the importance of increasing those specific skills and abilities. In other words, capacity building has been constructed by creating capabilities for sustainable economic development since concerns such as poverty, natural resource management and climate change have taken on international relevance.[[3]](#footnote-4) It is through capacity building initiatives or programmes that international organisations such as the United Nations are focusing efforts to create different mechanisms to improve economic development in developing countries and least developed countries (LDCs) according to each country’s own capacity. However, the terms ‘capacity’ and ‘capacity building’ are not exclusive to economic and social development, but have also been employed in other areas. For instance, *Promoting Access to Medical Technologies and Innovation to Medicines*, a the trilateral work carried out by the World Health Organisation (WHO), World Trade Organisation (WTO) and World Intellectual Property Organisation (WIPO), is a policy document for developing countries to increase capacity for ‘areas of intersection between health, trade and IPR’ related to access and innovation of medicines.[[4]](#footnote-5)

In the same way, there is no a single definition of developing countries as there are different levels of economic and social development in different countries, but the term usually refers to countries in which the gross national income (GNI) per capita does not exceed US$ 12,746 per year. Indeed, this category includes middle-income economies such as Colombia (US$ 7,010 GNI per capita) as well as more industrialised countries such as China (US$ 5,720 GNI per capita) and India (US$ 1,150 GNI per capita). Developing countries should not be confused with LDCs, the latter being a category of countries with high disadvantages in economic and social development. The UN has developed and established lists of LDCs and criteria.[[5]](#footnote-6) LDCs are countries that meet two out of three criteria: a low-income (GNI per capita below US$ 905); a human assets weakness that includes nutrition, health, etc.; and economic vulnerability that involves, for instance, trade shocks. The importance of the developing countries and LDCs’ categories is that it gives a different treatment or prioritisation in diverse areas of international law and economic development; for instance, it helps to obtain grants and loans from donors and financial institutions such as the World Bank.

Capacity complements this categorisation of countries since it provides tools to compare, assess and create a legal mechanism that responds to countries’ capacity in particular issues. In the case of access to genetic resources and to technology, this categorisation and capacity matters as it is given a different treatment and mention in the ABS regime and, in particular, TRIPs. Indeed, TRIPs granted developing countries a period of transition until 2005 to set up minimum standards in patent protection while it extended this transit period for LDCs until 2016 for pharmaceutical products.[[6]](#footnote-7) Furthermore, the Doha Declaration on the TRIPs Agreement and Public Health also allows members of the WTO, particularly LDCs, that have insufficient or no manufacturing capacities in their pharmaceutical sector, to issue compulsory licences to import pharmaceutical products from other countries.[[7]](#footnote-8) Equally, the Nagoya Protocol (NP) calls on States to prioritise efforts to increase the capacity of developing countries and LDCs. Indeed, capacity is a key element for the ABS regime. For instance, Article 22 of the NP establishes that States should aim to increase capacity in developing their own ‘endogenous research to add value to their own genetic resources’. In other words, capacity, in the context of access to genetic resources and to technology, seeks to assess and increase developing countries’ and LDCs’ capacity in the utilisation of their own genetic resources. Therefore, capacity aims at countries addressing regulation and policies on access to genetic resources and to technology according to their own capacity which, in the case of this thesis, refers to the drug development process.

Therefore, capacity in the drug development process requires further analysis; the process involves different stages: discovery, pre-clinical development, clinical trials, manufacturing, and marketing (see Annex I). The discovery stage involves basic research in order to understand and advance knowledge of genetic resources and applied research.[[8]](#footnote-9) Basic research on genetic resources as such that are available in nature (*in situ*) involves taxonomy activities or bioprospective initiatives. Taxonomy is the science of discovering, naming, describing and classifying organisms to understand their biodiversity. [[9]](#footnote-10) Therefore, through taxonomy activities, genetic resources are discovered, named, described and classified; while bioprospecting initiatives involve the activities of scanning and scoping of biodiversity for the collection of new biochemical compounds for drug production based on genetic resources.[[10]](#footnote-11) Eventually, these genetic resources are collected in *ex situ* collections (e.g. botanical gardens, genetic banks, compound libraries).[[11]](#footnote-12) In due course, genetic resources are isolated and/or synthesised to find new biochemical compounds or entities for drugs (applied research). The discovery stage includes organisations such as universities, botanical gardens, collections, etc.

Basic research is usually publicly funded and academic-related, rather than having a commercial interest, which means that governments play the role of providing funds and making knowledge available to carry out further research in this stage; however, it does not mean that publicly funded research does not have a commercial purpose. Technological breakthroughs, e.g. gene sequencing and legislation such as the US Bayh-Dole Act, have led publicly funded institutions to seek patent protection in the early discovery stage of promising compounds and to license or create partnerships with private companies.[[12]](#footnote-13) Equally, small labs (start-ups) that have emerged from universities rely heavily on the patent protection of new biochemical compounds as their portfolio involves either a single or a few compounds which they hope to license to downstream users in subsequent stages of the drug development.

In a second stage (pre-clinical development), the compounds are assessed in laboratories and tested on animals to anticipate their safeness and effectiveness for humans. If there is a promising compound, it is taken to the next stage of the drug development process, i.e. clinical trials, which involve four different phases: Phase I investigates the safety of the drug by testing it on 200-400 healthy volunteers; Phase II assesses if the product has any therapeutic value for patients (between 400-600); and Phase III makes an evaluation of the efficacy of the therapeutic value and side effects by comparing the product with other treatments – in this phase at least 3,000 patients are required;[[13]](#footnote-14) Phase IV involves an assessment of the long-term risks, benefits and optimal use, after a product has already been approved and is on the market.

It is the clinical trials stage which requires the most economic resources. Indeed, the cost of taking a medicine through clinical trials represents 15.5%[[14]](#footnote-15) of turnover of originator companies involved in the trials. Traditionally, large originator companies, such as Novartis or Pfizer, located in developed countries are involved in clinical trials, but there has been increased licensing of clinical trials by other stakeholders in the drug development process. For instance, there are clinical research organisations (CROs), e.g. Quintiles (the largest CRO in the world) which partners with large pharmaceutical companies such as Novartis, Merck and Pfizer, to carry out clinical trials.[[15]](#footnote-16) CROs and large originator companies have also shown interest in carrying out clinical trials in developing countries such as India and China, because of the lower costs, and the greater population size and diseases burden.[[16]](#footnote-17)

If the product goes through clinical trials successfully, it requires marketing authorisation (MA); when this is obtained the product can be manufactured and launched on the market. It is originator companies which normally undertake the cost of MA and marketing as they control the distribution and manufacturing of medicines through exclusivity mechanisms such as patent protection. Additionally, clinical trials and MA require complying with specific and robust regulation that aims to provide safe, quality medicines. For instance, the European Union (EU) has enacted legislation in order to harmonise different aspects of the regulation of the drug development process in the Union, which include regulation on the following: clinical trials, which provides legal protection for participants in clinical trials; manufacturing authorisation, which involves control over premises, equipment and facilities for drug production; MA, which is a risk-benefit and efficacy assessment of drugs before they enter the market; pharmacovigilance, that takes place after the MA has been granted; labelling and packaging, compensation and advertisement.[[17]](#footnote-18) Developing countries also regulate different aspects of the drug development process, e.g. the Chinese Drug Administration Law and the Indian Drugs and Cosmetics Act and Rules.[[18]](#footnote-19)

The WHO also identifies that in manufacturing there are three different levels of production that reflect countries’ capacity. First, primary production of medicines (i.e. manufacturing of active pharmaceutical ingredients, mixing and packing them) is highly concentrated in five developed countries (the US, Japan, Germany, France and the UK).[[19]](#footnote-20) However, countries such as India and China are also able to carry out primary production of medicines, a situation that has led them to have a large volume production of lower priced medicines.[[20]](#footnote-21) Second, other developing countries such as Colombia have developed a generic industry capable of the mixing of active pharmaceutical ingredients and the production of different dosage formulations (i.e. secondary medicine production).[[21]](#footnote-22) Finally, LDCs mainly focus on packaging and small-scale production of medicines (tertiary manufacturing).[[22]](#footnote-23)

Because the drug development process involves different stages, regulations and stakeholders, studies have estimated that the entire drug development of a new drug or originator (from discovery to marketing) could cost up to US$ 1.3 billion and take up to 15 years.[[23]](#footnote-24) However, the cost of the drug development process varies, depending on the source of information, time periods and methods that were employed to estimate the cost. These figures have been questioned for their lack of transparency, as they do not disclose, for instance, information related to names of companies and products due to confidentiality issues.[[24]](#footnote-25) Yet, the trilateral study carried out by the WHO, WIPO and WTO points out that despite the fact that there is a lack of transparency in assessing drug development cost, it is indeed high.[[25]](#footnote-26)

The cost and time to develop a drug requires that originator companies not only take into account the potential of biochemical compounds based on or derived from genetic resources but also that it demands important economic resources and technologies to develop new treatments. This is more relevant since it is only one out of 1,000 compounds (in the discovery stage) that can make it through the whole drug development process (from discovery to marketing) and become originators (see Annex I).[[26]](#footnote-27)

As a result, originators are subject to patent protection. Patents on pharmaceutical inventions can be granted from the discovery stage providing they are new,[[27]](#footnote-28) involve an inventive step[[28]](#footnote-29) and are capable of industrial application.[[29]](#footnote-30) This aims to encourage users of genetic resources (including universities, labs and large originator companies) to invest time and resources in the development of originators based on genetic resources. Although large originator companies were considered to be economically and technically capable of taking a compound through the whole drug development process (in house R&D),[[30]](#footnote-31) the participation of publicly funded institutions such as universities and start-ups provides different dynamics in the drug development process. This is because publicly funded institutions and small companies cannot afford to go through all the stages so rely on originator companies to take promising compounds further up the drug development process. For instance, there is the case that bioprospecting initiatives in developing countries (in which small labs and universities participate) might identify a promising biochemical compound that could become an originator, but they do not have enough capacity to take the compound through the pre-clinical and three phases of clinical trials and MA. A patent grants exclusivity to users in the first stages of the drug development to reach agreements with other users to take a biochemical compound through the rest of the drug development, especially clinical trials, MA and marketing.

This is why a common justification for providing patent exclusivity to industries, such as the pharmaceutical industry, is that despite the fact it grants the right of exclusivity over an invention, patents promote further R&D by disclosing information on how to carry out an invention. This enables the proliferation of technology, especially once the exclusivity period has expired, information that otherwise would be protected by trade secrets.[[31]](#footnote-32) In the case of the pharmaceutical industry, biochemical compounds based on genetic resources could be kept in *ex situ* collections and not publicly disclosed if adequate patent protection is not given. However, a more realistic approach is that there are self-revealing inventions, such as pharmaceutical inventions, that do not have any other option than to obtain patents as the pharmaceutical industry could not afford to protect their inventions through secrecy.[[32]](#footnote-33) In other words, despite the cost and time required for the discovery of new biochemical entities, most pharmaceutical inventions could be self-revealing and replicated by competitors, particularly generic pharmaceutical companies.

Generic pharmaceutical companies manufacture and commercialise originators whose patents have expired, i.e. generic medicines. Generic medicines are medical products that have the same qualitative and quantitative composition in active pharmaceutical ingredients (bulk pharmaceuticals) and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference (originators) has been demonstrated by appropriate bioavailability studies.[[33]](#footnote-34) Generic companies also have to obtain MA in order to commercialise generic medicines. However, there are generic producers who, although a patent has not come to an end, still manufacture and distribute them anyway. Warren-Jones identifies these pharmaceutical products as ‘illegal generics’,[[34]](#footnote-35) which does not refer to counterfeit medicines or copycat drugs. These two latter terms are linked to medicines that do not even meet the quality and safety standards needed to be legally commercialised, hence could affect patients’ health.

The three product-market identities (i.e. originators, generics and illegal generics) are important elements not only to assess what is capacity in the drug development process but also to explain the shift in the global pharmaceutical market. The shift in global markets is an analytical approach adopted from the academic research of Warren-Jones who argues that this global shift is the result of the way that both developing countries and LDCs have adapted to comply with TRIPs and the ABS regime. [[35]](#footnote-36)

**The Global Markets in the Pharmaceutical Industry**

Capacity does not only serve as a benchmark to assess what the abilities or skills in the drug development process are, but also provides an understanding of how the pharmaceutical market is transforming globally. This is because States, particularly those which used not to recognise patent protection, are transforming their pharmaceutical industry in order to comply with international standards of patent protection set up by TRIPs, which is part of the agreements related to the international trade of the WTO, and amplified by Free Trade Agreements (FTAs), also known as TRIPs-Plus standards. TRIPs-Plus provisions include limits to the use of compulsory licensing (which grants the right to (usually) local producers to manufacture a patent invention without the consent of the patent holder, provided they meet some conditions (i.e. compensation)),[[36]](#footnote-37) data exclusivity (i.e. protection over the data or test employed to obtain MA in pharmaceutical products) and patent linkage (the linking between the process of obtaining MA and patent status).

Indeed, Warren-Jones identifies that originator companies are naturally located in developed countries since these countries offer a greater degree of protection to originators as well as originator control distribution and manufacturing; while developing countries which used to manufacture and distributive illegal generics, are moving towards production and manufacturing of generic medicines, and distribution towards other developing countries and developed countries.[[37]](#footnote-38) Finally, LDCs, which have little capacity to manufacture and distribute medicines, are filling the gap of illegal generics left by developing countries as the latter have moved from illegal generics towards generics.[[38]](#footnote-39)

As a result, developed countries have delivered policies that aim to encourage drug development within their territory, by granting patent protection on their inventions and by facilitating access to starting material such as genetic resources *in situ*. In order to encourage and increase the production of originators, developed countries campaign for originator companies to obtain patent protection on their invention ahead of generic pharmaceutical companies located in developing countries. This is particularly reflected in TRIPs, as the aim of TRIPs is to set up minimum standards, within Members of the WTO (including developing countries and LDCs), and substantive rules in intellectual property rights (IPRs), including patents. Therefore, developed countries also demand that developing countries allow users of genetic resources to easily access those resources and reduce any administrative burden that deters R&D, especially in the discovery stage of the drug development process.

However, although developing countries lack capacity to carry out the entire drug development process, they have increased their capacity to manufacture and distribute generic medicines. India, China and other developing countries, such as Colombia, are consolidating production and distribution of generics both in developing and developed countries, as their cost of production and manufacturing is lower than in developed countries. Furthermore, even if there is patent restriction on the manufacturing and distribution of generics, these countries are entitled to circumvent patents on pharmaceutical inventions and reduce the exclusivity rights of patent holders within their territory through mechanisms such as compulsory licensing. By excluding pharmaceutical inventions and reducing exclusivity rights, developing countries seek to create a competitive, local generic pharmaceutical industry. Finally, LDCs play an increasing role in the global market since they are filling the gap that developing countries have left behind as the latter have moved from illegal generics towards generics. This results in new centres of production and/or distribution of illegal generics with an opportunity for LDCs to increase capacity, as TRIPs granted a transition period time up to 2016 to implement minimum standards of patent protection on pharmaceutical products.[[39]](#footnote-40)

In terms of access to genetic resources, developing countries rich in biodiversity also aim to obtain benefits from the utilisation of genetic resources by trading access to them for access to technology, as regulated in the ABS regime which includes three different international instruments: the Convention on Biological Diversity (CBD),[[40]](#footnote-41) the Bonn Guidelines[[41]](#footnote-42) and the NP.[[42]](#footnote-43) In addition, these countries have campaigned for developed countries to implement locally measures that oblige users of genetic resources to comply with the ABS regime. This means that countries rich in biodiversity, and hence rich in genetic resources, are entitled to trade off genetic resources for access to technology. The next section identifies what the role and importance of genetic resources is for the pharmaceutical industry.

**Genetic Resources**

Although the scope of the nature of genetic resources is a matter of discussion in this thesis, the definition of genetic resources as such includes genetic material (from plants, microorganisms and animals) and the information encoded in the DNA or RNA. Equally, traditional knowledge associated with genetic resources is also an important element for drug development as local or indigenous communities through their ancient knowledge of plants could facilitate the discovery of new biochemical compounds.

For the pharmaceutical industry, genetic resources form the starting material in the drug development process. Different studies indicate that between 25% and 50% of medicines in the market are based on compounds that originate in, or are derived, from genetic resources.[[43]](#footnote-44) Those compounds are usually small molecules that could derivate from generic resources. Those compounds are usually small molecules that could be derived from genetic material from plants. Instead, Biopharmaceuticals are usually derived from human tissues or cells, or components of human blood, such as antibodies, cytokines, growth factors, hormones and clotting factor products; since there are derived from human beings, they are not within the scope of the regulation on access to genetic resources;[[44]](#footnote-45) but there have been examples of hormones synthesised from natural products, such as the *barbaso* (a species of yam) in Mexico, which was employed in the production of cortisone and contraceptive pills.[[45]](#footnote-46)

Furthermore, despite the fact that there has been a decrease in the number of new biochemical compounds or entities approved by the US Food and Drug Administration (FDA), Cragg et al. point out that there have been 1,073 small molecules that have led to new biochemical entities related to genetic resources in the period from 1980-2010.[[46]](#footnote-47) Although Cragg et al. also identify that 66% of those small molecules are ‘formally synthetic’, they highlight that they were either derived from or inspired by natural products.[[47]](#footnote-48) Indeed, 16% of those formally synthetic molecules contain ‘pharmaphores[[48]](#footnote-49) derived directly from natural products’, while 14% of the molecules were models of ‘a natural product inhibitor of the molecular target of interest’ or they mimic ‘the endogenous substrate of the active site’.[[49]](#footnote-50) This means that only 36% of the 1,073 molecules were purely synthetic or free from any natural inspiration.

Nonetheless, it is important to mention that some of those new biochemical entities could be developed from existing compounds which had already been discovered. For instance, Telavancin (marketed under the name of Vibativ to treat infections) is a derivate of Vancomycin and was launched on the US market in 2009.[[50]](#footnote-51) Vancomycin was isolated for the first time in 1953, after a missionary in Borneo sent a sample to the originator company Eli Lilly. [[51]](#footnote-52) Furthermore, Oldham et al.’s paper on patent activity on biodiversity estimates that the research activity on genetic resources and traditional knowledge associated with genetic resources is very low as it represents only 4% of taxonomically described species on the planet.[[52]](#footnote-53) Nevertheless, as molecular biology tools have become faster and cheaper, research centres such as the National Institute of Cancer in US have maintained interests in carrying out bioprospecting projects in areas rich in biodiversity such as Panama (i.e. the Panama International Cooperative Biodiversity Group (ICBG)).[[53]](#footnote-54)

De Luca et al. also highlight that despite the fact that originators have lost interest in genetic resources due to the costly chemical synthesis of small molecules, the low cost of gene sequencing is increasing the possibility of research on new pathways and enzymes of genetic resources, as well as different technologies (e.g. virus induced gene (VIG) silencing, RNA interference (RNAi), and improvements in RNA isolation) that help to identify gene functions.[[54]](#footnote-55) These developments could lead to the creation of new medicines or improvement of existing ones based upon genetic resources.[[55]](#footnote-56) Oldham et al. [[56]](#footnote-57) and Kursar et al.[[57]](#footnote-58) also find that biodiversity represents an important source for the treatment of neglected diseases, i.e. diseases that affect large populations in developing countries and LDCs, and in which there are no, or few, medicines to treat them. Oldham et al. highlight that research activity on neglected diseases is increasing in both developed and developing countries, particularly in bacterial infections (e.g. leishmaniasis and trypanosoma brucei).[[58]](#footnote-59) Even more, Oldham et al. call on large economies such as India and China to engage in R&D on species that could treat these diseases as these countries’ capacity could improve the development of new treatments.[[59]](#footnote-60)

There are also other examples of potentially new biochemical compounds to treat diseases such as cancer being derived from genetic resources, including the *Croton* and *Jatropha* plants located in areas rich in biodiversity.[[60]](#footnote-61) Therefore, although originators have lost interest in genetic resources for drug development, the low cost of gene sequencing, and new tools and technologies indicate that genetic resources are, and will remain, an important source for drug development.

Despite the fact that genetic resources (including traditional knowledge associated with those resources) are an important source for drug development, they require going through the drug development process before they can be lunched on the market. As explained above, States, particularly developed countries, have designed a legislation that recognises patent rights on genetic resources if a patent holder demonstrates that it has made generic resources markedly different from the original sources or naturally occurring genetic resources (or genetic resources *in situ*). Hence, it will depend on countries’ legislation to determine whether a technology that employs genetic resources actually makes those resources different from what is in nature. For instance, the US allows patents on complementary DNA (cDNA), which is created in labs and only contains exons, rather than both exons and introns as a naturally occurring DNA sequences does; the naturally occurring DNA sequences, even if isolated, is not patentable in the US.[[61]](#footnote-62) However, developing countries rich in biodiversity either restrict or limit patent protection on genetic resources. This is because these countries aim to conserve the sovereign rights over the genetic resources located within their territory. As a result, these countries could trade off genetic resources with access to technology according to the ABS regime.

In sum, genetic resources play a twofold role in the normative analysis of this thesis. First, genetic resources and countries’ capacity are elements that help to analyse whether or not genetic resources should be appropriated. In this case, developed countries give patent protection to the technology that employs genetic resources (e.g. patents on cDNA), and facilitate access to naturally occurring genetic resources or genetic resources *in situ*. On the other hand, developing countries aim to restrict or limit patent protection on genetic resources because of their sovereign rights over those resources.

Second, this thesis focuses its analysis of capacity on developing countries that are rich in biodiversity, and hence have the availability to provide and trade off genetic resources for technology that employs those resources, in order to increase capacity in the drug development process. In other words, those developing countries which have the availability to provide and trade off genetic resources, are the subject of this research. In particular, this thesis has selected Colombia. However, India and China are also analysed.

There are two reasons why these developing countries rich in biodiversity have been selected: first, as can be observed from Annexes II and III, India, China and Colombia are countries with high and medium-high biodiversity; as a result they have implemented the ABS into their national legislation with the aim of securing control of the access to genetic resources and to trade off these resources for the transfer of technology. This is particularly important since not all developing countries are rich in biodiversity; for instance, countries located in the Middle East and North Africa are either medium or low biodiversity countries (see Annex II).

Second, India and China are countries with which Colombia can be contextualised regarding industry capacity, policies and legislation. For instance, India’s leading role in the generic market is the result of different policies that have transformed its industry from being an exporter of medicines in the first half of the 20th century to becoming the largest supplier and distributor of illegal generics until India adopted the TRIPs standards in 2005. The adoption of TRIPs standards led India to become a leading country in the production of generic medicines and active pharmaceutical ingredients worldwide. However, India’s increasing capacity in the generic industry has not been effectively reflected in further R&D into new medicines based upon genetic resources. In the meantime, China, which also began its industry by manufacturing and distributing illegal generics, has taken on a more ambitious plan not only to increase its capacity in manufacturing and distributing generic medicines, but also to transform its pharmaceutical industry into an originator industry. The analysis of Colombia is also relevant since this developing country rich in biodiversity does not have the industrial capacity to compete on equal terms with India and China, and since it is not considered to be an LDC, it cannot benefit from TRIPs prerogatives (e.g. delaying the implementation of TRIPs or compulsory licensing to import). Additionally, Colombia is adopting further patent and exclusivity standards since it has signed FTAs with the US and the EU; as a result, Colombia is developing a generic industry that is not only adapting to TRIPs but also TRIPs-Plus standards. As a result, Colombia’s capacity in the drug development process is limited to the manufacture and distribution of originators under licensing agreements and generics; Colombia has not yet benefited from the utilisation of genetic resources in order to increase capacity in technologies that employ those resources.

Although India, China and Colombia are also part of organisations that group developing countries rich in biodiversity, such as Like-Minded Megadiverse Countries, this thesis refers to these countries as developing countries rich in biodiversity since international organisations and instruments, including ABS, WIPO and TRIPs, also employ the term ‘developing countries’. There are also some LDCs which are located in areas rich in biodiversity. Although the analysis of LDCs provides an understanding of the global shift in markets, as these countries are filing the market gap for illegal generics, this thesis does not discuss in detail these countries as they have at the moment little hope of investing in R&D for the development of new drugs based on genetic resources. However, it is important to clarify that through the analysis of the regulation on access to genetic resources and access to technology, this thesis refers to developing countries that are both rich and not rich in biodiversity, in particular in Chapter 3. This is because this thesis also analyses international instruments that were Pre-TRIPs and Pre-CBD, such as the Paris Convention, in which for historical reasons there was no need to categorise developing countries, whether rich or not in biodiversity. The interest in conservation and sustainable use of biodiversity, and access to genetic resources, emerged towards the end of the 20th century as biotechnology emerged as a promising technology in drug discovery in the 1980s, and the CBD and TRIPs were enacted in 1992 and 1994 respectively; hence, developing countries which are rich in biodiversity have acquired particular prominence in the discussion on ownership control of genetic resources and access to those resources.

It is also important to clarify that although most developed countries, such as the UK, Germany and Switzerland, do not have the same availability to provide genetic resources, there are other developed countries such as the US that are rich in biodiversity (see Annex II); yet the US has not even ratified the CBD since patent exclusivity prevails over sovereignty claims on control and access to genetic resources.

**The Thesis Research Question**

In the light of the conflicting developing countries rich in biodiversity and developed countries’ views on the implementation of the ABS regime and TRIPs and their impact on technologies that employ genetic resources for drug development, this thesis aims to answer the following question: To what extent do TRIPs and the ABS regime, and their implementation in developing countries rich in biodiversity, especially Colombia, impact on countries’ capacity to develop a pharmaceutical industry that could obtain benefits from the utilisation of genetic resources in the light of technologies that employ genetic resources for drug development?

Therefore, this thesis centres on developing countries’ capacity in order to assess their policies on the implementation of TRIPs and the ABS regime at the national (specifically Colombia) and regional level (e.g. the Andean region). The analysis of China and India provides an understanding of the global shift in the context of markets and developing countries’ in order to provide comparator regions within which Colombia can be contextualized. LDCs are also briefly analysed in order to understand the shift in the global market and the potential that these countries have in their pharmaceutical industry to eventually compete with developing countries rich in biodiversity, such as Colombia. This thesis also analyses the interaction and relationship between TRIPs and the ABS regime as they overlap on issues such as ownership of genetic resources, access to technology and IPRs.

**The Methodological Approach of the Thesis**

In order to answer the research question, this thesis provides a normative analysis of the two international regimes (i.e. TRIPs and the ABS regime) that affect the pharmaceutical industry in technologies that employ genetic resources for drug development in developing countries rich in biodiversity. This analysis leads to a series of recommendations on policies and legal mechanisms that will enable developing countries rich in biodiversity and their pharmaceutical industries to obtain benefits (especially access to technology) from the utilisation of genetic resources.

Other relevant international instruments are also mentioned in order to clarify the scope of TRIPs and the ABS regime, including other regulation related to IPRs in the WTO, i.e. the Doha Ministerial Declaration,[[62]](#footnote-63) the Doha Declaration on the TRIPs Agreement and Public Health, and IPRs provisions established in FTAs or TRIPs-Plus provisions. The patent treaties of the WIPO are also analysed. These are the Patent Cooperation Treaty (PCT)[[63]](#footnote-64) which seeks to provide the basis for a common procedure in each Signatory State, and the Patent Law Treaty (PLT)[[64]](#footnote-65) which aims to harmonise the patent granting procedure in patent offices worldwide.

The thesis also examines how developing countries rich in biodiversity (especially Colombia) have implemented TRIPs and the ABS regime in national and regional legislation. Although developed countries’ capacity is not assessed in detail, this research analyses those countries’ pharmaceutical industry policies and legislation on access both to genetic resources and technology, particularly in the US and the EU. This provides elements to help understand the role of the developed countries’ pharmaceutical industries in the drug development process, the global market shift, and the creation and subsequent implementation of TRIPs in developing countries, and in the ABS regime.

To all intents and purposes, this thesis embraces a doctrinal approach which focuses on a particular industry: the pharmaceutical industry. Primary and secondary sources are employed to analyse the impact of the implementation of TRIPs and the ABS regime at national and regional levels. In general, this research applies an enquiry-based learning (EBL) methodology within which the thesis is conducted by a process of enquiry which requires understanding, evaluating and analysing a problem (research question) in order to gather relevant knowledge to propose a solution to the problem in the final part of the thesis (i.e. discussion and conclusion chapter).[[65]](#footnote-66) In other words, a research question is formulated, and subsequently a descriptive analysis is conducted through the thesis in order to find an answer to the question.

**The Scope of the Thesis**

In addition, the formulation of legal mechanisms that enable developing countries to increase capacity in order to obtain benefits that arise from the utilisation of genetic resources (as TRIPs and the ABS regime have implemented) is significant to a broader audience in Colombia and those who are interested in understanding Colombia’s implementation of TRIPs, TRIPs-Plus and the ABS regime. First, policy makers in Colombia should identify what the country’s capacity is within its pharmaceutical industry, as they implement TRIPs-Plus, in particular provisions related to patents on genetic resources, and the ABS regime, especially the NP, which has not been fully implemented in Colombia. This thesis provides an assessment of whether the current legislation in Colombia requires amendment(s). Second, there are different users of genetic resources and stakeholders within the drug development process. They invest time and economic resources in developing new biochemical entities. Therefore, it is only natural that they are concerned about the scope of patent protection and the potential impact of the ABS regime on their R&D activities into genetic resources.

**Theoretical Framework**

This thesis contextualises the elements that underline the normative analysis of this thesis (i.e. capacity, global markets and genetic resources) and the impact of the implementation of TRIPs and the ABS regime in a specific (pharmaceutical) industry in Colombia. By carrying out this analysis on the implementation of TRIPs and the ABS regime in the pharmaceutical industry, the thesis identifies strengths and weaknesses in different developing countries rich in biodiversity’s capacity in technologies that employ genetic resources for drug development, i.e. India, China and, especially, Colombia. As a result, this thesis recommends different policies and legal mechanisms (based on TRIPs and ABS) to developing countries rich in biodiversity, especially Colombia, according to their pharmaceutical industry’s capacity.

This thesis does not oppose IPRs, rather it recognises the importance of IPRs not only for developed countries, but also developing countries rich in biodiversity in the drug development process. The importance of IPRs is in the three assumptions of this thesis. The first assumption is that IPRs recognise property rights for the intellectual activity required for the production of intangibles; in other words, property rights on intangibles is the recognition of the intellectual activity that transforms what is in nature into intangibles. As a result, an inventor is entitled to exclusively control intangibles to enjoy the fruits of their productive activity. The control of intangibles, however, might also entitle the IPRs holder to the control of tangible things as they embody intangibles. For instance, a patent on a new biochemical entity (intangible) entitles the patent holder to control the manufacturing and distribution of a drug (tangible object) in the markets in which the patent has been granted. Although the intangible is protected by IPRs, because it recognises that there is an intellectual activity that transforms what is in nature into intangibles, it is also important to mention that IPRs compel inventors to disclose their inventions. As intangibles are disclosed, and once exclusivity has come to an end, there is an increase of the ‘starting material’ which other inventors can appropriate again.

However, this does not mean the exclusivity character of IPRs is absolute (as long as the IPRs have not expired or been lifted), but there are situations in which third parties are entitled to gain access to technologies protected by IPRs. The need to balance IPRs holders’ and third parties’ interests leads to the second assumption. Since IPRs grant exclusivity to inventors, IPRs potentially trigger inequalities, which limits the access to both intangibles and tangibles. However, it has been through, or because of, IPRs that those inequalities have been addressed by creating limits to IPRs and distributive mechanisms in the law and court decisions. For instance, the doctrine of ‘fair use’ has allowed educational institutions to circumvent the exclusivity control that copyrights’ holders have over the distribution and replication of educative works in classrooms.[[66]](#footnote-67) In sum, IPRs recognise first the intellectual activity of inventors and second could provide limits and a platform from which inequalities that arise from IPRs are addressed. The third assumption highlights that the mechanisms (i.e. legislation and court decisions) which aim to balance the interest of inventors and the inequalities that IPRs’ exclusivity involves, have the potential to undermine the intellectual activity by imposing duties that either restrict or limit their inventive activity. In other words, distribution policies could lead to legal mechanisms or court decisions that contradict the first assumption, i.e. that it is the right of inventors to be granted IPRs as a reward for their intellectual activities.

Before these assumptions are addressed in more detail, it is important to clarify that this thesis does not attempt to carry out a fearless defence of IPRs, but rather it aims to provide a legal framework that recognises the right of inventors to exclude their inventions and third parties’ interests from access to inventors’ intellectual activity according to their capacity. As a result, this thesis finds echoes in the social contract theory,[[67]](#footnote-68) particularly Locke’s theory of property[[68]](#footnote-69) and Rawls’ theory of justice.[[69]](#footnote-70) In due course, the theoretical framework that emerges from the analysis of Locke and Rawls is extended to the three elements of the descriptive analysis of this thesis, i.e. capacity, global markets and genetic resources. However, it is important to introduce some basic concepts of the social contract theory, in particular Rawls’, and Locke’s theory of property, in order to have a better understanding of the thesis’ theoretical framework.

Social contract theories argue that legitimate authority and the content of moral norms derive from the implicit or express consent of the governed. This stems from the idea of an initial position (renamed the ‘original position’ by Rawls or the ‘initial bargaining position’ by Gauthier) and parties which are usually considered to be rational. There are two important approaches to this theory: (1) there are authors such as Hobbes[[70]](#footnote-71) and, more recently, Gauthier[[71]](#footnote-72) who argue that a person is motivated by self-interest and as a result of a rational, self-interested assessment comes to an agreement; (2) on the other hand, there is social contract theory based upon Kant’s theory which argues that rationality implies respect for others, and as a result principles are constructed to be justified for each person under commitment, such as cooperation; Rawls is the most well known contemporary author of this approach. This thesis follows Rawls as Hobbes and Gauthier’s theories necessarily mean that there will not be an agreement if self-interest is not maximised. Although the self-interest of maximising own goals is a reason why parties might come to an agreement, there should be principles in common that serve as a mechanism to achieve self-interest objectives. For instance, the ABS is an agreement in which, despite the fact that there are different self-interests from developed countries (e.g. IPRs protection) and developing countries rich in biodiversity (ownership in genetic resources), they have agreed principles to cooperate to create measures to achieve the CBD’s objectives. That is why Rawls, who offers a procedure that sets up principles of justice, helps us to understand the dynamics between developed countries and developing countries rich in biodiversity in the context of the ABS regime and TRIPs.

Locke’s property theory lays the foundations of how and why scientific and technical activities could appropriate intangibles from the commons (i.e. what is in nature). In the case of the pharmaceutical industry and genetic resources, Locke provides an understanding of how appropriation occurs. For instance, developed countries have granted patents on genetic resources, which have been isolated from nature (*in situ*) (i.e. the commons), as long as inventors have demonstrated that technology employed on genetic resources make them different from the natural source and add value (e.g. therapeutic value). In this context, it is the intellectual activity of scientists that isolates genetic resources and adds value that has led them to appropriate something that is in the commons. However, Locke does not grant absolute exclusivity to IPRs holders, but also limits the scope of property rights when this particularly affects the commons or third parties; this has been denominated ‘Locke’s proviso’, which is a twofold concept, i.e. the sufficiency proviso and spoiled (or no waste) proviso. Therefore, there are three important elements of Locke’s theory: labour which allows inventors such as scientists to appropriate from the commons; the commons; and Locke’s proviso.[[72]](#footnote-73) This thesis analyses Locke’s theory based upon the works of Hull,[[73]](#footnote-74) Gordon,[[74]](#footnote-75) Merges,[[75]](#footnote-76) Mossoff[[76]](#footnote-77) and Nozick.[[77]](#footnote-78)

Appropriation in Locke’s theory of property occurs through man’s labour. As every man has ‘property in his own person’, the labour that comes from his person is his property. Therefore, labour that is ‘mixed’ with the commons transforms into property because it ‘puts a distinction between [man’s property] and common’.[[78]](#footnote-79) It is labour that makes property different from what is found in nature or the commons. Therefore, the first element to discuss in Locke’s theory is the nature and scope of labour. As Locke mentions that appropriation occurs when labour is mixed with the commons, there are authors such as Hettinger,[[79]](#footnote-80) and Nozick who particularly criticise the difficulty to define labour and the way this is mixed with the commons.

These criticisms are particularly reflected in Nozick’s scepticism on the nature of mixing labour and the commons in Locke’s theory; ‘[i]f I own a can of tomato juice and spill it in the sea so that its molecules (made radioactive, so I can check this) mingle evenly throughout the sea, do I thereby come to own the sea, or have I foolishly dissipated my tomato juice?’[[80]](#footnote-81) However, Nozick defined mixing labour as a physical action, rather than productive labour as Locke originally affirm.[[81]](#footnote-82) Indeed, Locke does not qualify or measure mixing labour, but rather provides examples of productive activities in which, for instance, farmer or fisherman mixed their labour with the commons in order to appropriate part of it. Mixing labour is a metaphor that explains productive labour. What Locke argues, therefore, is that because of labour being a productive activity (harvesting, collecting apples, etc.) man is entitled to appropriate from the commons; hence the labourer is rewarded to claim property under Locke’s theory.[[82]](#footnote-83) Furthermore, Mossoff considers that productive labour is based upon Locke’s idea of self-preservation, in which man ‘takes the actions necessary to preserve himself, such as labouring to create the products necessary to maintain his life’.[[83]](#footnote-84)

However, labour, as a productive activity that appropriates from the commons, needs to be considered with another important element of Locke’s theory: value. Although Locke does not define value, he characterises labour that appropriates part of the commons as a value creating, productive activity. Indeed, Locke mentions that ‘the extent of ground is of so little value, without labour’[[84]](#footnote-85) and ‘the intrinsic value of things (…) depends only on their usefulness to the Life of Man’ or self preservation.[[85]](#footnote-86) In other words, labour productive activity produces value as long as it serves the main duty to maintain the ‘Life of Man’ or self-preservation. This approach to Locke’s theory is important since what Locke defines is the act of producing values not in economic or market terms but rather with a specific function to serve man’s duty of self-preservation. This clearly opposes both Nozick’s and Hettinger’s understanding of Locke’s work. Both have misinterpreted value as they employed this concept in purely economic terms; e.g. Hettinger was prompted to define value as ‘market value’ without further analyses of what value actually means for Locke.[[86]](#footnote-87) This indicates that Hettinger aims to explain Locke in economic theory terms and ignores Locke’s conception of labour as a productive activity that aims to maintain man’s life. In other words, Locke does not define value in economic terms but by the ‘labour of a creator’.[[87]](#footnote-88) Therefore, Locke’s labour is a productive activity that produces value for self-preservation. In the case of medicines, for instance, an isolated genetic resource adds value as long as it provides a therapeutic value.

Although it can be argued that Locke mainly focuses his theory on activities such as farming and fishing, hence his theory might only apply to the appropriation of tangibles, he also praises the use of the commons by the ‘industrious and rational’.[[88]](#footnote-89) For Mossoff, Locke praises the industrious and rational in Chapter V of his *Second Treatise of Government*. It is man’s intellectual nature ‘the ultimate source of labour that produces both intellectual values (…) and physical values’.[[89]](#footnote-90) Furthermore, although Locke did not mention property rights on intangibles in Chapter V, Hughes’ research on the history of copyrights finds that Locke promoted the granting of privileges to the Stationers’ Company to print authors in the English realm and create time limits to privileges after the death of the author or first time published.[[90]](#footnote-91) In sum, labour is not designated in physical or economic terms in Locke’s theory, but rather as a labour productive activity to sustain human life which also includes intellectual labour as the ultimate source of property. For instance, *Parke-Davis & Co. v. H.K. Mulford[[91]](#footnote-92)* reflects the importance of granting property rights to the intellectual activity that makes an invention different from the naturally occurring and that adds value, as the Circuit Court of New York recognises a patent over an isolated chemical product (adrenaline) in order to reward an inventor for being ‘the first to make [adrenaline] available for any use by removing it from a naturally occurring organism’.[[92]](#footnote-93) The Court highlights that the term used refers to ‘every practical purpose of a new thing commercially and therapeutically’.[[93]](#footnote-94)

Having introduced why intellectual labour rewards inventors with IPRs on intangibles, it is important to define how the act of appropriation of the commons occurs in the case of IPRs on intangibles. There has been great discussion of how to understand the relationship between intellectual labour and the commons, which has resulted in the appropriation of intangibles. For instance, Gordon and Merges both answer this dilemma through the Public Domain as the common that provides the starting material for appropriation through intellectual labour. Their main argument lies in the fact that the commons in IPRs come from intangibles (e.g. inventions, music, etc.) whose property exclusivity has ‘lapsed or expired’, becoming part of the public domain and, hence, those intangibles are available for appropriation.[[94]](#footnote-95)

However, the idea of the public domain represents some interpretative challenges in Locke’s theory. Damstedt considers that the concept of public domain cannot relate to Locke’s idea of the common since ‘Lockean commons contain undeveloped materials, whereas public domain contains developed goods’.[[95]](#footnote-96) Certainly, this is the case with genetic resources. As argued in this thesis, genetic resources are the starting material which has not been worked, hence, it is the intellectual labour (e.g. technical or scientific activities) that extracts those genetic resources from the common, and this makes them different from the natural source. That means that for Damstedt, as soon as a patent has come to an end the technology that employs those genetic resources could not return to the commons and it would not be appropriated again, but rather it would remain in the public domain – also in which it could not be appropriated again. This is a clear defence to keep the public domain free from IPRs. Nevertheless, Damstedt misinterpreted Locke’s common. Indeed, one cannot simply argue that Locke does not contemplate a scenario in which what has been appropriated by productive labour does not increase the commons. In fact, Locke states ‘who appropriates land to himself by his labour, does not lessen, but increase the common stock of mankind’.[[96]](#footnote-97) Merges’ and Gordon’s arguments not only recognise the contributions of inventors and authors through IPRs, but also the increase of the commons upon which other inventors and authors could build, as long as their productive activity adds value to what is in the commons. This is also in line with Hughes’ research on the history of copyrights, explained above, which finds that Locke’s campaign for time limits the privileges after the death of the author or first time published so the commons would increase.[[97]](#footnote-98)

Finally, there is Locke’s proviso which is a twofold concept: (1) the sufficiency proviso or as Locke explains it ‘…no man but he can have a right to what that is once joined to, at least where there is enough, and as good, left in common for others’;[[98]](#footnote-99) the waste or spoiled proviso (‘Nothing was made by God for man to spoil or destroy’).[[99]](#footnote-100)

The sufficiency proviso refers to the difficulty that property rights can trigger on access to the commons. This proviso states a priority over property, i.e. that labour could appropriate part of the commons as long as ‘…there is enough, and as good, left in common for others’.[[100]](#footnote-101) This proviso is constructed to keep a balance between rewarding the intellectual labour that allows appropriation from the commons and protecting, so that others could access the commons in order to increase the commons itself. Such a balance is reflected in Court decisions. For instance, the US Supreme Court of Justice in *Mayo v. Prometheus[[101]](#footnote-102)* highlights that the patent should keep a balance between rewarding intellectual activities that ‘lead to creation, invention, and discovery’ and the fact that such a reward could ‘impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created’.[[102]](#footnote-103) The US Supreme Court also took into account such a balance in order to deny patent protection to an isolated gene and grant a patent over a complementary gene (i.e. complementary DNA or cDNA) since the patent holder’s claims on the isolated genes only focus on the locations of those genes, hence, such a ‘discovery, by itself, does not render’ the genes to be patent subject matter; whereas, as the cDNA was produced in the lab, this was considered to be patent subject matter.[[103]](#footnote-104) Such a decision led to different labs being able to actually have access to those isolated genes and increase the technical bar that an inventor should reach in order to obtain a patent on genetic resources.

The spoiled proviso is a rather more difficult concept to contextualise in IPRs, especially because it is easy to examine cases in which tangibles are wasted (e.g. rotting apples), but it is rather more difficult to waste intangibles: how can an invention or a literal work be wasted? Hull answers this question by saying ‘compare to the absolute loss present by rotting apples (…) the value lost by hoarding an idea until it becomes obsolete’.[[104]](#footnote-105) For Hull this is particularly reflected in the unmet demand of tangibles that embodies intangibles such as medicines. For instance, in *Natco Pharma Ltd v. Bayer Corporation[[105]](#footnote-106)* India issued compulsory licensing on a medicine for the treatment of kidney cancer based upon the fact that the patent holder was not offering the medical treatment at an affordable price or manufacturing the pharmaceutical product in India, and as a result, the patent holder was not meeting the demand from patients for the medicine.

However, Merges disagrees with Hull as he considers that ‘…principle Locke was driving at, is not unsatisfied demand, but a thing that has been appropriated and then put to no productive use at all’.[[106]](#footnote-107) Merges’ argument seems to link Locke’s proviso with the intellectual labour and the duty of self-preservation. For Merges, the waste proviso operates when someone hoards all the products of labour and lets them rot. Furthermore, Merges considers that the exchange market is the best and most efficient way to avoid goods being spoiled.[[107]](#footnote-108)

The problem with Merges’ argument is that it does not consider situations in which intangibles are appropriated in a way that denies others from producing intangibles, such as the case of patent trolls; for Merges, a patent troll will not necessarily be against intellectual labour. In the case of patent trolls, the aim is not to exchange products in the market, but rather obstruct others from using intangibles. Instead, Merges proposes to employ what he calls the charity proviso in which legitimate owners have a duty to distribute good to those who need it or cannot provide for themselves. This is based on a general duty that man has to others, explained in Locke’s *First Treatise* (e.g. benevolence). Merges suggests that in a situation in which IPRs exclude ‘people in desperate need’,[[108]](#footnote-109) the charity proviso provides them with a ‘title’ to the tangibles that embodies intangibles even if those products are originally protected by law. However, Merges’ approach makes it difficult to enforce the ‘title’, on which ‘people in desperate need’ will necessarily depend, on IPRs holders to ‘give away’ their right to exclude others from accessing the technology protected by patents. Although this situation ‘makes good business sense’ for Merges,[[109]](#footnote-110) it undermines the possibility of those people in need to actually have access to both tangibles and intangibles; this situation hurts the duty of self-preservation of others by not distributing intangibles and tangibles that embody intangibles. If owners fail to understand that there is a situation of need, they are actually obstructing people from either manufacturing those products that they need or simply having access to them. There is, indeed, an unmet demand and a scenario to apply the spoiled proviso. Although Merges’ interpretation of Locke’s work is worth applying, his approach to the spoiled proviso and defence of the charity proviso is unfortunate, especially as it leads critics to highlight the inconvenience of justifying IPRs.

Indeed, Drahos argues that justification of property rights on intangibles promotes a ‘dangerous level of private power’ or proprietarism which could conflict with other interests such as early access to technology and unmet demand.[[110]](#footnote-111) This means that Locke’s argument, including Locke’s proviso, is incomplete to justify a distributive approach. Although the sufficiency and waste provisos might provide enough scope to prevent abuse from IPRs holders by limiting the scope of their claims, it is difficult to see that there might be something that could counterbalance IPRs’ scope when it affects others, especially regarding early access to technology in Locke. This means that although Locke’s theory provides an understanding of why there should be a reward for intellectual labour by granting IPRs, it lacks the distributive measures that could enable third parties to access technologies when there are interests that are different from those of IPRs holders at stake.

There is also another difficulty with Locke’s theory when it comes to genetic resources and the ABS regulation: Why should control of genetic resources be granted to those countries that do not carry out any productive labour on the commons? Although it can be argued that States that host biodiversity hold a stewardship obligation to protect it, hence they have to create technical and legal mechanisms to protect biodiversity (limits to land planning and property rights, etc.), there is no actual intellectual labour that entitles them to create limits on access to genetic resources.

This is particularly relevant since the ABS is the result of a ‘bargain’ between developed and developing countries, rather than the recognition of a productive labour involved. Such a bargain is the result of protecting two interests: first, the interests of States, particularly developed countries, in protecting the loss of biodiversity; and second, the interests of countries which host biodiversity to have access to technologies that enable them to utilise genetic resources. The former has been approached in the ABS and related international instruments of conservation and sustainable use of biodiversity, through cooperative mechanisms such as sharing of information and technical cooperation on biodiversity. The latter is rather more complex, particularly because it requires those who hold technology (inventors) to share the benefits that arise from the utilisation of genetic resources with countries that host biodiversity; yet, countries rich in biodiversity should also facilitate access to genetic resources. In order to create a balance between inventors’ exclusivity rights and the commons, and justify the existence of control over genetic resources and benefit sharing, distributive justice frameworks based upon Rawls’ *A Theory of Justice* are considered.

Rawls’ theory of justice offers an important procedural framework to counterbalance the inequalities that emerge from IPRs. Rawls’ theory of social contract centres on the ‘principles of justice’.[[111]](#footnote-112) These principles emerge from a veil of ignorance in which participants are in an original situation, in which everyone is equal, hence, they could establish the principles of justice as a result ‘of a fair agreement or bargain’.[[112]](#footnote-113) Rawls divided those principles as follows: (1) the first principle in which parties have an equal right; basic liberties such as freedom of speech, political rights and property are established in this principle; (2) the second principle permits inequalities as long as everyone benefits from them and they are accessible to everyone as well.

To sum up, although Rawls’ theory is itself egalitarian, it recognises the existence of inequalities. In other words, for Rawls’ classification of principles, inequalities are possible in society but there should be mechanisms that compensate for any inequality. In order to clarify what might trigger inequalities, Rawls points out that society distributes ‘primary goods’ which are things that any rational and equal person wants.[[113]](#footnote-114) In those primary goods that are equally distributed are included not only basic liberties, wealth and income but also intelligence and imagination as natural goods. It is upon those primary goods, Rawls argues, that a benchmark is established in which improvements could be judged and in which it is possible to find whether inequalities actually benefit those who are affected by them. In the case of this thesis, those public goods are the technology that is employed in genetic resources, and the genetic resources themselves. The CBD is an example of the distributive nature of Rawls.

Indeed, the CBD is an international treaty in which States agreed three main objectives; two of them create rights and duties to all parties of the treaty to promote and create mechanisms for the conservation of biodiversity and its sustainable use; however, these two goals limit developing countries rich in biodiversity’s sovereignty to exploit their natural resources. As a result, the CBD creates duties for developed countries, including economic and scientific cooperation, to share the benefits that arise from the utilisation of genetic resources with developing countries rich in biodiversity. By cooperating scientifically and technically, and sharing benefits with developing countries rich in biodiversity, the ABS aims to benefit developing countries rich in biodiversity from an inequality (i.e. limits on the exploitation of natural resources and lack of technology) in which both developed and developing countries rich in biodiversity have already agreed on a ‘fair agreement’ or ‘bargain’. Again, in this case technology is a public good that needs to be shared with developing countries so they can obtain benefits from the exploitation of genetic resources. These genetic resources are also public goods, but are assigned to developing countries rich in biodiversity, hence they could trade off them for access to technology.

However, by making a difference between the two principles of justice, Rawls considers that there are some exchanges that cannot occur; for instance, the exchange of political rights or protection of life for social and economic returns. It is in this particular conception of justice that Rawls’ theory represents a particular problem in justifying IPRs. One can ask: Why do vulnerable populations (e.g. patients with AIDS/HIV in Africa) have to wait for 20 years until a patent comes to an end to afford medicines? Why will developing countries have to be excluded from access to technology that would allow them to meet the three objectives of the CBD? These questions are particularly raised by utilitarian scholars who consider that Rawls is incompatible with patents as these kinds of IPRs trigger an inequality that does not benefit first principles and patents are not accessible to everyone since there is a term of protection. [[114]](#footnote-115) In this aspect, Drahos argues that although property rights are ‘one of the basic political liberties’, they cannot be created in a way that ‘subverts basic political rights’.[[115]](#footnote-116) In other words, although IPRs might derive from the rights and duties recognised in Rawls’ first principle of justice, IPRs could not deny basic rights such as access to medicines.

Nevertheless, when Rawls is extended into the dynamics between nations, his theory of justice raises some concerns. Indeed, Rawls’ veil of ignorance (i.e. participants are equal in an original position) does not recognise the existence of a situation in which there is no possibility that participants of the social contract are equal. In this particular aspect, James criticises Rawls’ veil of ignorance in international trade by saying it suggests ‘parochial egalitarianism’ that does not recognise the existence of economic, social and political differences of States.[[116]](#footnote-117) Nussbaum also points out that one of the unsolved problems of social contract theory (in particular Rawls’ theory of justice)[[117]](#footnote-118) is the fact that there is no ‘rough equality’ among States since there are nations which ‘impose on poorer nations conditions that reinforce and deepen existing inequalities’.[[118]](#footnote-119) For instance, developed countries have employed international trade as a mechanism to put pressure upon developing countries, including those rich in biodiversity, to implement IPRs’ minimum standards through TRIPs and TRIPs-Plus provisions, in order to obtain benefits from international trade.

Additionally, Nussbaum points out that Rawls’ account of primary goods, which is referred to as what rational and equal beings want, should be addressed in a ‘heterogeneous and plural set of indices, such as capabilities’. By focussing on capabilities rather than distribution of primary goods, it is possible to achieve common social goals such as human dignity or quality of life according to people’s capacity, i.e. ‘what people are actually able to do and to be’.[[119]](#footnote-120) This is known as the ‘Capability Approach’. As this approach focuses on functioning (doing and being) it requires assessing capacity in order to compare and address people’s capacity to achieve different goals. This means that the Capability Approach does not necessarily oppose Rawls, rather it aims to provide further information on parties’ capacity in the social contract in order to create distributive measures. However, capacity, capacity building and the capability approach are not equal concepts but complement each other within this thesis’ theoretical framework.

Capacity comprises a different set of skills and abilities within technologies that employ genetic resources for drug development. In the meantime, the concept of capacity building involves the importance of increasing those specific skills and abilities (i.e. capacity).[[120]](#footnote-121) However, capacity should not be understood exclusively in terms of capacity building mechanisms or programmes that aim to increase capacity, but rather in terms of entitling countries to identify and assess opportunities to achieve different goals. This means that even if there are mechanisms that aim to increase capacity building, for instance, granting property rights on genetic resources to States, if developing countries are not entitled to enhance local resources, initiatives and ownership, capacity building programmes could rather add an extra burden to countries and make them more dependent.

That is why capacity should be understood within the capability approach because the latter centres on functioning (doing and being)[[121]](#footnote-122) and involves an assessment of countries’ capacities to compare and address their capacity to achieve different goals.[[122]](#footnote-123) This is reflected, for instance, in Article 22.3 of NP as it not only calls for Parties to adopt measures to increase capacity in countries in managing genetic resources and transfer of technology, but also to ‘identify their national capacity needs and priorities through national capacity self-assessment’. This means that the NP not only seeks countries to trade off genetic resources for benefit sharing, but to entitle countries, particularly developing countries rich in biodiversity, to determine their own priorities and activities as they implement the ABS regime.

The WTO, WHO and WIPO trilateral work on access to technology in medicines for developing countries also seeks to provide policy making capacity to create ‘more effective and tailored capacity building activities’ based upon countries’ capacity.[[123]](#footnote-124) There are also a good number of policy documents from international organisations that aim to guide countries to implement international instruments such as TRIPs according to their own capacity. For instance, the Commission on IPRs, Innovation and Public WHO points out that developing countries ‘have widely varying levels of scientific and technological capacity’, hence, countries should respond to disease and risk burden according to their capacity for innovation.[[124]](#footnote-125)

Therefore, although developing countries, including those rich in biodiversity, adopt distributive mechanisms based upon public goods such as technology and genetic resources, this thesis addresses technology and genetic resources as indices that provide information on how to compare and assess countries’ capacity in order to create distributive measures that counterbalance the inequalities that emerge from the global pharmaceutical market.

Although a distributive approach to IPRs and access to genetic resources underlines and justifies the existence of the ABS and flexibilities in TRIPs, most of which are supported by this thesis, it is also important to analyse criticisms of this approach since a distributive justice might undermine scientific and technical activities. Nozick’s entitlement theory provides an interesting critique of Rawls’ theory of justice as the former argues that a distributive approach necessarily leads to ‘redistribute activities’[[125]](#footnote-126) and forces individuals to do certain work (‘unrewarded work’)[[126]](#footnote-127). For Nozick, distribution necessarily involves a shift from the notion of ‘self-ownership to a notion of (partial) property rights in other people’.[[127]](#footnote-128) Chapter 4 illustrates this point through its discussion of the implementation of the NP in the EU as this might create administrative burdens for R&D activities on genetic resources in order to benefit countries outside the EU.[[128]](#footnote-129) Although distributive measures in EU Regulation are important to balance the technology gap between Europe and developing countries, including those rich in biodiversity that lack capacity, those measures could affect researchers and universities as the former demand an administrative and economic burden that could lead the latter to reduce their scientific and technical activities.

In sum, this thesis argues in favour of recognising IPRs, particularly patents, on intellectual labour that adds value to the commons, an approach that is reflected, for instance in *Parke-Davis & Co. v. H.K. Mulford*. It also recognises that IPRs trigger inequalities that, in principle, could be sorted out by limiting the scope of IPRs holders, which prevent others from accessing the commons (sufficiency proviso) as exemplified in *Mayo*, and ensuring that if there is an unmet demand triggered by IPRs, owners’ rights should be restricted too (waste proviso) (see for instance *Natco Pharma Ltd v. Bayer Corporation*). Yet, distributive measures based upon a trade-off between parties offer a platform to correct other inequalities that limit parties’ ability to access technologies. This thesis addresses those inequalities in terms of capacity in which technology and genetic resources are assessed (e.g. Article 22 of NP). However, those distributive measures should not undermine intellectual labour.

Having explained the theoretical framework of this thesis, it is now important to turn and fit this into the underlying elements that support the descriptive legal analysis of the ABS and TRIPs in the pharmaceutical industry, i.e. capacity, global markets and genetic resources.

First, Locke’s work is employed to contextualise capacity in the pharmaceutical industry as the intellectual labour that adds value to countries’ genetic resources, so countries can appropriate those resources. In this context, countries should allow individuals (e.g. researchers, users of genetic resources, etc.) to maximise their capacities, i.e. intellectual labour, in the utilisation of genetic resources. Therefore, capacity requires that States address regulation on access both to genetic resources and technology according to their own capacity which, in the case of this thesis, refers to the drug development process. However, capacity does not only serve as a benchmark in which governments assess intellectual labour, but also provides an understanding of how States should define, according to their own capacity, limits to the appropriation of the commons (sufficiency proviso) and address situations in which patent holders are prevented from wasting the commons (spoiled proviso). For instance, countries which lack the capacity to develop a competitive biotechnology industry, limit the appropriation of genetic resources via patent protection. In the case of the spoiled proviso, there is the case in which countries do not have the capacity to secure access to life saving medicines, because of patent holders’ rights, but countries are entitled to issue compulsory licenses to meet unmet demand.

Additionally, capacity permits analysing how the pharmaceutical market is transforming globally. As explained above, originators are naturally located in developed countries as they not only offer a greater degree of protection but also have the technical capacity to bring originators into the market, while countries such as India and China which used to manufacture and distribute illegal generics, are moving towards the production and manufacturing of generic medicines. Finally, LDCs, which have little capacity to manufacture and distribute medicines, are filling the gap of illegal generics that was left by developing countries as the latter have moved from illegal generics towards generics. Capacity is also an element that allows this thesis to analyse to what extent genetic resources should be considered patentable subject matter.

Finally, Rawls’ theory of justice and the ‘Capability Approach’ provide a framework in which inequalities emerge from the lack of capacity of developing countries rich in biodiversity. Rawls provides an understanding of why the ABS grants property rights to developing countries over their own genetic resources, although they do not carry out any intellectual activity over those resources. This is because States, particularly members of the ABS, have agreed to grant property rights to biodiversity rich countries so they could trade off those genetic resources for access to technology (e.g. benefit sharing). The Doha Declaration on the TRIPS Agreement and Public Health, and the Doha Ministerial Declaration also exemplify how parties, through a fair bargain, could address inequalities that arise from the implementation of those Declarations.[[129]](#footnote-130) Indeed, both Doha Declarations were the result of developing countries’, including those rich in biodiversity, and LDCs’ concerns about access to medicine, the linkage between the CBD and TRIPs, and traditional knowledge. Issues that developing countries considered were not properly addressed in TRIPs. However, this thesis critically analyses the distributive nature of the ABS as it has created in developing countries an extra administrative burden and time-consuming factor which could undermine those countries’ efforts to increase capacity. That is why it is important to employ the capability approach with the distributive nature of Rawls’ social contract theory as the former complements the latter through an assessment of countries’ capacity in order to create tailored policies and legal mechanisms that entitle countries to pursue their own interests in technologies that employ genetic resources for drug development.

**Contribution to Knowledge**

In particular, this thesis contributes to existing knowledge with an in-depth analysis of the Colombian pharmaceutical industry, and its patents and access to genetic resources legislation. The thesis also provides guidance to other developing countries rich in biodiversity, especially Members of the Andean Community of Nations (ACN) (of which Colombia is a member), to adopt policies and legal mechanisms that will lead them to take advantage of their genetic resources. The ACN is a regional organisation comprised of four neighbouring developing countries rich in biodiversity (Bolivia, Colombia, Ecuador and Peru (see Annex III)). The ACN sets up the general guidelines and a common policy on patents and access to genetic resources which each Member should implement at the national level, according to their country’s legal system.

Inevitably, this thesis has a limited scope. Firstly, it does not analyse in detail the regulation of all stages of the drug development process (i.e. pre-clinical and clinical trials), but centres on drug discovery in which biodiversity and genetic resources have an important relevance in the discovery of new biochemical compounds. MA is also discussed, as developed countries have campaigned to amplify patent protection (patent linkage) in MA and to extend exclusivity protection on pharmaceutical inventions through data exclusivity in developing countries. This clearly affects the ability of developing countries, particularly local generic pharmaceutical companies, to access technologies. Although clinical trials are not studied in depth, this thesis does refer to them to illustrate how involved India, China and especially Colombia, are in the drug development process. A detailed analysis of clinical trials would include an assessment of different regulatory frameworks which simply goes beyond the scope of this thesis.[[130]](#footnote-131)

Secondly, this research centres on a specific industry: the pharmaceutical industry. Other important industries that are based on genetic resources are also beyond the scope of this thesis, e.g. the agricultural industry.[[131]](#footnote-132) This is because the regulation on plant genetic resources for agriculture and food involves different legal mechanisms and international organisations. Indeed, the discussion on plant genetic resources and IPRs is quite different from that of patents on genetic resources for drug development, as the former have shown a different evolution. The core regulatory framework for plant genetic resources and related IPRs is the plant variety rights system which is governed by the International Union for the Protection of New Varieties of Plants (UPOV, French acronym).[[132]](#footnote-133) Originally, this kind of protection was not intended to be introduced as an IPRs system, but as a legal mechanism to encourage the sector of plant breeders.[[133]](#footnote-134) Developing countries have also campaigned in the Food and Agriculture Organization (FAO) to create an alternative legal framework that benefits them, and especially farmers (i.e. the International Treaty on Plant Genetic Resources for Food and Agriculture).[[134]](#footnote-135)

Thirdly, the ABS regime focuses on genetic resources that are found in microorganisms, animals and plants, as defined by Article 2 of the CBD. Although such a definition is broad enough to include human genetic resources, the Conference of Parties of the CBD (the governing body of the CBD) has already excluded human genetic resources from the scope of Article 2.[[135]](#footnote-136) This indicates that the ABS regime does not regulate access to human genetic resources.[[136]](#footnote-137) However, there are important legislation and judicial and patent offices’ decisions regarding patents on human genetic resources, particularly DNA, that reflect the policy on patents of technologies that employ genetic resources for drug development in developing and developed countries.

Fourthly, the issue of traditional knowledge associated with genetic resources is not possible to exclude in the discussion of access to genetic resources and access to technology in TRIPs and the ABS. Indeed, the practice, cultural expression and knowledge that indigenous and local communities hold on genetic resources is also an important intellectual activity that deserves to be recognised. As a result, this thesis mentions the relevance of traditional knowledge associated with genetic resources in different chapters, particularly in the discussion of the relevance of traditional knowledge for drug discovery in countries such as China and India (Chapter 1) and its inclusion in the ABS and WIPO in Chapter 4. Indeed, the ABS regime has recognised within different provisions the importance of traditional knowledge in the regulation on access to genetic resources and benefit sharing (e.g. Articles 8 (j) of the CBD and 12 of the NP). Chapter 4 also mentions India’s effort to protect traditional knowledge associated with genetic resources through Internet databases in order to document developed countries’ patent offices and prevent the misappropriation of traditional knowledge. However, further research would need to be discussed in aspects such as the definition of the nature of traditional knowledge, the interaction between traditional knowledge and patent law, and *sui generis* mechanisms to protect traditional knowledge.[[137]](#footnote-138)

Finally, the thesis underlines policies and legal mechanisms to ensure that the benefits that arise from the utilisation of genetic resources are equally shared in developing countries rich in biodiversity according to TRIPs and the ABS regime, particularly access to technology. However, this thesis does not make a closer analysis of specific provisions in Mutually Agreed Terms (MATs). Even though this research mentions different types of benefit sharing agreements (i.e. licensing and joint ownership of IPRs, milestone payments, etc.), for a comprehensive examination further research would need to be carried out on different aspects of benefit sharing including: (1) analysis of different types of licensing agreements related to genetic resources and IPRs; and (2) alternative mechanisms of licensing technology in the context of biodiversity and genetic resources, such as patent pools, open sources, clearing houses, etc.

**The Thesis Roadmap**

This thesis is divided into five chapters.

Chapter One identifies the capacity, both of developing countries rich in biodiversity and developed countries, in the drug development process. As this chapter assesses the capacity of developing countries rich in biodiversity, it explains how the global market shift has been the result of the way in which countries have adapted to TRIPs and the ABS regime. In particular, the chapterassesses the capacity of India and China in their pharmaceutical industry. These two countries have developed a generic pharmaceutical industry capable of competing with developed countries’ pharmaceutical companies in terms of manufacturing capabilities and market participation, and are moving towards becoming involved in more innovative R&D activities. This analysis permits the contextualisation of the pharmaceutical industries of Colombia. Chapter Twoanalyses Colombia, highlighting the interests of Colombia in employing genetic resources for the drug development process. It also finds that this country has developed a pharmaceutical industry capable of manufacturing and distributing medicines (generics and originators under licensing agreements) at the national and regional level (i.e. the Andean region). However, it has prioritised international trade (particularly with the US) rather than increasing capacity in its pharmaceutical industry.

Having assessed the capacity of developing countries rich in biodiversity, the shift in the global markets and the importance of genetic resources for drug development, Chapter Three identifies the role of developed countries in creating international substantive patent standards via international trade in the WTO and TRIPs in order to incentivise originators to maintain and increase investment in the production and distribution of new medicines. The chapter also points out that developed countries keep expanding their protection on pharmaceutical inventions via FTAs (also known as TRIPs-Plus) in developing countries rich in biodiversity, such as Colombia. Instead, developing countries have campaigned within the WTO to address concerns on aspects such as patents on genetic resources and the relationship between TRIPs and the ABS regime. This has taken place through the Doha Declaration on the TRIPS Agreement and Public Health, and the Doha Ministerial Declaration. Chapter Three also studies the substantive patent standards of TRIPs on genetic resources and the way that these have been implemented.

Chapter Fouranalyses the ABS regime, its requirements and different elements established in the wording (i.e. capacity, the legal statutes and nature of genetic resources, Prior Informed Consent (PIC) and MATs). This chapter also identifies that although the ABS regime objectives include the conservation of biodiversity and sustainable use of its components, it also mentions that users of genetic resources are obligated to share the benefits from the utilisation of genetic resources. The latter objective has entitled developing countries rich in biodiversity to trade access to genetic resources for access to technologies that employ those resources. Chapter Four also discusses why developing countries and developed countries disagree in the way that such a trade-off should take place. This chapter also identifies how the implementation of the ABS regime has created further barriers in both access to technology and access to genetic resources

Chapter Fiveanalyses in depth how Colombia has implemented TRIPs and the ABS regime at the regional (the Andean region) and national level. This analysis identifies that as Colombia implemented both TRIPs and the ABS regime, it did not assess the capacity of its pharmaceutical industry. This has affected Colombia’s pharmaceutical industry in two ways: on the one hand, although local generic pharmaceutical companies campaigned to reduce patent protection in pharmaceutical inventions, Colombia not only implemented TRIPs substantive standards, but also adopted TRIPs-Plus provisions via FTAs. This has reduced the market participation of local pharmaceutical generic companies. On the other hand, the implementation of the ABS regime has had a negative impact on the users of genetic resources, especially Colombian, publicly funded institutions. R&D on genetic resources has been over-complicated by the implementation of legal mechanisms that define the nature of genetic resources, set-up procedures and new requirements to obtain patents on genetic resources and PIC, and to reach MATs.

The Discussion and Conclusion Chapter proposes a solution to the research question by identifying different elements that developing countries rich in biodiversity, especially Colombia, should take into account as they implement TRIPs (including TRIPs-Plus) and the ABS regime at the national and regional level. The chapter outlines that developing countries rich in biodiversity should establish a policy in which they implement TRIPs and the ABS regime according to their own capacity.

Chapter 1: The Global Context

**Introduction**

This chapter analyses pharmaceutical industries’ capacity in developing countries rich in biodiversity, especially in India and China, the role of genetic resources in this industry and the pharmaceutical global market from a practical perspective.

The introduction of this thesis highlights that capacity in technologies that employ genetic resources for drug development involves a different set of skills and abilities from discovery to clinical trials and the manufacturing of medicines in the drug development process. Equally, the introduction of this thesis considers different aspects of the drug development process including stakeholders (originators, generics companies, publicly funded universities, labs, etc.) and regulation in the different stages of the drug development process.[[138]](#footnote-139)

However, within the theoretical framework of this thesis, as explained in the introduction, capacity is understood within the capability approach. As a result, it is important to reconsider nature of capacity, as it is pivotal for the scope of this chapter. The introduction of this thesis highlights that capacity, capacity building and the capability approach are different terms, yet they are analysed together. Capacity is the intellectual activity that adds value to countries’ genetic resources in order to appropriate intangibles; it involves different sets of skill and abilities within technologies that employ genetic resources for drug development, while capacity building is an approach in international law which aims to increase skill and abilities (i.e. capacity). However, capacity, and capacity building, should not only centre on increasing capacities, but on entitling countries, particularly developing countries rich in biodiversity, to enhance local resources such as genetic resources to find and assess opportunities to increase countries’ capacity. As a result, capacity is analysed within the capability approach since the latter focuses on functioning (doing and being) and involves an assessment of countries’ capacities in order to compare and address countries’ capacity to achieve different goals.[[139]](#footnote-140)

Therefore, capacity is placed as an indicator with which countries assess whether they have the intellectual labour that actually adds value to genetic resources in the drug development process. In the introduction of this thesis, the nature of capacity as the intellectual labour that adds value to genetic resources is taken from Locke’s theory of property. Locke gives insights into the reasons why countries grant property rights to technologies that employ genetic resources for drug development. Therefore, Locke’s labour is the intellectual activity that adds value which allows inventors to make their own property.[[140]](#footnote-141) But Locke’s labour theory does not only provide an understanding of how appropriation from commons occurs, it also establishes limits to it through Locke’s proviso, which involves the sufficiency proviso (what it is in the commons that can be appropriated as long as ‘there is enough, and as good, left in common for others’),[[141]](#footnote-142) and the waste or spoiled proviso (‘Nothing was made by God for man to spoil or destroy’).[[142]](#footnote-143)

The importance of assessing countries’ capacity, as the intellectual labour that adds value to what is in nature, is that despite the fact that countries grant property rights on genetic resources, they could also limit them through Locke’s proviso. For instance, countries could limit the scope of patent claims on genetic resources, if it is found that those claims affect the capacity of other inventors to carry out R&D on genetic resources (sufficiency proviso) or that those claims, for instance, impede third parties’ access to medicines (spoiled proviso). This indicates that capacity serves as an indicator with which countries could assess whether to allow appropriation and limit patents on genetic resources.

Locke’s theory is also analysed along with Rawls’ social contract theory since the latter helps to clarify why countries have created TRIPs and the ABS regime, which are at the centre of the normative analysis of this thesis. Rawls’ egalitarian theory recognises the existence of inequalities within parties of a social contract, but that those inequalities should be permitted as long as there are mechanisms that compensate those inequalities.[[143]](#footnote-144) Indeed, TRIPs and the ABS regime are not necessarily international agreements that aim to recognise the intellectual activity that adds value to genetic resources, but they have been the result of a bargain between developed and developing countries, including those rich in biodiversity.

Regarding TRIPs, this thesis points out that the creation of minimum standards of patent protection were the result of a trade-off between developed and developing countries, in which the former demanded IPRs’ minimum standards for access by developing countries to international trade. Those IPRs have led to inequalities in developing countries which implemented TRIPs in their territories, i.e. access to medicines, access to technology, the relationship between TRIPs and the CBD, and traditional knowledge. However, State members of the WTO and Council of TRIPs, the executive body of TRIPs, have addressed those issues through the Doha Declaration on the TRIPS Agreement and Public Health, and the Doha Ministerial Declaration. Regarding the ABS regime, the introduction of the thesis points out that this entitles developing countries rich in biodiversity to ownership control over genetic resources, so these countries could trade-off access to genetic resources for access to technology, i.e. share of the benefits that arise from the utilisation of genetic resources (the third objective of the CBD). [[144]](#footnote-145) Despite the fact that developing countries rich in biodiversity might not carry out any intellectual labour that adds value to those resources. However, those distributive measures that have emerged from the ABS and the Doha Declarations could create legal, technical and administrative burdens on developing countries rich in biodiversity if there are no tailored policies that respond to countries’ capacity. Therefore, the assessment of countries’ capacity is also important since distributive measures, which are the result of Rawls’ work, cannot be considered in equal terms for every country, but rather should be according to countries’ own capacity with the aim that they could be entitled to define their own priorities to increase capacity.

As a result, this chapter studies how the pharmaceutical industry works in a global context and analyses in depth this industry within India and China. This analysis illustrates the dynamics between the pharmaceutical industry and the regulation on access to genetic resources and patents over technologies that employ genetic resources in China, India and developed countries. This chapter also identifies important elements to assess the capacity of other developing countries rich in biodiversity, especially Colombia, the key policies that shape their legal system to adapt to TRIPs and the ABS regime, and how this has led to a shift in the pharmaceutical global market.

This assessment is carried out by explaining the main trends of the pharmaceutical industry in developed countries, and developing countries rich in biodiversity. However, the capacity of drug production cannot be evaluated in terms that include all developing countries rich in biodiversity. That is why this chapter focuses on developing countries which not only have a large availability of genetic resources, but also have developed leading pharmaceutical industries that, while not yet completely involved in more innovative research and development (R&D) activities, do aim to catch up with the pharmaceutical industry located in developed countries[[145]](#footnote-146) These countries are China and India.

As this chapter assesses the capacity of India and China, it analyses the strengths and drawbacks of these countries’ policies towards their pharmaceutical industry, the implementation of TRIPs and the ABS regime locally, and if they employ their own genetic resources for drug development in order to increase capacity. In particular, it highlights that India has centred efforts to increase capacity by protecting its generic pharmaceutical industry which manufactures and distributes generic medicines and active pharmaceutical ingredients locally and globally, but it does not rely on its own genetic resources, including traditional knowledge associated with genetic resources, to develop new medicines; whereas, China is focusing on biotechnology in genetic resources – in particular, Chinese traditional medicine.[[146]](#footnote-147) However, despite the fact that China is on a fast moving track, there are challenges that remain, such as transparency in the regulation of its pharmaceutical industry and enforceability of patents.

This chapter also analyses the role of India and China in the global market shift. [[147]](#footnote-148) As analysed in the introduction of this thesis, the global shift is reflected in the three market identities: originators, illegal generics and generics. These three market identities have triggered a division in the global pharmaceutical market: on the one hand, developed countries have taken a lead in the production of originators; on the other hand, developing countries rich in biodiversity such as China and India have moved from manufacturing illegal generics to be important players in the production and distribution of generic medicines globally.[[148]](#footnote-149) As obtaining a licence from patent holders represents an additional cost in manufacturing medicines or a barrier to access to the technology, India and China enacted regulation on patents that allowed and encouraged local pharmaceutical companies to manufacture illegal generics in order to supply local and, eventually, international demand. This is a way to access technology that otherwise could only be obtained through the payment of royalties. Nevertheless, as India and China have to comply with TRIPs in order to be part of the WTO, they transformed their industry from illegal generics towards generics.

The examination of China and India’s capacity in technologies that employ genetic resources provides a framework to gather, analyse and understand information on other developing countries rich in biodiversity’s capacity in their pharmaceutical industries, particularly in Colombia. However, the analysis of the global market and its transformation would be incomplete if LDCs role in the global pharmaceutical market is not analysed. For that reason, this chapter also studies briefly the role of LDCs in fulfilling the gap of illegal generics left by India and China.

The analysis of Colombia, a developing country rich in biodiversity, is carried out in the next chapter. Colombia is a country which, despite having managed to develop a competitive local pharmaceutical industry, has experienced difficulties in moving from manufacturing generic medicines towards an R&D based industry – even though it is one of the richest countries in terms of biodiversity. Colombia is analysed separately because this country has a different capacity in the pharmaceutical industry from those in India and China and has also compromised to comply with higher standards of exclusivity through FTAs with developed countries such as the EU and the US (i.e. TRIPs-Plus). TRIPs-Plus provisions require this country to adopt higher standards of patent protection and other mechanisms of exclusivity protection such as data exclusivity. As a result, developing countries rich in biodiversity that have embraced FTAs with developed countries such as Colombia have a different dynamic and challenges in terms of increasing capacity according to ABS regulation, TRIPs and TRIPs-Plus standards.

In that sense, Chapters 1 and 2 give an insight into the global impact that the pharmaceutical industry has on issues such as patent legislation and regulation on access to genetic resources over technologies that employ genetic resources in India, China and Colombia.

This chapter is divided into two parts. The first explains how the pharmaceutical industry works in a global context. It observes both the role of developed countries, India and China in the global pharmaceutical market and the global shift in this market. The second part provides a general overview of the pharmaceutical industry in India and China. It explains how India and China have evolved from almost exclusively manufacturing illegal generics to taking part in other essential stages of the drug development process, such as carrying out clinical trials for originators. [[149]](#footnote-150) The second part concludes that India has centred efforts on producing high quality generic medicines and active pharmaceutical ingredients in order to supply local and worldwide demand; whereas China seems to address efforts to encourage R&D, including genetic resources, and particularly traditional knowledge associated with genetic resources or Chinese traditional medicine.

This provides insights for the next chapter on how Colombia, without the global political and economic strength of China and India could obtain benefits from the use of their biodiversity in the drug development process. Although this chapter primarily analyses China and India’s pharmaceutical industry, it also studies the pharmaceutical industry in developed countries since it is necessary to analyse how these countries have developed a pharmaceutical industry able to innovate. Therefore, this chapter begins by analysing the policies that developed countries have employed to encourage originators in the drug development process.

1. **The Pharmaceutical Industry and Genetic Resources: the Global Context**

This section studies the pharmaceutical market and R&D expenditure in developed countries, India and China, with the aim of establishing why R&D has been located primarily in developed countries’ pharmaceutical companies. Indeed, the originator companies are located in developed countries, e.g. Pfizer, Merck (US) and AstraZeneca (UK). The goal of encouraging (and/or creating) national pharmaceutical companies requires developing countries rich in biodiversity to take note of how the pharmaceutical industry works in developed countries, particularly in the US and the EU. By creating a competitive and innovative pharmaceutical industry, developing countries rich in biodiversity will be able to take advantage of their own biodiversity and contribute in the number of originators. This provides fundamental guidelines that underlie and explain what developing countries rich in biodiversity should (or should not) do in order to increase capacity, particularly innovation on technologies that employ genetic resources for drug development.

As the drug development process is costly and time-consuming, the World Health Organization (WHO) has stated that at the moment only developed countries can afford to develop a medicine from discovery to marketing.[[150]](#footnote-151) This situation has not occurred by chance.

One important element is that the demand for medicines is greater in developed countries. This is one of the reasons why originators have particularly focused their R&D resources where demand for new medicines is greater, i.e. developed countries. Indeed, developed countries’ demand for medicines in 2011 was more than 64% of the global pharmaceutical market,[[151]](#footnote-152) despite the fact that developed countries account for less than 18% of the world population.[[152]](#footnote-153)

As the demand is the largest in developed countries, its pharmaceutical industry has particularly focused R&D resources on developed countries’ diseases. Trouiller et al. identify that pharmaceutical companies invested little or not at all in diseases that impact significantly on developing countries and LDCs;[[153]](#footnote-154) these diseases are usually called neglected diseases (e.g. tropical diseases and tuberculosis). Trouiller et al. find that of the 1,393 new drugs marketed between 1975 and 1999 only 17 were for neglected diseases.[[154]](#footnote-155) As a result of the lack of medicines for neglected diseases, international organizations such as WHO and private public partnership have campaigned to encourage further funding on R&D and subsidise the demand for these diseases.[[155]](#footnote-156) In 2010, Cohen et al. reviewed the work of Trouiller et al. in which it was identified that despite having a significant increase in R&D, the number of new drugs for these diseases was only 26 in the period 2000-2009.[[156]](#footnote-157) Cohen et al. also point out that the R&D was unevenly biased towards malaria,[[157]](#footnote-158) for which demand has steadily increased in the last decade, in large part from governmental and private sector efforts to subsidise not only R&D, but also the demand.[[158]](#footnote-159) As a result, new medicines for malaria have increased by 250% compared with the 1975-1999 period; however, there were no new drugs developed for diseases such as tuberculosis, buruli ulcer, dengue fever, trachoma, rheumatic fever, typhoid and paratyphoid fevers in the 2000-2009 period.[[159]](#footnote-160)

However, demand is not the only driving force behind R&D in developed countries. These countries’ policies towards the pharmaceutical industry have been a fundamental key in driving R&D in developed countries since they aim to reward the scientific and technical activities carried out by stakeholders, such as originators, universities and research centres. For instance, in 2004 an EU Commission report pointed out the importance of further legal harmonisation among EU members with the aim of attracting more R&D to the EU pharmaceutical industry. [[160]](#footnote-161) In that sense, the EU has managed to harmonise different aspects of the regulation on the pharmaceutical industry, which include: manufacturing authorisation, MA pharmacovigilance, regulation on clinical trials, labelling and packaging, compensation and advertisement.[[161]](#footnote-162)

These policies are even more significant in the absence of demand for medicines. For instance, developed countries have enacted legislation to encourage R&D on new medicines for which demand is low. Orphan drugs are medicines that treat rare diseases that, according to WHO, affect a small part of the population (0.65 -1 out of 1000 inhabitants).[[162]](#footnote-163) As these drugs treat few people and the process of developing new drugs is costly, pharmaceutical companies usually do not address sources in R&D to develop medicines to treat these diseases.

Developed countries such as the US and the EU have created three sets of mechanisms to increase the number of orphan drugs: (1) marketing exclusivity, i.e. local authorities will only give authorisation to the company or lab that introduces the orphan drug, so no other pharmaceutical company could enter the same pharmaceutical product into the market, even if there is no patent protection; the EU gives 10 years of marketing exclusivity, while the US gives 7 years;[[163]](#footnote-164) (2) economic incentives which include grants and tax breaks;[[164]](#footnote-165) and (3) simplification of the risk-benefit assessment for orphan drugs, i.e. MA.[[165]](#footnote-166) As a result, there has been an increase in the number of orphan drugs that have entered into the developed countries’ market. For instance, between 1983 and 2008 the FDA approved more than 300 orphan designated products (representing more than 200 different drugs) to treat rare diseases such as multiple sclerosis, haemophilia and cystic fibrosis.[[166]](#footnote-167) Many of those treatments are considered to be medical breakthroughs.[[167]](#footnote-168) This means that regulation and policies towards the pharmaceutical industry and R&D are driving forces that actually encourage the development of new medicines, even when there is a lack of demand.

Indeed, developed countries’ policies towards the pharmaceutical industry are a key element that affects the way that R&D is employed in the drug development process. This means larger spending on R&D for drug development in developed countries rather than developing countries. Indeed, developed countries account for more than 80% of the US$ 120 billion spending on R&D for new drugs made by the pharmaceutical industry in 2010.[[168]](#footnote-169)

It is in the interests of developed countries to secure and increase the flow of R&D resources from originators. At the same time these companies demand policies that secure them exclusivity in developed countries. However, the increasing demand for medicines in both developing countries and LDCs, and particularly, the increasing global demand (including developed countries) for generic drugs[[169]](#footnote-170) are leading towards a global shift.

This global shift consists of originators being based mainly in developed countries as they provide a greater degree of exclusivity through patent protection and other exclusivity mechanisms.[[170]](#footnote-171) The WHO also points out that primary production of medicines (i.e. manufacturing of active pharmaceutical ingredients, mixing and packing them) is highly concentrated in five developed countries (the US, Japan, Germany, France and the UK).[[171]](#footnote-172) This has led these countries to share two-thirds of the value of all medicines produced worldwide.[[172]](#footnote-173) In the meantime, countries such as India and China are moving towards production and manufacturing of generic medicines, and distribution to other developing countries and developed countries.[[173]](#footnote-174) As a result, India and China are also able to carry out primary production of medicines, a situation that has led them to have a large volume production of lower priced medicines.[[174]](#footnote-175) Meanwhile, other developing countries such as Colombia have developed a generic industry capable of the mixing of active pharmaceutical ingredients and the production of different dosage formulations (i.e. secondary medicine production).[[175]](#footnote-176) Finally, LDCs are supplying the demand for illegal generics by enhancing capacity on manufacturing and distribution of these products.[[176]](#footnote-177) LDCs mainly focus on packing and small-scale production of medicines (tertiary manufacturing).[[177]](#footnote-178)

The increasing demand in the developing world is particularly reflected in countries such as India, China and Brazil, which had a 20% share of the global pharmaceutical market in 2011 and are predicted to increase their demand to 30% by 2016.[[178]](#footnote-179) As explained in more detail below, the increase in demand for medicines in developing countries is not only the result of economic growth, but also the result of local pharmaceutical companies helping to supply local – and eventually international – demand for medicines, especially generics. For instance, Indian local generic companies have increased exports from US$ 3.7 billion in 2003 to US$ 7.2 billion in 2011;[[179]](#footnote-180) these companies supplied between 70 and 80% of the Indian market.[[180]](#footnote-181)

However, the demand for generics is not only a concern for the developing world. As a good number of patents have expired recently and there are concerns about the sustainability of public health systems globally,[[181]](#footnote-182) the demand for generic medicines has increased.[[182]](#footnote-183) For instance, Plavix, a medicine for patients that have recently suffered a heart attack or stroke, lost its patent protection in May 2012; Bristol-Myers, the American pharmaceutical company that owned the patent, reported that Plavix made US$ 42.8 billion in 15 years of patent protection.[[183]](#footnote-184) The New York Times reported that around 19 medicines lost patent protection in 2012 in the US: [[184]](#footnote-185) these include Lipitor (anti-cholesterol) by Pfizer that lost patent protection in May 2012[[185]](#footnote-186) and Actos (diabetes treatment) by Takeda Pharmaceuticals whose patent expired in August 2012.[[186]](#footnote-187) Although the loss of patent protection represents an economic loss for patent holders (in the case of Lipitor, Plavix, Actos and the other medicines, there will be a loss of US$ 38.5 billion in sales[[187]](#footnote-188)), the impact of generic entry is reflected in the reduction of prices. The EU Commission has pointed out that generic entry reduces prices of medicines by 25% in the first year and by 40% in the second year compared with the prices of the brand-name medicine.[[188]](#footnote-189) This has led to an increase in the demand for generic medicines from 20% in 2005[[189]](#footnote-190) to 25% in 2011 worldwide, and it is expected that it will have increased by 35% in 2016.[[190]](#footnote-191)

Another important issue in this transforming environment in the global pharmaceutical industry is the production of new biochemical compounds or entities. Although the new biochemical compounds drooped to 148 between 2003 and 2007 from 223 a decade earlier, there has been a slight increase of 163 new biochemical compounds in the last 5 years.[[191]](#footnote-192) However, such an increase does not necessarily reflect that pharmaceutical companies are bringing actual new biochemical compounds into the market, but rather indicates that there is a focus on improving existing medicines. For instance, follow-on products and second indications of a biochemical compound, which are the result of further R&D on existing medicines, might result in new therapeutic uses or indications of already known biochemical compounds (i.e. second indications) or products that are the result of incremental innovation of an existing product (follow-on products).[[192]](#footnote-193) Although follow-on products and second indications are based on existing biochemical compounds, they require further R&D (e.g. clinical trials) after the patent has come to an end or during the term of the patent in order to prove their efficacy and safety.[[193]](#footnote-194) A 2006 report of the US Government Accountability Office (GAO) identified that the 32% of medicines filed for FDA approval were actual new biochemical compounds, while 68% were on second indications or follow-on products. [[194]](#footnote-195) GAO also points out that the reason why originators are not investing in new drugs is the complex legislation that takes place to obtain approval by the FDA and the increasing cost of the drug development process.[[195]](#footnote-196)

This clearly indicates that, despite the fact that there has been an increase in R&D spending, this has not been completely allocated to the production of new products, but rather to improve existing ones. Additionally, Correa argues that developed countries have also been very flexible in granting patents on drugs that do not involve ‘a genuine therapeutic innovation’, which only has led to the proliferation of patents on pharmaceutical products with inexistent innovation.[[196]](#footnote-197)

Although developed countries are analysing the way to change this trend in the production of new medicines,[[197]](#footnote-198) this might also be an opportunity for India and China to take a more active role in drug development process. For instance, the unmet demand of medicines for neglected diseases represents an opportunity for India and China to participate actively in developing new medicines from their genetic resources. Indeed, as explained in the introduction of this thesis, Oldham calls on China and India to deploy their research capacity to participate more in developing new biochemical entities based upon genetic resources for neglected diseases. [[198]](#footnote-199) However, the increasing global demand for generic medicines have led pharmaceutical industries in China and particularly in India to pay close attention to manufacturing generic medicines and active pharmaceutical ingredients to supply the global demand, rather than investing in R&D on genetic resources.

Therefore, it is necessary to establish whether India and China could engage in the development of new drugs and not only in the manufacturing of generic drugs. This question is especially relevant for this thesis since developing countries rich in biodiversity such as India and China have a large availability of genetic resources that could be employed for drug development. As a result, these countries are well-placed to supply the global demand for generic drugs, as well as to increase the production of new drugs based on genetic resources.

In the case of India and China, with the increasing demand and production of drugs, it is important to understand whether these countries are transforming their industries from manufacturing and distributing generics medicines to innovating. Such an analysis also provides two important lessons: (1) to understand these countries’ approach to the ABS regime and TRIPs as China and India could be important points of reference for other developing countries rich in biodiversity, especially Colombia; and (2) to assess the global shift triggered by China and India’s policies on patents and access to genetic resources.

1. **China, India and the Pharmaceutical Industry**

Having provided an overview of the global pharmaceutical market, this section explores the trends and policies of the pharmaceutical industry in India and China in order to determine what these countries’ capacity is in their pharmaceutical industries.

In the case of India, this section studies how this country has delivered different policies to incentivise the local pharmaceutical industry, especially the manufacturing of generic pharmaceutical products. Although in the case of China the importance of generic production is also mentioned, this section analyses in more detail the growing Chinese biotechnology sector for innovative drug development. This is because China’s innovation policy in its pharmaceutical industry has centred itself around biotechnology. By understanding China and India’s pharmaceutical industries, this section explains what the capacity of these two countries is in their pharmaceutical industry.

* 1. **The Rise of China and India’s Pharmaceutical Industries**

In the past 25 years both India and China have gone through a vigorous and constant economic growth.[[199]](#footnote-200) Indeed, China and India are the third and fourth largest world economies, respectively, in terms of GDP,[[200]](#footnote-201) and both countries have the two largest populations in the world (i.e. 37% of 7.2 billion people). [[201]](#footnote-202) However, both countries have different economic and political strengths. For instance, India is deemed to be a major destination for global outsourcing and information technology as well as a West-like democracy; whereas China is considered to be a manufacturing hub with a state controlled economy.[[202]](#footnote-203)

Although India and China have different political and economic systems, there are common developments and historical circumstances that have made them important players in the global pharmaceutical industry, even though they have particular trends and policies within their respective pharmaceutical industries that make them distinctly different. In general terms, the success of the growing pharmaceutical industry in India and China rests in the interests of these countries to supply local and global demand for generics (and illegal generics), and their governments’ efforts to support the national pharmaceutical industry to make them more competitive with originators in the manufacture of medicines.

However, both countries face two challenges: (1) China and India have opened their economies to international trade, in which they have accepted the provision of patent protection on pharmaceutical products as a condition for having access to international trade.[[203]](#footnote-204) This represents a particular challenge to China and India’s pharmaceutical industries, because both countries, which encouraged manufacturing and distribution of illegal generics, are moving towards generic production; and (2) as both countries have accepted providing patent protection, they face the necessity of delivering a policy in which their pharmaceutical companies are transformed from being generic producers to originators.

This situation is more evident if it is compared with the pharmaceutical industry in developed countries. Indeed, India’s pharmaceutical market was worth US$ 11.2 billion in 2011,[[204]](#footnote-205) but India’s pharmaceutical’s R&D expenditure was less than US$ 500 million in the same period of time.[[205]](#footnote-206) This means that India’s pharmaceutical industry only invested 5% of its pharmaceutical market’s size into R&D; whereas, the US pharmaceutical market’s size was US$ 320 billion[[206]](#footnote-207) and R&D investment was around US$ 77 billion in 2011.[[207]](#footnote-208) This indicates that around 25% of the US’s pharmaceutical market size goes to R&D. Such a situation leads to the question whether it is in the interests of India and China to deliver policies on their pharmaceutical industry to make them competitive, not only in terms of manufacturing but also innovation with developed countries. This means that the global shift in markets should not only have developing countries such as India and China involved in manufacturing and distributing generics, but also in producing and distributing originators eventually. Furthermore, since countries such as China and India offer a large availability of genetic resources (including traditional knowledge associated with genetic resources), it is also important to determine if they actually employ those resources for drug development of new medicines in order to increase capacity.

Therefore, the following sections analyse whether India and China are actually interested in and/or are taking the right policies to encourage R&D in their pharmaceutical industry, particularly in genetic resources for drug development.

* + 1. **The Birth of the Indian Pharmaceutical Industry**

In the case of India, in the first half of the 20th century there were important developments that led India’s companies to the creation of a significant pharmaceutical industry which was able to manufacture medicines, yet India remained dependent on imports of basic chemicals to manufacture drugs and had no investment in R&D for new chemical entities.[[208]](#footnote-209) This situation is explained by the fact that India was under the rule of the British Empire; hence, the colonial government underlined India’s economic policy. As a result, different plants and facilities to manufacture drugs were set up around the country by the British government and Indian scientists (trained in colonial institutions). The national pharmaceutical industry, although focused only on manufacturing, participated to some extent in the Indian medicines market. However, after the Second World War and the independence of India from the British Empire in 1947, the Indian pharmaceutical industry suffered a considerable loss of domestic market share to originators. For instance, local pharmaceutical companies dropped their share of the Indian market from 62% in the early 1950s to 32% in 1970; whereas, those companies that imported either pharmaceutical products or active pharmaceutical ingredients for the production of pharmaceutical products increased their share in the market from 38% in 1952 to 68% in 1970.[[209]](#footnote-210) The main reason for this decline in the local industry is that originators could compete with local producers by obtaining patents for the drugs that they had produced. India’s patent legislation (enacted by its former colonial power) allowed patents in new drugs, so non-local pharmaceutical companies managed to obtain patent protection in India, but at the expense of the local industry.[[210]](#footnote-211) Such a situation, as well as early developments in the synthesis of chemicals in India, indicates that India’s capacity at that time was mainly focused on the marketing of imported drugs and in gaining technical capabilities for manufacturing drugs.

Nevertheless, India began a process of transformation from a safe haven for patents on pharmaceutical products to a country in which policies aimed to openly encourage local pharmaceutical companies to produce illegal generics.[[211]](#footnote-212) Pressures from the Indian pharmaceutical industry led the government to call for a consultation, with the aim of making legal amendments in order to increase local companies’ capacity in manufacturing and supplying the local demand for drugs.[[212]](#footnote-213)

As a consequence two reports were issued in the 1950s: the Chand Report, chaired by Justice Bakshi Teck Chand of the Indian Supreme Court in 1948-1950,[[213]](#footnote-214) and the Ayyangar Report, led also by a Justice of the Supreme Court, Rajagopala Ayyangar in 1959.[[214]](#footnote-215) Both reports concluded that it was necessary to encourage innovation in local industries (e.g. the pharmaceutical industry) by deterring exclusivity rights of patent holders, which were mainly overseas companies.[[215]](#footnote-216) For instance, in 1968 the Bombay High Court granted an injunction against an Indian drug producer for infringement of a patent owned by the German corporation Hoechst.[[216]](#footnote-217) Although the Court recognised that the process of obtaining the pharmaceutical product was different from the process claimed and the product was known, the Indian Patent and Designs Act of 1911 (legislation enacted under British Empire rule) did not provide any mechanism to limit the patent;[[217]](#footnote-218) hence the Court considered that the patent claim was wide enough to include other alternatives to obtain a known pharmaceutical product.[[218]](#footnote-219)

* + 1. **The Consolidation of the Indian Pharmaceutical Industry**

The Chand and Ayyangar reports sought to create a legal framework that protected local pharmaceutical companies. For instance, between 1950 and 1952 a new regulation was introduced on the compulsory licensing of the Indian Patent and Designs Act of 1911 as suggested by the Chand Report, with the aim of protecting national interests.[[219]](#footnote-220) The Ayyangar Report suggested an even more radical amendment to the Indian patent law to protect the local pharmaceutical industry, i.e. that Indian authorities should select what inventions deserve patent protection in the light of national interests.[[220]](#footnote-221) Almost ten years later, the Indian Patent Act (1970) was enacted. This legislation cleared the way for the Indian pharmaceutical industry not only to supply local demand for illegal generics, but also to lead this industry as an important player in the global pharmaceutical industry in supplying these illegal generics to other countries. This means that the most significant change for the Indian pharmaceutical industry was having no recognition of patent protection to pharmaceutical products.

Having been denied patent protection of pharmaceutical products, the Indian pharmaceutical industry gained enough capacity to overtake developed countries’ pharmaceutical companies in supplying local demand. Indeed, Indian pharmaceutical companies increased their share of the market from 32% in 1970 (before the Indian Patent Act was enacted) to 77% in 2004.[[221]](#footnote-222) Furthermore, the Indian pharmaceutical industry not only benefitted from the local demand, but has also become an important stakeholder in the global industry. In 2005, before India began to comply with TRIPs standards, the Indian industry was worth US$ 8 billion and ranked 4th globally in terms of volume.[[222]](#footnote-223) The resources and knowledge that India has capitalised on from its patent legislation, as well as public support, have led Indian pharmaceutical companies to carry out some R&D activities such as clinical trials. This means that as India assessed its own capacity in the pharmaceutical industry, it was able to accommodate its patent legislation to increase capacity in its generic industry.

That being said, India’s most recent challenge is to define whether Indian pharmaceutical companies could turn into important R&D companies for the development of new drugs. However, market boost and manufacturing capability are not the only reasons why the Indian pharmaceutical industry could become a leading innovative country that rewards the intellectual labour in adding value to their own genetic resources. Chaudhuri points out that originators could reduce the cost of medicine production when these companies carry out R&D and manufacturing activities in India.[[223]](#footnote-224) For instance, the labour and infrastructure cost is up to 80% and 40%, respectively, less expensive than in developed countries.[[224]](#footnote-225) Marketing analyses have estimated that the cost of developing a new drug could be reduced to 10% of the cost in developed countries.[[225]](#footnote-226) As a result, companies such as AstraZeneca, Bayer and Eli Lilly have all carried out clinical trials [[226]](#footnote-227) and set up manufacturing facilities in India.[[227]](#footnote-228)

Nevertheless, the Indian pharmaceutical industry’s growth does not necessarily indicate that India is turning into a more internationally innovative country in drug development. The reason that India’s pharmaceutical industry is not transforming into an R&D based sector is that the interest of India in meeting demands for generic drugs and active pharmaceutical ingredients could affect Indian potential, for example, in exploiting its biodiversity through technologies that employ genetic resources. Indeed, Kedron and Bagchi-Sen find that one of the main strengths of Indian pharmaceutical industry R&D capacity relays in fulfilling the requirements of developed countries’ drug approval agencies (e.g. the US FDA and the European Medicine Agency (EMA)) in order to gain entry into these countries markets.[[228]](#footnote-229) This indicates that India targets the US and the EU for exports of generics, in which the US market alone accounts for 20% of total of India exports.[[229]](#footnote-230)

In this sense, India aims to consolidate its generic industry rather than enhance innovation. For instance, in 2003 the Indian government established a committee, led by R.A. Mashelkar, which gave recommendations on how to improve manufacturing practices in order to enhance the quality of generics.[[230]](#footnote-231) Therefore, India has engaged globally as a supplier of generic versions, rather than being an innovation hub. This trend has been even more noticeable after India officially enforced TRIPs in its national legislation by enacting the 2005 Indian Patent Act.

The implementation of TRIPs provision in India has led to the transformation of its pharmaceutical industry from an illegal generic industry into a generic industry. In other words, India aims to adapt its pharmaceutical industry by implementing its patent legislation, in order to comply with the WTO’s requirements and, hence, to obtain benefits from international trade, including getting generic products into developed countries markets.

* + 1. **Post-TRIPs era: the Challenges ahead of India in the Pharmaceutical Industry**

Since India signed TRIPs in the 1990s and a new Indian Patent Act was enacted in 2005,[[231]](#footnote-232) questions have been raised about the impact of these legal changes and whether the Indian pharmaceutical industry was ready to embrace the new requirements set up by the WTO in TRIPs.[[232]](#footnote-233) The previous patent legislation’s major amendment was the removal of the recognition of patents on pharmaceutical products; the Indian Patent Act’s (2005) major amendment was to abolish such a prohibition. However, judicial authorities and the Indian patent office have issued different decisions that have eased the 2005 reforms on the Indian Patent Act. These decisions include use of compulsory licensing and refusal to grant patents on follow-on products.

This subsection analyses (1) the impact of 2005 Indian Patent Act’s amendments in India; (2) the recent judicial decisions which have reduced the scope of TRIPs obligations in India; (3) and how the Doha Round of negotiations which led to the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health have benefitted the Indian generic industry and its consequence for the worldwide industry.[[233]](#footnote-234)

First, Grace considers that the legal amendment did not represent a real challenge for the already established local production of medicines, as India managed to obtain a transit period in order to gain time to adapt its pharmaceutical industry to the compromised amendments in patent legislation to fulfil its TRIPs requirements.[[234]](#footnote-235) Such a compromise is that India should allow originators to enter into its pharmaceutical market, as well as providing patent protection for originators in India.[[235]](#footnote-236) However, as India has joined the WTO and TRIPs, two questions arise: (1) Is India actually interested in transforming its pharmaceutical industry from being a generic medicines producer towards being an innovative industry?;[[236]](#footnote-237) and (2) does India aim to compete with originators in bringing into the market new biochemical entities based upon the utilization of their own genetic resources, including traditional knowledge associated to genetic resources?

There are some policy documents and reports that might indicate that Indian authorities have been trying to encourage innovative initiatives and obtain the transfer of technology from originators. For instance, the Indian Ministry of Commerce and Industry (MCIC) has pointed out the importance of a more R&D based innovative strategy in the pharmaceutical industry.[[237]](#footnote-238) The Indian government has also promoted public-private partnerships and alliances between India and originators in order to incentivise innovation in the pharmaceutical industry.[[238]](#footnote-239) For example, the MCIC and the Conference of Indian Industry have created different public-private partnerships focusing on the pharmaceutical industry. Arora et al.[[239]](#footnote-240) and Grace[[240]](#footnote-241) consider that implementation of TRIPs in India has led to further investment in R&D by originators. Furthermore, Chaudhuri finds that the implementation of TRIPs in India has led to some Indian companies such as Dr. Reddys and Ranbaxy to carry out R&D on discovering new biochemical entities.[[241]](#footnote-242) However, Chaudhuri also considers that originators have not substantially engaged in R&D to develop new drugs in India, but are importing and manufacturing medicines (via outsourcing).[[242]](#footnote-243) This is despite the fact that developed countries have praised India for adopting a more developed countries patent orientated legislation.[[243]](#footnote-244) There is evidence that R&D drug development in India has been reduced in the post-TRIPs era.[[244]](#footnote-245) Abrol et al. identify that companies such as Hoechst, AstraZeneca and Ciba-Geigy have either closed down research facilities or moved R&D in drug discovery activities from India to developed countries.[[245]](#footnote-246)

Furthermore, although some Indian pharmaceutical companies have increased capacity in R&D on discovering new biochemical entities, these efforts are addressed towards diseases that have a global demand, particularly in developed countries (e.g. diabetes, cancer, heart diseases, asthma and obesity) rather than neglected diseases that largely affect the Indian population.[[246]](#footnote-247) Indeed, India shares 24% of the global tuberculosis burden in 2014[[247]](#footnote-248) and 61% of malaria cases in the South-East Asia region in 2012.[[248]](#footnote-249) Additionally, Bhattacharya & Phushkaran carried out an study on 98 Indian pharmaceutical companies, in which the authors found that only three were actually engaged in R&D activities in neglected diseases in 2011, despite the fact that the Indian government has sought to encourage research on the diseases via public-private partnerships.[[249]](#footnote-250) According to Bhattacharya & Phushkaran, these companies are motivated by the profit margins from medicines to treat diseases that mainly affect developed countries rather than neglected diseases.[[250]](#footnote-251)

Second, there have been recent trends which indicate that India is focusing on the manufacturing and distribution of generics rather than encouraging R&D via patents. This can be seen through two post-TRIPs cases. In *Novartis v. Union of India*, the Supreme Court of Justice of India denied patent protection of a follow-on product, a beta crystalline form version of Imatinib Mesylate which is employed to treat chronic myeloid leukaemia and marketed under the names of Glivec or Gleevec. [[251]](#footnote-252) For the patent applicant, the beta crystalline form was new and had superior properties to the original form such as increased bioavailability as well as better facilitated production and storage.[[252]](#footnote-253) Although a patent was granted to the beta crystalline form by the US and European patent offices,[[253]](#footnote-254) the Indian court deemed that although the follow-on product represented an improvement in terms of processability and storability, its therapeutic efficacy was not demonstrated, as required by Section 3(d) of the Indian Patent Act[[254]](#footnote-255) which establishes:

*…the mere discovery of a new form of a known substance which does not result in the enhancement of the* ***known efficacy*** *of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.* (Emphasis added)

For the court the term efficacy in Section 3(d) relates to ‘the ability to produce a desired or intended result’ and its evaluation depends on ‘the result the product under consideration is desired or intended to produce’; hence, in the case of pharmaceutical products, the claims is to cure or treat diseases, i.e., therapeutic efficacy. Therefore, the court found that not all ‘advantageous or beneficial properties’such as processability and storability of a follow-on medicine demonstrated an enhanced therapeutic efficacy as established in Section 3(d).[[255]](#footnote-256) Furthermore, the court emphasised that the therapeutic efficacy must be judged ‘strictly and narrowly’ based on research data which the patent applicant did not demonstrate.[[256]](#footnote-257) The consequence of this case is that India has set higher standards for follow-on medicines in order to benefit from the entry of generic competitors in its local markets. As a result, Indian generic producers (the majority of plaintiffs were Indian pharmaceutical companies) benefit from the possibility of early access to technology;[[257]](#footnote-258)yet, representatives of originators claimed that this decision created legal uncertainty for investing in R&D in India.[[258]](#footnote-259)

*Natco Pharma Ltd v. Bayer Corporation* [[259]](#footnote-260) is another important case that revealed the interest of India in keep increasing capacity through generic production. In this case, the Indian Controller of Patents issued (for the first time) a compulsory licence on a pharmaceutical product (for the treatment of kidney cancer) owned by Bayer. [[260]](#footnote-261) The Indian Controller based their decision on two grounds: first, the drug was not available to the public at an affordable price; and second, the patent had not been manufactured in India.[[261]](#footnote-262) As Bayer appealed the decision before the Intellectual Property Appellate Board, this judicial court upheld the Controller’s decision to grant a compulsory licence on Bayer’s pharmaceutical products based upon the Controller’s arguments.[[262]](#footnote-263) The second argument in particular imposed an obligation on originators to either manufacture the invention locally or license Indian pharmaceutical companies to produce the drug in India.

In sum, *Novartis v. Union of India* and *Natco Pharma Ltd v. Bayer Corporation* facilitates Indian generic companies’ early access to technology as it restricts patent protection (by creating higher standards in patent requirements) and compelled originators to transfer technology to India by either setting up manufacturing facilities in India or licensing local producers (via compulsory licensing). Chaudhuri also highlights that although both decisions benefit local genetic production, they affect the few efforts by Indian pharmaceutical companies such as Dr. Reddys and Ranbaxy to invest in R&D.[[263]](#footnote-264)

Third, these decisions contribute to the consolidation of India’s leading role in manufacturing generic drugs that meet both local and international demand. Indeed, India has already taken a prominent role in the negotiations of TRIPs that led to the Doha Declaration on the TRIPs Agreement and Public Health with the aim of protecting its generic pharmaceutical industry interests in exporting medicines. As explained in more detail in Chapter 3, the Doha Declaration allows LDCs, which lack the capacity to manufacture medicines, to obtain a compulsory licence to import medicines in case of national emergency or other circumstances of extreme urgency, regardless of whether those medicines are under patent protection.[[264]](#footnote-265) This benefits the Indian pharmaceutical industry, as it is a world leader in exporting generic medicines. According to Doctors without Borders, India supplies 67% of generic medicines for small and emerging economies.[[265]](#footnote-266) For example, African nations account for 17% of India’s pharmaceutical exports.[[266]](#footnote-267) Furthermore, India is the main supplier of antiretroviral medicines for HIV/AIDS from health programmes and global funds (e.g. Doctors without Borders, Clinton Foundation and UNICEF).[[267]](#footnote-268) Those antiretroviral generic medicines are mainly delivered to African patients, which account for 69% of cases globally.[[268]](#footnote-269)

In addition, there are also other reasons which indicate that India has set up a restrictive patent protection, including on genetic resources. Although authorities have paid special attention to biotechnology (the first patent on a pharmaceutical product in a post-TRIPs era was granted to a biotechnology invention),[[269]](#footnote-270) Indian patent law requires disclosure of origin over the use of genetic resources.[[270]](#footnote-271) As explained in more detail in Chapters 3 and 4, developing countries rich in biodiversity such as India, and some developed countries such as Denmark and Switzerland, have added an extra requirement to the patent applicant within the obligation to disclose all information relevant to the invention. Disclosure of information is a requirement which aims to prove that an ordinarily skilled person can replicate the invention subject to patent protection. The extra requirement obligates the applicant to also disclose all information related to the origin of the genetic resources. In this way, India could verify whether the patent applicant has lawfully accessed genetic resources.

A similar situation occurs in microorganisms. In principle, Section 3 (j) of the India Patent Act allows the granting of patent protection to microorganisms.[[271]](#footnote-272) Although the India Patent Act adopts patents on microorganisms (to comply with TRIPs) India is still discussing whether or not patent protection on microorganisms responds to public concerns such as public health and affordability of invention based upon microorganisms.[[272]](#footnote-273) This has led to a discussion in India in which, on the one hand, the Mashelkar Committee pointed out that India should not exclude microorganisms from patent protection, otherwise it would be in breach of TRIPs commitments;[[273]](#footnote-274) on the other hand, Indian generic pharmaceutical companies (which have campaigned in favour of public health and access to medicines) are interested in expanding, for instance, their biosimilars (i.e. generic biopharmaceuticals) portfolio in India and overseas rather than innovating, which requires having no patents on biotechnological inventions. Malhotra argues that as patents on biotechnological inventions in developed countries have come to an end, the Indian pharmaceutical industry has an important opportunity to meet the demand of biosimilars in India and overseas.[[274]](#footnote-275) Indeed, India has over 100 generic pharmaceutical companies that have exclusively focused on producing high quality biosimilars to enter in developed countries and other developing countries’ markets.[[275]](#footnote-276) This means that in the case of biotechnology, the Indian pharmaceutical policy also aims to increase capacity in the manufacturing of high biosimilars, rather than to bring new medicines into the market.

In addition, although the Indian generic pharmaceutical industry has played a key role in reducing patent protection, Mueller claims that such negativity towards the endorsement of a more open patent protection and new requirements such as disclosure of origin, is due to a coherent decision by India to globally campaign against the misappropriation of biodiversity (or biopiracy).[[276]](#footnote-277) Indeed, India has adopted a more defensive approach towards patents on genetic resources and traditional knowledge associated to genetic resources in order to put these into the public domain. For instance, India has pioneered defensive strategies through the Traditional Knowledge Digital Library (TKDL) which document genetic resources and traditional knowledge associated with genetic resources in order to provide information to patent offices, including USPTO, EPO, etc., so they could prevent the granting of patents over genetic resources and traditional knowledge associated with genetic resources.[[277]](#footnote-278)

However, there are other scholars who claim that India’s approach to patent protection on medicines could harm R&D in this sector. For instance, Chandran et al. argue that by fully endorsing patents over technologies that employ genetic resources, India could benefit from both the faster transfer of technology and foreign investment.[[278]](#footnote-279) Nevertheless, Chandran et al. also suggest that patents on these technologies should be granted in India to Indian companies, rather than non-Indian ones, as has occurred with cases such as that of the neem, a plant that has been employed for more than 200 years by local communities for different uses (pesticides, fungicides, etc.).[[279]](#footnote-280) Indeed, the antimycotic agent, for the treatment of fungae, is extracted from the leaf of the neem or *Azadirachta indica* which has been patented in both the USPTO and the EPO. The EPO patent was withdrawn in 2012 after evidence of prior art was undisclosed before the EPO, thanks to the efforts by TKDL;[[280]](#footnote-281) yet the US patent remains valid.[[281]](#footnote-282)

India has been successful during the last 40 years in encouraging a vigorous pharmaceutical industry through policies that aim to protect its national interests. In other words, India is focusing on meeting global trends for generics (including biosimilars); yet it has enacted a legislation that is transforming its pharmaceutical industry and led the industry to shift from being an illegal generic producer to a generic manufacturer in order to meet local and international demands for generics and developed countries’ markets requirements on quality of medicines.

Certainly, decisions such as those taken by the Indian Patent Controller and the Indian High Court seem to prove that India is more concerned with protecting the interests of the Indian generic industry, despite the fact that this could hamper further innovation in the pharmaceutical industry. Additionally, India has also adopted a defensive strategy in developed countries’ patent offices to prevent misappropriation of genetic resources and traditional knowledge associated to genetic resources through TKDL as well as implementing disclosure of origin in patents. This indicates that a more rigorous implementation of patents locally and internationally goes against Indian generic companies’ interests in manufacturing and supplying international and national demand for generic drugs and active pharmaceutical ingredients. However, originators such as Pfizer are already complaining of the negative impact of India’s pharmaceutical policy that benefits local generic companies. Indeed, Pfizer has already briefed the US Congress on the negative impact of this policy for innovation in the pharmaceutical industry.[[282]](#footnote-283)

The discontent from originators, Indian defence of its generic industry, and defensive approach in TKDL, all indicate that India’s capacity is addressed towards securing that it remains as leading country in manufacturing and supplying generic medicines locally and globally, rather than innovating in new medicines based upon its genetic resources.[[283]](#footnote-284)

In sum, India’s adoption of TRIPs has contributed to a global shift in the market in which India is taking over the generic market locally and globally. Patents for India, is a necessary evil in which India provides patent protection to originators in order to gain access to international trade. Such a situation indicates Indian pharmaceutical companies are not concerned with engaging in R&D activities on diseases that affect the country (i.e. neglected diseases) and taking advantage of genetic resources and traditional knowledge associated with genetic resources for drug development, but rather in supplying demand for generics and active pharmaceutical ingredients for diseases that respond to the global demand.

* + 1. **China: A Wolf in Sheep’s Clothing**

China and India have a similar focus in their pharmaceutical industry. For instance, both countries started their pharmaceutical industry by relying on illegal generic production and national industries, and have become an attractive prospect for outsourcing for originators.[[284]](#footnote-285) Nevertheless, there are two significant differences between China and India in terms of capacity. First, China’s government has played a fundamental role in encouraging R&D in technologies that employ genetic resources, especially biotechnology. Second, despite China being ruled by a communist government, China has embraced international trade; hence, this country has been more flexible and open to grant patents to originators and progressively to Chinese companies.[[285]](#footnote-286)

However, China did not adopt patents on pharmaceutical products when it enacted its first patent law in 1984,[[286]](#footnote-287) rather pharmaceutical patents were introduced as part of evolving economic and political reforms. [[287]](#footnote-288) As a result, China implemented a Western-style patent system which grants patents on technologies that employ genetic resources. This has occurred thanks to the Chinese government’s determination to encourage the flow of foreign direct investment (FDI) into the country and obtain economic benefits from international trade. Yet, China is showing signs that granting patents on pharmaceutical products was not only designed to attract FDI, but also to enable China to increase capacity in R&D, so this country could compete with other economies, including India and developed countries.

* + 1. **Trends on Technologies that Employ Genetic Resources in China**

Before China moved to a market economy with the reforms of Deng Xiaoping during the latter part of the 1970s, the Chinese government, especially local government, incentivised the pharmaceutical industry with the aim of encouraging industrial development and creating jobs.[[288]](#footnote-289) During this time (Cultural Revolution) and in a highly regulated and hostile economic environment, originators were not interested in entering the Chinese market.[[289]](#footnote-290) As a result, there was only a moderate development of local pharmaceutical companies which manufactured illegal generics with low quality standards across China, and there was low investment in technologies that employ genetic resources.[[290]](#footnote-291) Since 1978 the situation changed as the Chinese government engaged not only in incentivising the local production of drugs, but also in increasing capacity in R&D.[[291]](#footnote-292) During the first half of the 1980s, China increased its investment in biotechnology by 25% in research programmes such as basic genetic engineering and plant genetic engineering.[[292]](#footnote-293) Such an increase in investment was also accompanied by the creation of different institutions that helped to develop this sector, e.g., the China National Centre for Biotechnology Development, which helped to coordinate research activities and funding.[[293]](#footnote-294)

During the decade of the 1990s and the beginning of the 21st century, the Chinese biotechnology sector increased steadily and consolidated as an important world player. By 2002 there were around 300 biotechnology firms operating in China.[[294]](#footnote-295) The increasing number of local biotechnology firms also triggered an increase in patent applications outside China. For instance, the biotech company United Gene Holdings filed around 1,000 global patents by 2003 via the PCT.[[295]](#footnote-296)

The biotechnology sector in China was also boosted during the 1990s with the participation of the Beijing Genomics Institute (nowadays known as the BGI-Shenzhen) in the Human Genome Project, making China the first developing country to take part in this project.[[296]](#footnote-297) It is also important to note that efforts by China to make their pharmaceutical companies more competitive continued in the first decade of the 21st century; this increased its technical infrastructure and public funding, as well as encouraged developed countries’ companies to invest in China’s R&D in biotechnology.[[297]](#footnote-298) Companies such as Pfizer, Merck and Novartis have invested up to US$ 1.5 billion in R&D in China.[[298]](#footnote-299)

There are three fundamental reasons for China becoming a very attractive market for originators. Firstly, local demand for medicine has increased recently (for instance different reports have highlighted the ambitious government plan to expand healthcare to most of its large population).[[299]](#footnote-300) This could make China an even a more attractive pharmaceutical market than the US.

Secondly, China has managed to transform traditional Chinese medicine, especially herbs, into a promising source for the discovery of new medicines,[[300]](#footnote-301) yet traditional Chinese medicine has core differences in comparison with modern (or Western) medicine. Indeed, the production of modern medicines involves either purification (or extraction) of a chemical compound or the isolation and purification of the genetic information encoded in the DNA or RNA; whereas, traditional Chinese medicine comprises a 2000 year tradition of curing diseases by correcting ‘the imbalance of the disorder’.[[301]](#footnote-302) Traditional Chinese medicine involves the combination of some Chinese theories (e.g. yin-yang and five elements) and physical treatments such as herbal remedies, acupuncture, acupressure and moxibustion.[[302]](#footnote-303) This practical and theoretical approach towards diseases might not be completely understood by originators, but scientists and biotechnological companies have employed traditional Chinese medicines in the drug discovery process. For instance, the Biotechnology Research Institute in Hong Kong is screening and isolating new chemical entities from traditional Chinese medicine to treat neurodegenerative diseases.[[303]](#footnote-304) Another example is the joint effort by the Shanghai Traditional Medicine Innovation Centre and the American biotechnology firm PhytoCeutica to create a database of 9,000 traditional herbs and 150,000 recipes.[[304]](#footnote-305) Moreover, there are 90 drugs that have been developed from Chinese traditional medicine and herbal drugs since 1949.[[305]](#footnote-306) An emblematic case of the importance of Chinese traditional medicine in modern drug discovery is the use of *Artemisinin* (sweet wormwood, annual wormwood) to treat malaria (considered to be a neglected disease) in combination with other anti-malaria therapies (i.e. the Artemisinin Combination Therapy (ACT)). ACT is the ‘most potent weapon in treating’ malaria, according to the WHO.[[306]](#footnote-307) Such an interest in Chinese traditional medicine and herbal medicines has even been reflected in developed countries’ medicine regulation. For instance, in 2004, the EMA created the Committee on Herbal Medicinal Products (HMPC) that is responsible for giving opinions to EMA and EU members on the safety and efficacy of herbal medicines.[[307]](#footnote-308) As a result, in 2010 the EMA issued guidelines on the identification, quality, preparation, safety and efficacy of herbal medicinal products.[[308]](#footnote-309)

Thirdly, growing local demand for medicines and the interest of employing Chinese traditional medicine for drug development followed an interesting change in China’s attitude towards patent protection.

* + 1. **Regulatory Framework for Pharmaceuticals in China**

Since China decided to open its economy to the global market, the Chinese authorities have encouraged FDI by adopting a developed country-style patent law. At the end of the 1970s, when Deng Xiaoping’s economic reforms were being implemented, the Chinese government decided to study different patent legislation around the world in order to establish which patent law could allow it to attract FDI and gain entry to different international organizations such as the WTO.[[309]](#footnote-310) Chinese scholars, sponsored by the government, went to different developed countries to study their patent legislation.[[310]](#footnote-311) As a result, China showed particular interest in the European patent system, especially German patent law.[[311]](#footnote-312)

The interest of China in providing legal patent protection led it to join the WIPO in 1980 and to enact a patent law in 1984.[[312]](#footnote-313) China’s commitment to adopting a Western-style patent system was also ratified by the different cooperation agreements subscribed to since 1985 by the EPO and the (Chinese) State Intellectual Property Office (SIPO).[[313]](#footnote-314) Those agreements have included, for example, technical cooperation and sharing of information on prior art.[[314]](#footnote-315)

Aditionally, China’s interest in entering the WTO has left Chinese authorities an incredibly short period of time to make legal amendments to meet TRIPs patent requirements. Although China’s first patent law (1984) did not protect on pharmaceutical and chemical synthesis, eight years later Chinese authorities embraced patents on those technologies.[[315]](#footnote-316)

However, although there were amendments made to Chinese patent law to broaden the scope of patent legislation to meet WTO requirements, China did not get rid of the worldwide perception that it had an economy which relies on unlawfully copying IPRs. Accountability by Chinese authorities for the safety and quality of medicines is also a concern. This was evident when in 2007 the Chief of the State Food and Drug Administration was sentenced to death after it was established that he was involved in a series of incidents that compromised the quality and control of medicines and food.[[316]](#footnote-317) More recently, GlaxoSmithKline has been involved in a bribery row in which this pharmaceutical company was found to be channelling payments through third parties to hospitals’ staff and State authorities to increase market share and prices of prescription medicines.[[317]](#footnote-318)

Nevertheless, Andrews[[318]](#footnote-319) considers that China has made considerable progress in a short period of time; especially if it is taken into account that patents were an alien concept not only for communist China, but throughout China’s entire legal history.[[319]](#footnote-320) Despite the fact that China has problems to solve regarding corruption and enforceability of patents, there are trends that show how Chinese authorities have begun to accept patents and how Chinese pharmaceutical companies are using patents as part of their business models, rather than just producing illegal generics. This is illustrated in the case of Pfizer’s Viagra patent.[[320]](#footnote-321)

In 2001 Pfizer obtained a patent from the SIPO for its erectile dysfunction medicine; only three years later Chinese pharmaceutical companies, which had already invested in producing generic versions of the drug, demanded the invalidation of the patent on the grounds that it did not disclose all information on the drug.[[321]](#footnote-322) The patent was invalidated by SIPO, but after years of litigation Pfizer regained patent protection for Viagra in 2006;[[322]](#footnote-323) a decision which was upheld by the Beijing High Court in 2007.[[323]](#footnote-324) Although there were great pressures from developed countries, the case of Viagra is an important landmark not only because Pfizer’s patent was protected in the end, but because the Chinese pharmaceutical companies decided to opt to invalidate the patent by legally challenging it, rather than just copying the invention. It has also been reported that Chinese pharmaceutical companies have engaged in battles to challenge pharmaceutical product patents from companies such as GlaxoSmithKline on similar grounds to those of the Viagra patent.[[324]](#footnote-325) Therefore, challenging patents within the Chinese patent legal system has become part of the Chinese pharmaceutical industry’s business model.

Such a transformation, from having companies that used to rely more on their production of illegal generics to companies that are legally challenging patents, is also reflected in the number of patents filed by Chinese residents in China. WIPO has reported that in 2012 China had the most active number of local filers of patents in the world, overtaking countries such as Japan and the US.[[325]](#footnote-326) These trends show that, although the Chinese patent law is only 30 years old, it is on the way to meeting developed countries’ standards. Furthermore, China has even adopted greater exclusivity protection on data exclusivity (i.e. protection on data or test which is employed to obtain an MA and patent linkage (linking MA procedure with the status of the patent) with the aim of securing the transfer of technology and increasing the flow of FDI from originators.[[326]](#footnote-327)

However, the fact that Chinese pharmaceutical companies are challenging patents does not necessarily mean that China is turning its pharmaceutical industry into a more innovative sector. Xuc and Liang considered that what Chinese pharmaceutical companies aimed to achieve by challenging patents before the SIPO and Courts is to use patent law as a tool for competitive advances (e.g. facilitating early generic entry) but not spread innovation in China.[[327]](#footnote-328) This means that although China has rapidly adopted a Western-style patent legislation, in practice the Chinese pharmaceutical industry might be doing what Indian pharmaceutical companies have carried out on patents for pharmaceutical products; i.e. to employ patent legislation to protect generic production of medicines, rather than innovating.

However, the new Chinese government’s policy on innovation will demand that the Chinese pharmaceutical industry has a different attitude towards patents. The National Patent Development Strategy (2011-2020) (NPDS) aims to create not only a more competitive China but also a more innovative country.[[328]](#footnote-329) The NPDS acknowledges that China has not used patents in a way that could fully promote innovation into her economy.[[329]](#footnote-330) As a result, the NPDS set up goals to encourage innovation that include making China a world ‘top two’ country in filing patent applications by 2015, becoming a ‘master’ in core technologies, improving patent protection, increasing the number of patent examiners by 9000 in 2015 and raising cultural awareness among the Chinese population of patents as an instrument of innovation for the benefit of the country.[[330]](#footnote-331) This 10-year plan proves that China has recognised that patent law has not played an innovative role in the local pharmaceutical industry, but has simply been a tool to attract FDI. More importantly, the plan is also a clear illustration that China is delivering an innovative policy to increase its capacity and transform this country into a world leader in patenting.

China is already showing signs of its determination to become an innovator country. For instance, in 2010 the China Development Bank supported, via a credit line, the BGI-Shenzhen to acquire 128 DNA sequencing machines, which led the BGI-Shenzhen to account for some 10-20% of all DNA data produced globally (including animals, humans and plants); the BGI-Shenzhen even sequences DNA for other research institutes in developed countries.[[331]](#footnote-332) Another example of innovation in biotechnology is the ShanghaiBio Corporation, a subsidiary of Shanghai Biochip, which provides services in R&D for originators and biotechnological companies as well as preclinical trials and support for clinical trials.[[332]](#footnote-333) The ShanghaiBio Corporation has even opened a branch in the US. Equally, China has also increased its number of patent filings and patents granted in developed countries: patent fillings in EPO increased from 5835 in 2007 to 18812 in 2012; whereas the USPTO has reported that the number of patents granted to Chinese nationals grew from 772 in 2007 to 5341 in 2012.[[333]](#footnote-334)

Regarding access to genetic resources and benefit sharing, China has not been completely clear on its stand on genetic resources, but there are some legal steps that indicate that China aims to control access to patent legislation. This means that although China has not enacted a comprehensive legislation on access to genetic resources and benefit sharing, it has already made modified its patent legislation to include disclosure of origin in patents[[334]](#footnote-335) with the aim of ensuring that users of genetic resources share benefits from the utilisation of those resources.[[335]](#footnote-336) Yet, China still needs to develop and enact a legislation that indicates how benefit sharing takes place.[[336]](#footnote-337) This means that while research institutes such as the BGI-Shenzhen benefits (economically and technologically) from sequencing genetic resources from developed countries, China seems to be aiming to control access to genetic resources through legal instruments, such as disclosure of origin in patents, in order to secure a share of the benefits that arise from the utilisation of genetic resources.

In summary, the Chinese pharmaceutical industry and patent regulation have steadily evolved. The beginnings of the Chinese pharmaceutical industry and patent law after the Cultural Revolution were characterised by Chinese determination to obtain FDI and the transfer of technology from developed countries. Nevertheless, during this period China was not completely committed to implementing and enforcing its own patent legislation, as this country did not have a strong national pharmaceutical industry. However, as local pharmaceutical companies have been able to compete and work alongside overseas companies, China’s attitude towards patents on pharmaceutical products has been transformed. Chinese pharmaceutical companies are employing patent law not as an innovative tool but as an instrument to legally protect their generic industry – something that can be compared with the Indian pharmaceutical industry’s experience.

However, China is taking the lead to implement more policies (e.g. NPDS) that could create a truly innovative country, as Chinese pharmaceutical and biotechnology companies have started to be involved in R&D for drug development and not only in manufacturing. Yet, China is taking important steps to control access to genetic resources and secure benefit sharing via disclosure of origin in its patent legislation, though further legislation needs to be enacted in order to establish how benefit sharing could take place.

As a result, China’s policies clearly indicate that this country has acted according to its capacity, i.e. China has a clear understanding of the strength of its pharmaceutical industry, scope of its patent legislation and importance of its genetic resources, including Chinese traditional medicine. This means that if China maintains and masters these policies on IPRs and innovation, it could become a strong advocate of patents on technologies that employ genetic resources for drug development.

* 1. **Filling the Gap: LDCs in the Global Market**

As developing countries have been complying with TRIPs standards and, as a result, moving towards the production and distribution of generic medicines in the global market, there has been left a gap regarding illegal generics in LDCs. These countries could supply the demand for illegal medicines by either importing those medicines from a third country (as established in the Doha Declaration on the TRIPs Agreement and Public Health) or manufacturing and distributing locally as they are not compelled to comply with TRIPs standards until 2016.

On the importation of medicines to supply local demand, Kaplan and Laing claim that LDCs should prioritise resources to other needs, such as access to medicines, rather than encouraging the creation of a pharmaceutical industry.[[337]](#footnote-338) Kaplan and Laing consider that it is pointless to incentivise local production and R&D in countries that lack the infrastructure to produce medicines to global standards, since the drug development process is very complicated and demands highly legal and technical capacity; hence, they conclude that LDCs opt for importing medicines to supply local demand rather than engaging in expensive long-term initiatives to incentivise a local pharmaceutical industry.[[338]](#footnote-339) Additionally, Anderson[[339]](#footnote-340) and Al-Bader[[340]](#footnote-341) et al. share similar concerns to those explained by Kaplan and Laing, but they consider that there are efforts that could benefit LDCs.

Indeed, LDCs could increase capacity to manufacture and distribute, as they are not obliged to comply with TRIPs until 2016. A trilateral study by the WHO, WIPO and WTO points out that this could ‘provide opportunities to set up local production in LDCs for products that are still under patent protection in other countries.’[[341]](#footnote-342) As a result, international organization such as the UN Conference on Trade and Development (UNCTAD) and the UN Industrial Development Organization (UNIDO) have backed different initiatives in LDCs located in Africa with the aim of making LDCs engage in the production of illegal generic medicines.[[342]](#footnote-343) These attempts are initially focused on creating and encouraging local pharmaceutical companies to produce affordable drugs for local production and consumption, and for export to neighbouring countries. These efforts have taken place in countries such as Ethiopia, Kenya, Tanzania and Uganda.[[343]](#footnote-344)

However, LDCs still rely on the importation of active pharmaceutical ingredients for drug production from countries such as India and China.[[344]](#footnote-345) As a result, the cost of producing even illegal generic medicines makes manufacturing too expensive. Yet there are alternatives to increase capacity in LDCs which include India and China.[[345]](#footnote-346)

India and China aim to take advantage of LDCs’ TRIPs flexibilities. Indian and Chinese companies have either imported generic drugs or invested in LDCs’ pharmaceutical companies, as TRIPs and the Doha Declaration on the TRIPs Agreement and Public Health allows LDCs to delay implementation on patents over pharmaceutical products and processes, and to import generic medicines in case of national emergency or other circumstances of extreme urgency, regardless of whether those medicines are under patent protection.[[346]](#footnote-347)

This makes LDCs a very attractive destination, for example, for Indian companies that aim to keep a similar approach to that which they carried out in the pre-TRIPs era in India.[[347]](#footnote-348) For instance, the Indian pharmaceutical company Cipla began to export antimalarial and antiretroviral medicines to Uganda and eventually Cipla, among other shareholders, invested US$ 80 million to expand industrial facilities for generic production by the Ugandan pharmaceutical company QCI.[[348]](#footnote-349) Nevertheless, China and India’s interest in breaking into LDCs’ markets might not be positive for LDCs, as China and India could benefit from TRIPs and Doha flexibilities on importing medicines to these countries rather than manufacturing locally. Despite the risk that LDCs could become dependent on China and India, transfer of technology from China and India to LDCs is a reasonable approach to increase capacity in these countries, especially if the aim is first to create a pharmaceutical industry able to replicate technologies that have already been employed in China and India.

**Conclusions**

This chapter has analysed the global context of the pharmaceutical industry with particular interest in developed countries, China and India. It finds that developed countries are the global leaders in R&D and innovation in the pharmaceutical industry because their market size is larger than that of other countries; their originators’ companies invest far more on R&D than somewhere else (80% of the US$ 120 billion spent worldwide); and these countries have also delivered policies that have encouraged further investments in R&D (e.g. orphan drugs). However, there are also challenges that largely concern developed countries’ pharmaceutical industries. For instance, the decline of new biochemical compounds, the increasing cost of the drug development process, the end of patent exclusivity on different medicines and the boom of generic medicines globally.

This means that although the pharmaceutical industry is growing in terms of market size (particularly in developing countries) and even expenditure on R&D, there is a decline in new medicines. Another particular problem is that although neglected diseases are being taken more seriously by countries and international organizations such as the WHO, there is still little interest in promoting R&D for those diseases.

However, recent trends in the global market indicate that countries such as China and India could play a more prominent role in the global pharmaceutical industry. India and China have delivered policies in which their pharmaceutical industries have gained different capacities.

In the case of India, it has increased capacity in manufacturing and distributing generic medicines and active pharmaceutical ingredients in order to supply local and global demand. Indeed, India’s pharmaceutical industry is well known for its chemical skills and the quality of its pharmaceutical products. This has even allowed the Indian generic industry to enter the developed countries markets. Since India has implemented TRIPs, it also appealed to originators to invest in due to the low cost of production and professional skills, as well as some local companies making efforts to innovate in the discovery of new biochemical compounds.

However, the decisions of the Controller (Novartis) and the Indian Supreme Court of Justice (Glivec) have actually benefitted the Indian generic industry since both decisions limit patents on pharmaceutical products and the ability of originators to enforce their patents in India. It is also important to highlight that India is adopting a defensive approach to patents on genetic resources and traditional knowledge associated with genetic resources by challenging developed countries’ patent offices’ decisions that have granted patent on those resources, rather than encouraging local companies to file for patents on them, as well as employing disclosure of origin in patents. This illustrates that India’s interests centre in increasing the capacity of its generic pharmaceutical industry in order to supply local and international demand. In other words, although there are initiatives to increase India’s capacity for R&D (e.g. public-private partnerships), India has rather focused on increasing capacity for production and distribution of high quality generic medicines and active pharmaceutical ingredients. In the case of neglected diseases which affect the Indian population, local companies aim to prioritise demand for medicines for global diseases that affect particularly developed countries, rather than engaging in R&D in neglected diseases. Finally, India is already taking advantage of TRIPs transit period for LDCs to boost its manufacturing capacity and import generic medicines.

In the meantime, China is aiming to encourage an innovative pharmaceutical industry based on its biotechnology sector and traditional Chinese medicine. It is also important to note the increasing demand for pharmaceutical products in China has attracted originators. However, the most important trend is China’s commitment to develop and encourage an innovative pharmaceutical industry through patents. Chinese authorities and pharmaceutical companies have begun to understand that granting patents is not only a requirement to obtain benefits from international trade, but an engine for innovation in the Chinese pharmaceutical industry. Therefore, China’s challenge is not only to set up a policy to encourage R&D, but to implement it. Bribery, corruption and a lack of awareness of the importance of innovation in the Chinese population are the barriers that China needs to overcome in order to become an innovative country. For the global context, the rise of a Chinese innovative pharmaceutical industry could make this developing country rich in biodiversity team up with developed countries on providing strong patent protection on technologies that employ genetic resources.

In conclusion, China is taking a lead in terms of increasing capacity for innovation. This is the result of Chinese policies to increase China’s capacity in technologies that employ genetic resources. China has a long way to go to deliver those promises though. Meanwhile, India has decided to focus on increasing capacity in its generic industry and protecting its generic resources from appropriation, even from local companies.

In the case of LDCs, this chapter finds that they aim to fill the gap for illegal generics left by India and China as they are entitled to employ mechanisms that ease the implementation of TRIPs, such as the delay to implement TRIPs standards and compulsory licensing for imports. Such a situation has also led to China and India transferring technology to these countries which helps them to increase capacity in manufacturing generics.

The next chapter translates the analysis and conclusion carried out in this chapter to the case of Colombia. Colombia also aims to consolidate a generic manufacturing industry that helps them to supply medicines locally and regionally, but they face important challenges, such as increasing pressure from developed countries to expand patent protection through bilateral trade agreements also known as TRIPs-Plus, lack of a clear policy, and a deficiency of capacity in Colombia’s pharmaceutical industry, particularly in R&D in its own biodiversity.

Chapter 2: The Colombia Context

**Introduction**

The analysis that was carried out in Chapter 1 continues in Chapter 2 as it provides an understanding of both China’s and India’s capacity for technologies that employ genetic resources for drug development, the role of genetic resources in the pharmaceutical industry and the pharmaceutical global market in order to provide comparator regions in which Colombia’s capacity that can be contextualised.

The importance of analysing countries’ capacity is explained in the introduction of this thesis, as capacity relates to the intellectual labour that adds value to genetic resources for drug development. According to authors such as Mossoff, Locke’s labour theory can be extended to IPRs since it is inventors’ labour that adds value, which leads them to appropriate what are the commons.[[349]](#footnote-350) Locke’s labour theory also creates two provisos (Lockean provisos) to prevent right holders from abusing what they have appropriated from the commons: sufficiency proviso, which prevents right holders from appropriating all the commons, so there are enough, and as good, left in common for others[[350]](#footnote-351). This proviso is exemplified in the limits that legislation and courts place on the scope of patent claims; there is also the waste or spoiled proviso, in which property rights that have emerged from inventors’ labour cannot spoil or destroy what is in the commons; this proviso is illustrated by the value lost by hoarding an intangible that embodies a tangible, as occurs in the unmet demand of medicines.

However, Locke’s theory is complemented in the global context through Rawls’ social contract theory and Nussbaum’s capability approach, as TRIPs standards and the ABS are the result of a bargain between developed and developing countries, including those rich in biodiversity. In the former, patents’ standards are the result of a trade-off of access to international trade for access to technology, while the latter is a trade-off of access to technology for access to genetic resources. Therefore, such a bargain is better assessed by Rawls’ procedural analysis of how participants in a social contract come to an agreement. Nussbaum’s capability approach also complements this analysis by assessing parties’ capacity, i.e. what they are capable of and what they want in an agreement.[[351]](#footnote-352) This means that capacity is encapsulated within the capability approach since countries should not only focus on increasing capacities but enabling them, particularly developing countries rich in biodiversity such as Colombia, to improve resources and opportunities according to what countries want to do and are capable of. As a result, countries can construct a tailored policy and legislation that entitles them, in the case of this thesis, to increase capacity in the drug development process in the light of technologies that employ genetic resources. By analysing countries’ capacity, Chapters 1 and 2 provide indicators for assessing whether developing countries rich in biodiversity are implementing TRIPs and the ABS according to their own capacity in technologies that employ genetic resources for drug development.

Therefore, Chapter 1 identifies that India has focused its capacity on improving the production and distribution of generics and active pharmaceutical ingredients, while it has adopted a defensive stance on protecting genetic resources and traditional knowledge associated with those genetic resources. Such an approach has discouraged originators and some local companies (i.e. Dr. Reddy’s and Ranbaxy Laboratories) from investing in R&D in new biochemical entities.[[352]](#footnote-353) Furthermore, although companies such as Dr. Reddy and Ranbaxy have some interest in R&D, they have rather focused on diseases that affect mainly developed countries (e.g. obesity, diabetes, etc.) rather than neglected diseases that affect the Indian population. As a result, Chapter 1 highlights that the reason why Indian pharmaceutical companies focus on manufacturing and distributing generics, and on developed countries’ diseases, is that they are rather more motivated by profit margins in order to supply to the global demand for medicines for those diseases. In the meantime, China is making efforts to increase capacity in biotechnology and the use of Chinese traditional medicine. China is also adopting similar policies on patents to those of developed countries. However, China has amended its patent legislation to include disclosure of origin in order to control access to these resources and secure benefit sharing; yet, China has not clarified the scope of benefit sharing. Although China has not yet taken a strong advocacy on patent protection of technologies that employ genetic resources, its growing biotechnological industry and the interest of the Chinese government to make this country a world leader in innovation could eventually lead this country to side with developed countries in campaigning for stronger rules on patent protection. Chapter 1 also points out that LDCs are filling the gap that developing countries such as China and India have left as the latter two countries have adopted TRIPs standards, since TRIPs granted a waiver to LDCs having to implement TRIPs provisions on pharmaceutical products until 2016.

Conversely, Chapter 2 analyses Colombia’s capacity in its pharmaceutical industry, the role of genetic resources in drug development for this country and Colombia’s position within the global pharmaceutical market. This chapter illustrates that Colombia had managed to develop a generic pharmaceutical company that supplied local demand for medicines before it adopted TRIPs standards. However, as Colombia opened its economy to international trade, Colombia adopted TRIPs standards and, eventually, TRIPs-Plus standards. This means that Colombia has not only transformed different aspects of its patent legislation to include TRIPs provisions (e.g. patents on pharmaceutical products and limits to compulsory licensing) but has also created a new mechanism of exclusivity protection on pharmaceutical products, especially data exclusivity (i.e. protection on data or tests which are employed to obtain an MA) via TRIPs-Plus standards. As a result, local generic pharmaceutical companies have to compete with originators for a share of Colombia’s local market. This chapter also finds that despite the fact that Colombia adopted TRIPs and TRIPs-Plus standards, its local pharmaceutical industry has not actively been involved in R&D. This indicates that Colombia’s IPRs policy does not aim to reward patent exclusivity to scientific and technical activities that adds value, but rather it has prioritised trade over increasing capacity in its pharmaceutical industry. In other words, Colombia has developed a generic industry able to manufacture and distribute generics and originators under licensing agreements, but has not been able to encourage R&D. Furthermore, Colombia’s generic industry relies on imports of active pharmaceutical ingredients from other countries such as India. Additionally, Chapter 2 analyses policy documents and legislation which indicate that Colombia aims to encourage users of genetic resources to utilise them for drug development; however, Colombia’s regulation on access to genetic resources and benefit sharing has created legal uncertainty among potential local users of genetic resources, such as publicly funded universities, about accessing those genetic resources.

This chapter is divided into two parts. The first part contextualises Colombia in the global pharmaceutical market and highlights why Colombia seeks to take advantage of its genetic resources for the drug development process. The second part analyses in detail the trends, figures and policies of the pharmaceutical industry, and technologies that employ genetic resources for drug development in Colombia.

1. **Colombia within the Global Context**

Chapter 1 concludes that there are positive signs for the global pharmaceutical industry in terms of size and expenditure, particularly in developing countries rich in biodiversity. India and China have become important players in the pharmaceutical market; they have both contributed to making their respective generic industries main players, able to compete with developed countries’ pharmaceutical companies. However, there are concerns that this growth has not been reflected in a more innovative pharmaceutical industry in these two countries, particularly in India. In the meantime, LDCs are filling the gap in manufacturing and distributing illegal generics since they can delay the implementation of international standards of patent protection set up by TRIPs.

Although Colombia does not have the capacity of India and China, or LDCs’ international legal flexibilities to fill the gap of illegal generics’, it is important to evaluate how Colombia fits within the global market and whether the policies that have been implemented in Colombia could lead the country to create or encourage a local pharmaceutical industry able to take advantage of biodiversity in the light of technologies that employ genetic resources.

Colombia is a developing country, rich in biodiversity, that is not only adopting TRIPs standards of patent protection, but since Colombia has an increasing interest in opening its economy to trade with developed countries such as the US[[353]](#footnote-354) and the EU,[[354]](#footnote-355) it has adopted higher standards of patent protection via FTAs (TRIPs-Plus), which not only limit the use of compulsory licensing, and expand patent protection to pharmaceutical products (as established by TRIPs), but also create new mechanisms of exclusivity protection in the pharmaceutical industry including, data exclusivity (i.e. protection on data or tests which are employed to obtain an MA). Colombia is also signing up to FTAs with other economies, including Singapore[[355]](#footnote-356) and South Korea,[[356]](#footnote-357) and more recently has signed up to a regional trade agreement with Chile, Mexico and Peru in what has been called the Pacific Alliance.[[357]](#footnote-358)

Since the interest of Colombia in gaining access to international trade has led this country to adopt higher standards of patent protection, local pharmaceutical companies cannot rely on copying originators to obtain transfer of technology, unless they obtain licences from patent holders or patent protection is not longer enforceable. However, Colombian authorities have pointed out that Colombia’s pharmaceutical industry could obtain benefit sharing, including transfer of technology, from the utilisation of genetic resources. In fact, a 2008 governmental White Paper highlights that biodiversity provides Colombia with a “unique comparative advantage” to develop new products in industries such as the pharmaceutical industry. [[358]](#footnote-359) Therefore, it is important to define two fundamental points to find out if Colombia’s pharmaceutical industry could actually benefit from the utilisation of genetic resources: (1) The availability of genetic resources in Colombia and (2) Colombia’s actual interest in employing those resources for drug development.

First, Colombia is indeed one the most mega-diverse countries in the world. Since Colombia is in the north west area of South America, different biodiversity ‘hot spots’ converge in this country: the Choco/Darien coast in the west, the tropical Andes which begin in the centre and end in the north east of the country, and the Amazon rainforest in the south (see Annex III).[[359]](#footnote-360) As a result, Colombia has the largest diversity of amphibians and birds in the world, the second largest in plants, third in reptiles and fifth in mammals.[[360]](#footnote-361) Colombia also enjoys a growing economy (with an output of 6.6% in 2011 and 4% in 2012) thanks, for the most part, to the exploitation of natural resources such as oil and gold, and the flow of FDI.[[361]](#footnote-362) This means that Colombia is well placed to employ its large availability of genetic resources for drug development.

Second, regarding Colombia’s actual interest in employing genetic resources for drug development, the Colombian authorities have already pointed out how important the country’s biodiversity should be for its economic development. For instance, the President of Colombia, Juan Manuel Santos, has repeatedly mentioned that Colombia has the biodiversity that the world needs today.[[362]](#footnote-363) In the last two presidential periods (i.e. those of both the former President Alvaro Uribe and the current President) the National Development Plan or *Plan Nacional de Desarrollo*[[363]](#footnote-364) points to the importance of biodiversity and genetic resources for both the economic development and technological innovation of the country.[[364]](#footnote-365) On genetic resources for drug development, the Colombian government has stressed that biodiversity is an important asset for the pharmaceutical industry.[[365]](#footnote-366) Nevertheless, this apparent interest of the Colombian authorities in encouraging innovation through the exploitation of Colombian biodiversity is not reflected within the Colombian pharmaceutical industry in using biodiversity as a source of drug development.

Indeed, the development of Colombia’s pharmaceutical industry reveals the lack of coherence in implementing a legal framework that might lead Colombia to encourage an innovative industry that could take advantage of the country’s biodiversity. Such a lack of clarity from Colombia’s government has resulted in a local pharmaceutical industry that, despite increases in sales and size over the years, remains dependent on developed countries’ technologies, and the importation of products and active pharmaceutical ingredients to supply local and regional demand, and to manufacture generics. Additionally, Colombian pharmaceutical companies have failed to engage in R&D in technologies that employ natural and genetic resources, regardless of the Colombian government having granted patents on pharmaceutical products.

The lack of clarity can also be observed in the regulation of access to genetic resources. Despite Colombia giving patent protection to pharmaceutical products, it has enacted legislation on access to genetic resources that limits even Colombian publicly funded research. This indicates that Colombia misunderstands the scope of technologies that employ genetic resources for drug development and the role of regulation on patents and access to genetic resources. Furthermore, Colombian legal scholars reinforce this misconception of the role of legal frameworks in encouraging R&D in genetic resources for drug development; the rhetorical discussion from authors such as Andia,[[366]](#footnote-367) Gomez-Lee[[367]](#footnote-368) and Uribe[[368]](#footnote-369) appear to focus exclusively on the negative impact of patents for the local generic industry and on biopiracy, rather than on analysing legal mechanisms that actually encourage R&D in Colombia. Unfortunately, there are neither reports nor legal studies that determine the reasons why Colombia has not encouraged R&D in genetic resources for drug development. The next section aims to clarify this point by providing an analysis of the evolution of the Colombian pharmaceutical industry and its policies on access to genetic resources and technology.

1. **Colombia**

Despite the fact that the Colombian pharmaceutical industry only began its development from the middle of the 20th century, there has been a common trend: the Colombian Government has not delivered a coherent policy that supports its pharmaceutical industry. Instead, Colombia has relied on overseas pharmaceutical companies and international trade to supply local demand and to secure the transfer of technology by importing pharmaceutical products and raw materials. This section analyses this common trend in three specific events.

First, early developments of the Colombian pharmaceutical industry illustrate that Colombia did not support local pharmaceutical companies but it rather encouraged imports and distribution of pharmaceutical products.

Second, between the 1950s and 1960s, local companies that used to import and distribute pharmaceutical products aimed to increase their capacity by manufacturing medicaments, but the Colombian government sought to support originators in opening manufacturing facilities in the country as trade with developed countries, especially the US, became an important factor for this Colombia. However, different economic events and political reforms in Colombia and countries of the Andean region (Bolivia, Ecuador, Peru and Venezuela) in the 1970s led them to create a common market. As a result, these countries created the Andean Community of Nations (ACN) in which they sought to protect and encourage national industries, including the pharmaceutical industry. As a result, the ACN aimed to benefit local generic companies by not providing patent protection and allowing compulsory licensing on pharmaceutical products, hence local companies could imitate and adapt the manufacture of pharmaceutical products. This boosted local generic companies, though Colombia did not seek to encourage R&D in its pharmaceutical industry at the time.

Third, as Colombia carried out different economic, social, political and legal reforms in the 1990s in order to open its economy to international trade, Colombia, along with the ACN, amended its patent legislation to comply with TRIPs standards, especially patent protection on pharmaceutical products and limits to compulsory licensing. Eventually, Colombia adopted higher standards of protection on pharmaceutical products as it signed up FTAs with the US and the EU (TRIPs-Plus standards); as a result, originators have increased its market share, while local companies have reduced it. In the meantime, since there was an interest in conservation and sustainable use of biodiversity, and access to genetic resources during the 1980s and 1990s, and biotechnology became a promising technology in drug discovery in the 1980s, Colombia, as a biodiversity rich country, paid particular attention to access to genetic resources and benefit sharing. This led this country and the ACN to adopt a comprehensive legislation on access to genetic resources, which has not necessarily led to obtaining benefit sharing but has created legal uncertainty among users of genetic resources, including local ones. Therefore, Colombia has, on the one hand, affected its local generic industry by granting higher standards of exclusivity protection to originators. On the other hand, Colombia has also affected users of genetic resources by adopting a comprehensive legislation on access. These three points are analysed in detail in the next subsections.

* 1. **The Birth of the Pharmaceutical Industry in Colombia**

In the 19th century Colombia did not import medicines, hence the supply of medicines was reliant upon being manufactured in local laboratories. Indeed, the core of the pharmaceutical production in the middle of the 19th century was the *boticas* (pharmacies) where pharmacists prescribed medicines based on plants and raw materials.[[369]](#footnote-370) By the end of the 19th century, the most popular *boticas* become labs, which started large-scale production of medicines based on plants such as *ipecacuanha* and *quinua*.[[370]](#footnote-371)

As there were no overseas pharmaceutical companies that could supply the local demand for medicines, some labs such *Laboratorio Roman* increased their share in the local market through the production of natural medicines which did not demand any chemical synthesis.[[371]](#footnote-372) However, by the end of the 19th century *Laboratorio Roman* imported machinery and hired foreign experts in chemistry and pharmacy in order to begin to manufacture pharmaceutical products that were chemically synthesised in Colombia.[[372]](#footnote-373) *Laboratorio Roman* even exported medicines to other countries in the region.[[373]](#footnote-374) The rise of labs such as *Laboratorio Roman* was not only due to the lack of importation of medicines, but also due to family links between its owners and the political elite of Colombia; hence this lab enjoyed a monopoly status and privileges in the distribution of medicines from the Colombian Government.[[374]](#footnote-375)

However, these attempts to create a pharmaceutical industry able to locally employ natural resources were eclipsed by the increasing number of Colombian companies that imported and distributed medicines manufactured in developed countries. The Colombian government soon abandoned emerging local labs in favour of the importing of medicine from overseas pharmaceutical companies. For instance, in 1901 a Presidential Decree was enacted in which Colombia recognised the privileges and monopoly status of French goods, including pharmaceutical products.[[375]](#footnote-376) As a result, in 1911 the *Laboratorio Franco Colombiano* (Lafrancol) began commercial activities by locally distributing French pharmaceutical products from the port of Barranquilla to other parts of the country.[[376]](#footnote-377) Similarly, Tecnoquimicas S.A. was established in 1930 to import and distribute pharmaceutical and chemical products in Colombia under distribution agreements with overseas pharmaceutical companies.[[377]](#footnote-378) As a result, the importation of medicines weakened local labs such as *Laboratorio Roman*, which were not able to compete with companies such as Lafrancol and Tecnoquimicas S.A. that distributed overseas pharmaceutical products.[[378]](#footnote-379)

During this time the most important R&D activity for the pharmaceutical industry in Colombia was the partnership between the American Rockefeller Foundation and the Colombian government to produce vaccines in Colombia to treat yellow fever.[[379]](#footnote-380) As this initiative only focused on the production of yellow fever vaccines, as soon as the disease was eradicated, the Colombian government lost interest in supporting local production and the Rockefeller Foundation concentrated on other initiatives in the country, such as agriculture and nutrition.[[380]](#footnote-381)

Although there were some measures at the beginning of the 20th century that aimed to secure a monopoly in supplying local demand to local labs, this policy did not last long enough to allow small labs to transform into companies that could compete with the importation of pharmaceutical products from originators. Instead, Colombian authorities granted privileges to local distributors who imported pharmaceutical products. In the case of R&D, the decision to support this activity was only limited to a specific case (yellow fever) and did not last long enough to encourage further R&D in Colombia. Early developments in the industry provide an example of what has remained a common trend in Colombia’s current policy on its pharmaceutical industry: Colombia has not delivered a policy that increased capacity by supporting local pharmaceutical companies in order to compete with overseas companies.

* 1. **Towards a Generic Industry (or Illegal Generic Industry?)**

By the middle of the 20th century, as local distributors gained an important share of the local market, they slowly began to move towards manufacturing pharmaceutical products as the country had started to open its economy during the 1920s and 1930s, and universities and the government embarked on training and improving professions related to the pharmaceutical industry, such as medicine and chemistry.[[381]](#footnote-382) This provided skilled labour and FDI for the young Colombian pharmaceutical sector. Local distribution companies took advantage of these developments and decided to transform their business model. Colombian companies whose main activities were importing and distributing pharmaceutical products began to manufacture medicines. For instance, Lafrancol inaugurated its first lab for the production of generics in 1944 and Tecnoquimicas S.A. opened its first manufacturing facility in 1949.[[382]](#footnote-383)

At the same time that local pharmaceutical companies started to manufacture pharmaceutical products, the Colombian government decided not to support them. Instead, the government embraced economic reforms that allowed originators located in developed countries to enter the Colombian market.[[383]](#footnote-384) As the US began to exert a major influence over Colombian affairs, the US put pressure on Colombia to adopt a free trade economy and facilitate the flow of FDI.[[384]](#footnote-385) This led originators to open branches in Colombia rather than signing distribution or manufacturing agreements with local companies.[[385]](#footnote-386) For instance, Merck founded a subsidiary in 1938, Baxter opened a plant for the production of solutions in 1956, McNeil (Johnson & Johnson) and Boehringer Ingelheim entered into the market in 1962.[[386]](#footnote-387) This increase in the number of originators participating in the Colombian market led overseas companies to become rapidly established.

In 1957, 70 overseas pharmaceutical companies and labs with interests in the pharmaceutical industry in Colombia created the first association of pharmaceutical companies, called the *Asociación de Fabricantes y Representantes Exclusivos de Productos Farmacéuticos* (AFIDRO). This organisation had the aim of securing exclusivity of the Colombian market ahead of local industries and manufacturing medicines in Colombia with due respect to patents.[[387]](#footnote-388) It is important to note that, although AFIDRO gained the favour of Colombian authorities to facilitate the importation of their products, AFIDRO accepted that its associates would open manufacturing facilities, and not only import medicines.[[388]](#footnote-389) This agreement between AFIDRO and the Colombian government was called a ‘gentlemen’s agreement’ or *pacto de caballeros*.[[389]](#footnote-390) This meant that Colombia was committed to engage its pharmaceutical industry as a generic industry that recognised and respected originators’ exclusivity rights over their pharmaceutical products.

It took more than a decade for local pharmaceutical companies to establish a similar association. In 1971, the Association of Colombian Pharmaceutical Industries or *Asociación de Industrias Farmacéuticas Colombianas* (ASINFAR) was created. ASINFAR aimed to protect and incentivise the local pharmaceutical industry by removing any barrier that creates dependency on overseas companies.[[390]](#footnote-391) The main barrier was considered to be patents on pharmaceutical products.[[391]](#footnote-392) ASINFAR gained importance in the next 20 years because the patent reforms in the 1970s led Colombian pharmaceutical companies to transform from being generic producers to illegal generic manufacturers. Certainly, in the 1970s, political and economic circumstances led to a dramatic shift of policy towards the Colombian pharmaceutical industry which benefited local industry; these events even influenced the regulatory frameworks of other Andean countries. The Colombian government modified its economic policies in order to protect the national industry more, rather than encouraging overseas companies to invest in Colombia.[[392]](#footnote-393) As a consequence, the government aimed to incentivise the national industry by restricting the flow of FDI and importation of products.[[393]](#footnote-394)

The government policy on protecting the national pharmaceutical companies was supported by different studies. For instance, Vaitsos compiled and analysed reports, which pointed out that 60% of the patents on pharmaceutical products in 1970, were owned by 10% (all overseas companies) of patent holders.[[394]](#footnote-395) Vaitsos also highlighted that granting patents on pharmaceutical products did not lead to further R&D in Colombia as only 10 patents out 3513 (including 2534 that were owned by pharmaceutical companies) ‘were actually produced in the country’.[[395]](#footnote-396) Instead, patents were employed by originators to secure markets ahead of local producers. In other words, patents on pharmaceutical products during this period did not aim to reward intellectual labour. Instead, Vaitsos considered that patents deterred local generic pharmaceutical companies from accessing technology as they were not able to ‘technologically advance through imitation and adaptation’.[[396]](#footnote-397) Vaitsos, as head of the ACN Secretariat’s policy on foreign investment and technology, influenced Andean countries to adopt a tough stance on patents, since patents granted “monopoly privileges” to developed countries, while Andean countries could not receive anything in return, other than increasing economic dependency on developed countries.[[397]](#footnote-398)

As a result, Andean countries excluded pharmaceutical products from patentability. For instance Colombia did not grant patents on pharmaceutical products in Article 538 of the 1971 Colombian Codex of Commerce.[[398]](#footnote-399) A similar nationalism and protectionism took place in other Andean countries (Ecuador, Bolivia, Peru and Venezuela), which led to the creation of the ACNin which Andean countries created a regional market to protect national and regional interests from developed countries, especially the US.[[399]](#footnote-400) As a result, in 1974 ACN enacted a common regime on IPRs that did not grant patent protection on pharmaceutical products, i.e. (Article 5 (c)) Decision 85 of 1974.[[400]](#footnote-401) In other words, the Colombian Codex, amended eventually by Decision 85, reflected the interests of Colombia, and the Andean region, at that time, i.e. to secure access to technology for local companies by restricting the patent exclusivity of originators.

The result of Colombia’s new policies, during the 1970s and 1980s, led local pharmaceutical companies to manufacture with no recognition of patents on originators (illegal generics); in consequence the Colombian pharmaceutical industry expanded. Local companies such as Tecnoquimicas S.A. and Lafrancol increased their share in the pharmaceutical market in Colombia by absorbing and merging with small labs and local pharmaceutical companies.[[401]](#footnote-402) There were also new small and medium sized local pharmaceutical companies (SMEs) such as Riosol, Farmaceuticos Estelar, Casar, America and Unipharma.[[402]](#footnote-403) This situation is similar to those that occurred in India and China, whose policy towards their pharmaceutical industry was to secure that local generic companies could supply the demand for medicines. Indeed, exclusion of patents on pharmaceutical products in Decision 85 aimed to benefit local generics companies in the same way that India and China did for their generic companies before they adopted TRIPs.[[403]](#footnote-404)

In terms of R&D in technologies that employ natural and genetic resources for drug development, Colombia was not concerned with incentivising R&D since, as mentioned above, the aim of Colombia was to secure access to technology by not recognising originators’ exclusivity rights; also there was no interest in technologies that employ genetic resources, such as biotechnology. Despite the lack of any policy that encouraged R&D, in 1988 the Colombian scientist Manuel Elkin Patarroyo synthesised the peptide sequence of the *Plamodium falciparum*, which is the parasite that causes malaria, for the production of anti-malaria vaccines.[[404]](#footnote-405) The vaccine was effective in areas of low intensive malaria activity, such as South America, and was even proved to be effective in Phase I clinical trials in intensive malaria areas such as Tanzania.[[405]](#footnote-406) However, further clinical trials (Phases II and III) carried out years later proved the vaccine to be ineffective.[[406]](#footnote-407) A study carried out in Gambia on infants between the ages of 1 and 5 shows that Patarroyo’s vaccine was only effective in 31% of cases.[[407]](#footnote-408) Similar results were also found in Thailand where the vaccine was effective in 30% of participants who aged were between 2 and 15.[[408]](#footnote-409) In 2006, the Cochrane Collaboration recommended not employing the vaccine.[[409]](#footnote-410) Since the time that Patarroyo’s vaccine was developed, there has not been any relevant research in drug development in Colombia. Patarroyo’s sole attempt to develop a new medicine vaccine is evidence that Colombia had no interest in encouraging R&D in genetic resources for drug development but rather in securing that local pharmaceutical companies had access to technology with no regard for patent rights.

The Colombian pharmaceutical industry has been characterised by the different shifts in Colombia’s policies towards this industry. First, between 1950 and 1970, there were incentives to facilitate the flow of FDI that assisted pharmaceutical companies located in developed countries to enter the Colombian pharmaceutical market and open manufacturing facilities across the country. This enabled the consolidation of the Colombian pharmaceutical industry as a generic manufacturing hub. Second, 20 years after Colombia decided to start to open its economy, Colombian authorities shifted their policies towards the national industry. As a consequence, the Colombian government (by not granting patents on pharmaceutical products) increased capacity in the Colombian pharmaceutical industry by enabling local pharmaceutical companies to expand and gain experience in manufacturing medicines with no recognition of originators’ patents (who would not invest in Colombia without appropriate legal protection being in place). However, the lack of patent protection did not lead to an increase in local R&D since Colombia was more concerned with securing that local generic companies could freely access technology as otherwise they would have had to pay for patent licensing in order to manufacture and distribute medicines locally and in the region. As a result, Patarroyo’s research on malaria was the sole significant breakthrough in R&D in genetic resources in Colombia.

In summary, the lack of patent protection strengthened the ability to copy medicines for the Colombian pharmaceutical industry. This is similar to what occurred in India and China, before both of them adopted TRIPs standards.[[410]](#footnote-411) However, Colombia did not create a generic pharmaceutical industry able to compete with developed countries as India and China did; neither did it address sources nor create policies that could have led Colombia to encourage R&D, as China did. Indeed, as explained in Chapter 1, despite the fact that China manufactured and distributed illegal generics, it also began to increase capacity by investing in biotechnology and employing genetic resources, particularly traditional knowledge associated to genetic resources (e.g. *Artemisinin*) before it accepted the adoption of TRIPs standards.[[411]](#footnote-412)

As a result, in the 1990s, with the interest of the Colombian government being to open the economy to international trade and hence comply with international standards in patent protection, the national pharmaceutical industry was not prepared to compete with originators.

* 1. **The *Apertura*, Patents on Pharmaceutical Products and Regulation on Access to Genetic Resources: An ‘Un-Innovative’ Combination?**

The 1990s were characterised by the efforts of the Colombian government to carry out social reforms and to open the economy to international trade.[[412]](#footnote-413) The most relevant social reform for the interests of the pharmaceutical industry was the creation in 1993 of the Social Security Health System or *Sistema de Seguriadad Social en Salud* that aimed to provide healthcare for all Colombian citizens through a private-public health insurance scheme.[[413]](#footnote-414) In order to secure health coverage for all the Colombian population, this health system is divided into two regimes:[[414]](#footnote-415) first, there is a contribution regime (CR) which targets the sector of the population that is able to afford health insurance.[[415]](#footnote-416) Affiliation to this regime is compulsory for all employees whose monthly income is equal to or more than the national minimum wage, and for those who are self-employed and earn at least twice the national minimum salary. The CR is provided by health insurance companies (which can be public, private or public-private companies). The second regime is a subsidised regime (SR) for members of the population who earn below the national minimum salary.[[416]](#footnote-417) Health insurance companies are obliged to provide health care products and services that are included in the national mandatory health plan or *Plan Obligatorio de Salud* (POS).[[417]](#footnote-418)

Regardless of the fact that the Colombian government faced access, financial and administrative problems in implementing this system,[[418]](#footnote-419) the National Department of Statistics indicates that in 2012 91% of the Colombian population was included in the health care system.[[419]](#footnote-420) As a result, there has been a significant increase in the demand for medicines in Colombia. For instance, the pharmaceutical market, including retail sales and public sales, was US$ 3.9 billion in 2011 and is expected to grow to US$ 5.1 billion by 2016.[[420]](#footnote-421)

However, there has been another important development in Colombia regarding its pharmaceutical industry. During the 1990s Colombia implemented a major plan for liberalisation of the economy or *apertura* (e.g. selling public companies and softening tax on FDI).[[421]](#footnote-422) This was the result of a series of compromises that Colombia (as well as the other four members of the ACN) adopted progressively under pressure from the US, and before Colombia joined the WTO in 1995 and signed up to TRIPs.

Although the Colombian pharmaceutical industry was growing, the *apertura* obligated Colombia to shift its policy towards patents on pharmaceutical products, in order to fulfil the requirements of TRIPs. The local pharmaceutical industry, not only in Colombia but also in other members of the Andean Community, was concerned about the impact of patents on the illegal generic industry that emerged after the reforms of the 1970s.[[422]](#footnote-423) However, intensive pressure from the US led the ACN countries to progressively make legal amendments that resulted in benefiting pharmaceutical companies located in developed countries.

Although local pharmaceutical companies lobbied governments to delay patents on pharmaceutical products, the ACN partially derogated Article 5(c) of Decision 85 of 1974 through Article 7(c) of Decision 311 of 1991[[423]](#footnote-424) and Article 7(e) of Decision 344 of 1993[[424]](#footnote-425) which allowed patents on pharmaceutical products, except those pharmaceutical products that were in the list of essential medicines of the WHO.[[425]](#footnote-426) In other words, it opened the door to originators to obtain patents on pharmaceutical products in Colombia. The inclusion of the list of medicines was a small victory for the local generic pharmaceutical companies. Indeed, 90% of the medicines listed are off patent[[426]](#footnote-427) and only represent 16% of the total sales of originators.[[427]](#footnote-428) However, crucially ACN refused to protect the second indication of a biochemical compound[[428]](#footnote-429), despite the US campaign to include it.[[429]](#footnote-430)

ACN included three years’ protection on the submission of data exclusivity or undisclosed tests/data for MA of new pharmaceutical products, which made generic entry more difficult.[[430]](#footnote-431) A subsequent ACN Decision[[431]](#footnote-432) allowed patents on any pharmaceutical products (as required by TRIPs) and extended the protection of data exclusivity to five years. Furthermore, in 2006 Colombia signed up to an FTA with the US in which Colombia agreed to make further amendments on patent law that include strengthening protection for the submission of data exclusivity, and restricting the use of compulsory licensing (Article 16.10 (3) of the US-Colombia FTA). Nonetheless, in 2006 congressional elections in the US were held in which the US Democratic Party took control of Congress. This political event in the US led to some reforms in the final text of the US-Colombia FTA, which includes public health safeguards on patents, including the use of compulsory licensing, and considerations on the protection of Colombia’s biodiversity; [[432]](#footnote-433) but still, data protection remains in the final text of the FTA.[[433]](#footnote-434)

Local pharmaceutical companies have also failed in lobbying to obtain more favourable legislation. Although they are associated within ASINFAR, in 1993 the National Association of Entrepreneurs or *Asociacion Nacional de Empresarios de Colombia* (ANDI) created the pharmaceutical chamber or *Cámara de la Industría Farmacéutica* in order to link the largest pharmaceutical companies together, regardless of the nationality of their members. ANDI and the pharmaceutical chamber have overshadowed ASINFAR by campaigning on behalf of both large local pharmaceutical companies (e.g. Tecnoquimicas S.A. and Lafrancol) and originators. Nevertheless, ANDI demonstrated support for patent reforms in the 1990s and the FTA with the US, which cleared the path for originators to invest in building manufacturing facilities and licence patents with local pharmaceutical companies for generic production.[[434]](#footnote-435) The pharmaceutical chamber’s associates account for 90% of the market sales.[[435]](#footnote-436) The different patent reforms and concentration of the pharmaceutical market in large local generics and originators have produced two consequences in this industry. First, the local pharmaceutical industry manufactures only generics and originators that have been licensed by originators. Secondly, originators with branches in Colombia are either importing pharmaceutical products and active pharmaceutical ingredients, or manufacturing their medicines with the aim of commercialising them in Colombia and other Andean countries.[[436]](#footnote-437)

Both consequences are reflected in other trends in the Colombian pharmaceutical industry. Although Colombian pharmaceutical companies have increased sales of medicines in Colombia and exports to other ACN countries, originators have also increased their share in the market of both pharmaceutical products and raw materials. Espicom found that although the pharmaceutical market leader in 2010 was the Colombian company Tecnoquimicas S.A., the following four leading pharmaceutical companies were all non-Colombian (Baxter, Roche, Abbott and Bayer).[[437]](#footnote-438) Furthermore, the same report mentioned that the balance of pharmaceutical trade in Colombia was negative;[[438]](#footnote-439) progressive increases in the importation of active pharmaceutical ingredients for drug development and pharmaceutical products (e.g. in 2005 it imported a total of US$ 462 million and in 2009 US$ 1.3 billion) have outstripped pharmaceutical companies’ exports (especially to countries in the region) e.g. US$ 195 million in 2005 and US$ 379.3 million in 2009).[[439]](#footnote-440) This is a 40.4% negative balance in trade.

The changes in patent regulation after the *apertura* have not enhanced Colombia’s capacity to carry out R&D in technologies that employ natural and genetic resources. For instance, the Colombian patent office or *Super Intendencia de Industria y Comercio* (SIC) reported that from 2005 to 2011 non-Colombian pharmaceutical companies filed 5,388 patents on pharmaceutical products, whereas Colombian pharmaceutical companies filed only 155.[[440]](#footnote-441) In the case of biotechnological inventions for the same period, non-Colombian biotechnological companies filed 1,068 patents, while Colombian biotechnological companies and labs filed only 40.[[441]](#footnote-442) These are similar trends to those illustrated by Vaitsos in section 2.2 of this chapter. Vaitsos pointed out that a reason why ACN members, including Colombia, should not have adopted patents on pharmaceutical products in Decision 85 was that only 10 out of 3513 in the pre Decision 85 era belonged to Colombian residents. However, these figures also indicate that local pharmaceutical companies were not interested in increasing R&D, despite the fact that during the 1970s and 1980s they did not have to comply with patents so they could imitate and adapt technologically to compete with originators. As patents illustrate the R&D of a country, these figures highlight that amendments in Colombian patent legislation have not had the effect of encouraging R&D in drug development.

Other figures are similarly discouraging for R&D. AFIDRO has reported that their associates were the companies that accounted for all the R&D activities carried out in the country, particularly clinical trials. Between 2000 and 2006, AFIDRO members invested around a total of US$ 24 million in clinical trials. AFIDRO claims that its members’ investment in R&D is a significant contribution to the pharmaceutical industry, yet it remains low since (as mentioned above) the Colombian pharmaceutical market is estimated at US$ 3.9 billion and is confined mainly to a small number of companies. Similarly, although the Colombian government (through the Administrative Department of Science, Technology & Innovation or *Departamento Administrativo de Ciencias, Tecnologia e Innovacion* (COLCIENCIAS)) has launched a series of initiatives to link universities and companies to carry out R&D in biotechnology,[[442]](#footnote-443) the Espicom report indicated that there are no data regarding R&D in biotechnology in local pharmaceutical companies such as Technoquimicas or developed countries’ originators.[[443]](#footnote-444) This suggests that, despite the fact that Colombia has embraced patents on pharmaceutical products, there are no clear indications that greater patents will automatically mean innovation within local pharmaceutical companies or originators.

Conversely, the Colombian authorities seem to be more concerned about the quality of medicines manufactured by local pharmaceutical companies. A 2003 White Paper by the Colombian Ministry of Social Protection identified that national policy on the pharmaceutical industry should address resources (including R&D) for improving the quality of generic medicaments rather than allocating resources to R&D in drug development.[[444]](#footnote-445) As a consequence, Colombia has created comprehensive legislation on drug surveillance led by the National Institute for Drug and Food Surveillance or *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA) to promote better manufacturing practices among local pharmaceutical companies.[[445]](#footnote-446) Although INVIMA has been successful in improving manufacturing practices in the country, Andia finds that the implementation of safety and security regulation has increased SMEs’ operational costs, hence they have not been able to compete with other pharmaceutical companies. [[446]](#footnote-447)

However, Andia’s point of view is more related to the idea of protecting the generic industry rather than encouraging R&D. In fact, in an interview in 2007, the president of ASINFAR declared that, since Colombia granted patents and strengthened regulation on safety and security, the local pharmaceutical industry has been reduced from 275 companies in 1995 to 100 companies in 2000.[[447]](#footnote-448) Criticisms by local pharmaceutical companies of Colombian authorities on safety and security should not only focus on how these regulations affect generic production, but also on how the government should encourage R&D in the national industry. However, patents and regulation on safety and security are not the only concerns when considering aspects related to genetic resources. Regulation on access to genetic resources has also proved to be a barrier to innovation.

* 1. **Regulation on Access to Genetic Resources**

Trade and history not only link Andean countries to each other, but these countries also share their biodiversity. Colombia shares all its biodiversity hotspots with at least two other Andean countries. For instance, the Tropical Andes hotspot crosses all current and former members of the ACN (see Annex III). Pressure from environmentalists and NGOs over the ACN has led Andean countries to enact a very comprehensive and strict regulation on access to genetic resources that is aimed at protecting biodiversity from undue exploitation from originators. [[448]](#footnote-449)

Even though the Andean legislation on access to genetic resources sought to provide benefit sharing to Andean countries and to deter biopiracy, the result of the implementation of this legislation has been averse to R&D in genetic resources. This legislation creates strict requirements on access to genetic resources and benefit sharing (e.g. procedure to obtain prior informed consent from local authorities), as well as creating new requirements on patents (e.g. disclosure of origin) and restricting patents on genetic resources. Indeed, Decision 391 of 1996 on the Common Regimen on Access to Genetic Resources[[449]](#footnote-450) and Articles 3 and 15 (b) of Decision 486 of 2000 create legal barriers to obtaining a patent on genetic resources and access to genetic resources.

While scholars such as Gomez-Lee[[450]](#footnote-451) and Uribe[[451]](#footnote-452) consider this Andean legislation important for protecting biodiversity, they do not formulate any policy that could encourage transfer of technology and R&D to drug development. In this context, it is not surprising that patents granted in Colombia are almost exclusively for overseas companies rather than national ones, as illustrated above.

Colombia’s legislation on access to genetic resources and to technology highlights the need for this developing country rich in biodiversity to assess its capacity in order to deliver a coherent legal framework that focuses on increasing capacity through R&D in genetic resources for drug development. Although Colombia’s capacity has increased in terms of manufacturing (generics and originators under licensing agreements) and distribution (locally and regionally), the country’s policies towards the pharmaceutical industry and R&D remain unclear. As mentioned above,[[452]](#footnote-453) the Colombian government has claimed that Colombia should exploit its biodiversity and genetic resources commercially in order to develop a more competitive national biotechnology and innovative sector, but the Colombian pharmaceutical industry still depends on other countries to manufacture even generics.

After the reforms of the 1990s, Colombia decided to attract the transfer of technology via international trade and patents, but the result has been that the Colombian pharmaceutical industry has become an importer of pharmaceutical products (generics and originators) and active pharmaceutical ingredients, and a local producer of generics and originators under licensing agreements with originators. Furthermore, government policies towards this industry have recently focused on improving the safety and security of pharmaceutical products. As a result, originators have strengthened their share in the Colombian market while local generics have reduced their share.

Colombia has not had a clear policy on the regulation of access to genetic resources even though it opened the door via FTA with the US to granting patents on pharmaceutical products; whereas Andean regulation limits patents on genetic resources, creates new requirements (e.g. disclosure of origin) and overcomplicates R&D. A lack of clear policy towards the Colombian pharmaceutical industry, patents, and regulation about access to genetic resources exemplify the inconsistency of Colombia to deliver a regulatory framework which locally incentivises technologies that employ genetic resources.

**Conclusions**

The analysis of countries’ capacity carried out in Chapters 1 and 2 provides indicators for assessing whether developing countries rich in biodiversity are implementing TRIPs and the ABS according to their own capacity in technologies that employ genetic resources for drug development.

In the case of Colombia, its government has constantly affirmed that genetic resources are important for the development of different industries including the pharmaceutical industry. However, it has not delivered a coherent policy framework that aims to increase capacity from the utilisation of its own genetic resources.

Chapter 1 points out how India and China have adopted different policies to encourage their pharmaceutical industries, i.e., India has centred its policies in protecting its generic pharmaceutical industry in order to supply local and global demand for generics and active pharmaceutical ingredients; while China is increasing capacity not only in its generic industry, but also in its biotechnology industry and genetic resources. Yet, both countries have maintained a restrictive approach on access to genetic resources by including, for instance, disclosure of origin in patent legislation. As a result, the implementation of TRIPs and the ABS regime in China and India has been according to their capacity.

Colombia sought to apply a similar policy to those of China and India in patents, as Decision 86 aimed to provide Colombian generic pharmaceutical companies with a legal framework that would enable them to imitate and adapt technologically to compete with originators. However, within the rule of Decision 86, Colombia was not concerned with employing the country’s biodiversity for drug development.

Colombia’s decision to open its economy, increase patent protection and establish new mechanisms of exclusivity to originators in the 1990s and 2000s led the Colombian pharmaceutical industry to manufacture generics and originators under licensing agreements as well as becoming an importing country of active pharmaceutical ingredients and pharmaceutical products. This situation has also led originators to increase their share in the Colombian pharmaceutical market. This means that Colombia’s policy towards its pharmaceutical industry has long depended on international trade with developed countries and that Colombia has transformed its patent legislation in order to secure access to international trade.

As a result, Colombia has not only accepted TRIPs requirements on patents but has also amplified protection on pharmaceutical products and processes from developed countries by signing up to bilateral agreements with developed countries, particularly the US (i.e. TRIPs-Plus). This has given an important competitive advantage to originators over local ones in Colombia. Although Colombia is aiming to commercially integrate with neighbouring countries via the ACN and the Pacific Alliance, this could serve only the interests of originators, as Colombia manufactures and distributes generics and originators under licensing agreements for the region.

Colombia has not yet achieved access to technologies that employ genetic resources through patents. Indeed, the number of patent applications from locals is much lower than those from developed countries. Likewise, Colombia’s legislation on access to genetic resources has rather created barriers for local R&D efforts to obtain benefits from Colombian’s genetic resources, despite the country’s availability of genetic resources and apparent interest from Colombian government to employ genetic resources for drug development.

In other words, Colombia’s pharmaceutical industry is not an innovative industry that relies on genetic resources, despite the fact that the government has pointed out in different policy documents that the local industry should obtain benefits that arise from the utilisation of genetic resources in order to increase capacity. Consequently, it is necessary to analyse what policies and legal mechanisms Colombia should adopt in order meet government interest in increasing capacity in the Colombian pharmaceutical industry based upon the utilization of genetic resources. As a result, Colombia should focus on the following aspects: (1) as Colombia has already compromised giving patent protection to pharmaceutical products and processes, it should facilitate further patent protection on genetic resources located in its own territory in order to incentivise local users of genetic resources; (2) Colombia should facilitate access to genetic resources R&D activities in order to attract, for instance, bioprospecting initiatives which could result in the transfer of technology to this country; (3) Colombia should clarify its policy on R&D in genetic resources by setting up an ABS legislation that offers legal certainty to those who pursue R&D in Colombia’s genetic resources.

Before these three aspects are analysed in detail in Chapter 5, it is important to study the legal framework that has an impact on Colombia’s capacity, i.e. TRIPs and the ABS regime. This means that the implementation of TRIPs and the ABS regime should focus on capacity so that Colombia can not only have access to technologies that employ genetic resources but also engage in those technologies according to their pharmaceutical industry’s capacity.

Chapter 3:  
The Dilemma of TRIPs in Genetic Resources

**Introduction**

Chapters 1 and 2 analysed developed countries’, and developing countries rich in biodiversity, capacity in the drug development process, in particular China, India and Colombia. The aim of analysing countries’ capacity in technologies that employ genetic resources for drug development is to identify the capacity of these three selected developing countries that are rich in biodiversity.

For the scope of this thesis, capacity relates to the intellectual labour that adds value to genetic resources for drug development. As discussed in the introduction of this thesis, Locke provides an understanding of how and why countries should grant property rights to technologies that employ genetic resources for drug development. In general terms, it is the intellectual labour that adds value from inventors that allows them to appropriate what is in nature or the commons.[[453]](#footnote-454) The introduction of this thesis also highlights that Locke’s labour theory does not only grant rights to those who appropriate from the commons or what is in nature, but it creates two provisos to limit the scope of those rights: sufficiency proviso, which states that those who add value to what it is in nature can appropriate from it as long as ‘there is enough, and as good, left in common for others’ (e.g. limiting the scope of patent claims);[[454]](#footnote-455) and the waste or spoiled proviso (‘Nothing was made by God for man to spoil or destroy’) (e.g. unmet demand of medicines and the use of compulsory licences).[[455]](#footnote-456) However, Locke’s labour theory is studied along with Rawls’ social contract theory and Nussbaum’s capability approach.

As analysed in the introduction of this thesis, it is possible to justify flexibilities on IPRs and ownership on genetic resources in Rawls’ theory, because they emerge as a result of a ‘fair agreement’[[456]](#footnote-457) between developed countries and developing countries. However, Rawls considers that there might be inequalities in a fair agreement which can be solved through that agreement. Inequalities are triggered by situations in which primary goods are not equally distributed along participants.[[457]](#footnote-458) As studied in the introduction of this thesis, those primary goods are technologies that employ genetic resources and the genetic resources themselves, for the purpose of this thesis. Rawls also points out that participants in the initial bargaining position are equal as they are under a ‘veil of ignorance’.[[458]](#footnote-459) However, it is difficult to find that in relationships between countries, participants are equal. This is because there are developed countries which could strengthen economic and political power by imposing their interest on those of developing countries. That is why Nussbaum’s capability approach complements this analysis, as she points out that an unsolved problem of social contract theory is that there is no ‘rough equality’ among States as they have different capabilities.[[459]](#footnote-460) In order to solve this problem, Nussbaum highlights that Rawls’ explanation of primary goods needs to be addressed in a set of indices that represent different aspects, i.e. capabilities. Capabilities operate as an indicator of what countries want and are actually capable of in an agreement.

As a result, this thesis articulates together capacity and the capability approach, although these terms are not similar, they complement each other to provide a framework in which countries’ capacity could be assessed in order to create policies that entitle them to obtain benefits that arise from the utilization of genetic resources. This means that capacity is not exclusively focused on increasing capacities, but on entitling developing countries rich in biodiversity to enhance genetic resources in order to find and assess opportunities to increase countries’ capacity. Hence, Nussbaum’s capability approach is employed in this thesis to assess capacity since the former centres on functioning (doing and being) to create opportunities for developing countries rich in biodiversity regarding the utilization of genetic resources for drug development.[[460]](#footnote-461) Therefore, what is negotiated in international agreements between developed and developing countries (including those rich in biodiversity such as Colombia) is the result of ‘a fair agreement or bargain’ that should take into account countries’ capacity.

Consequently, this assessment of capacity allows an understanding of what the actual capacity of countries for drug development is (i.e. technology capacity for drug development, availability of genetic resources), the dynamics of the global market and whether developing countries rich in biodiversity are effectively employing genetic resources to obtain benefit sharing from the utilization of those resources. In this way, what policies and legal mechanisms developing countries rich in biodiversity should or should not employ in order to increase capacity in the light of TRIPs and the ABS can be assessed.

As a result, Chapter 1 identified that developed countries reward the intellectual labour that emerges from the drug discovery by granting exclusivity rights through mechanisms such as patents and data protection to pharmaceutical inventions.[[461]](#footnote-462) That is why developed countries aim not only to grant exclusivity rights within their own territory but also campaign for patent protection in other countries in order to secure markets for originators ahead of local companies (i.e. generic companies), hence originators are encouraged to innovate. Chapter 1 also pointed out how India and China have designed and created policies and legislation to implement TRIPs and the ABS according to their own capacity.

This situation has led to a global market shift in the pharmaceutical industry which involves developed countries employing exclusivity mechanisms of protection, especially patents, to encourage originators to invest in further R&D, including technologies that employ genetic resources for drug development.[[462]](#footnote-463) However, India and China, which have transformed from illegal generics to generic producers, are promoting and taking over generic production globally. The principal focus of both countries has been the use of IPRs’ flexibilities (e.g. compulsory licensing) for protecting their generic industries. As analysed in the introduction of this thesis and Chapter 1, following Locke’s labour theory, patents do not necessarily grant absolute rights to the intellectual labour that adds value, but patents could entitle countries to employ IPRs’ flexibilities when they affect, for instance, the access to technology and genetic resources, or third parties (e.g. access to medicines), i.e. Locke’s proviso.[[463]](#footnote-464)

However, China’s increasing patent applications at home and overseas, as well as growing investment in biotechnology, indicate that China is heading towards a more R&D-based economy in which IPRs will play a more prominent role. Yet, China and India restrict access to genetic resources in order to obtain benefit sharing via disclosure of origin in the former and the ABS regulation in the latter. Although LDCs are not studied in detail, the analysis of LDCs and their pharmaceutical industry helps to complement the study of the shift in the global markets since these countries aim to fill the gap for illegal generics as they can delay implementation of TRIPs because of its lack of capacity; hence they can produce and distribute illegal generics, and import medicines from third countries such as India. Chapter 2 pointed out that Colombia’s interest in gaining access to international trade via TRIPs and TRIPs-Plus provisions has led this country to design contradictory policies on access to technology and access to genetic resources which have not resulted in obtaining benefits that arise from the utilization of genetic resources in order to increase capacity. In other words, Colombia’s policies and law on pharmaceutical products and genetic resources have resulted in a generic industry which could distribute and manufacture generics and originators under licensing agreements, but have not encouraged R&D on genetic resources for drug development. Therefore, capacity and the shift in global markets has not only been the result of implementing TRIPs in developing countries rich in biodiversity but is also outlining defining the post TRIPs era.

Consequently, the present chapter assesses to what extent the TRIPs of WTO and TRIPs-Plus provisions deter or increase the capacity of developing countries rich in biodiversity on access to technologies and on control over genetic resources.

Originators in developed countries have played a key role in the international harmonisation of patent legislation. This industry takes high risks, and uses investment and time to develop a new biochemical compound in order to commercialise a new drug in different markets.[[464]](#footnote-465) As a result, it has stressed the importance of granting exclusivity rights in order to incentivise the intellectual productive activity that adds value to what is in the commons or nature. In a global context, originators observe patents as mechanisms to secure exclusivity for the exploitation of their inventions in new markets ahead of local companies that aim to replicate their drugs. Although patent protection has been available in most developed countries from the first half of the 20th century for pharmaceutical products and processes, the pharmaceutical industry in developed countries has been concerned that countries such as India and China (which did not provide patent protection for these inventions) would produce illegal generics of their drugs and sell them for a fraction of the original price. Therefore, it was important for originators to extend patent protection beyond developed countries, to include, for instance, developing countries rich in biodiversity. As a result, originators in developed countries advocated for an international standardisation of patent legislation, which has been led by two common trends: the linkage between trade and patents (which basically involves a bargain between access to markets for access to technology) and the gradual expansion of patentable subject matter.[[465]](#footnote-466)

Nevertheless, the growing interest in extending patent protection on pharmaceutical inventions to developing countries rich in biodiversity has clashed with the interests of these countries in increasing capacity within their local industry and preserving ownership control over their own genetic resources.[[466]](#footnote-467) Yet, developing countries rich in biodiversity are under pressure to accept patents on pharmaceutical inventions and, to some extent, biotechnological ones, as a condition for obtaining other benefits from international trade.

These two views have played an important role in the drafting process and final wording of TRIPs. On the one hand, developed countries succeed in adapting the substantive minimum standards in patent protection by implementing patentable subject matter and provisions that forbid countries from excluding inventions on the grounds of the technological field that they fall within and the origin of the invention. Moreover, developed countries, especially the US, have managed to keep expanding the scope of protection via bilateral trade agreements with developing countries rich in biodiversity such as Colombia; these agreements are known as TRIPs-Plus. On the other hand, there are still some mechanisms by which developing countries rich in biodiversity restrict patent protection on inventions related to pharmaceutical inventions, such as the use of compulsory licensing and exclusion of patentability with the aim of increasing capacity. Furthermore, developing countries rich in biodiversity have also campaigned within the Council for TRIPs of the WTO (the administrative body of TRIPs) and the Ministerial Conference of the WTO (the top decision making body of the WTO) to delay the implementation of TRIPs to LDCs and to modify substantive aspects of TRIPs (e.g. compulsory licensing for import and patent subject matter). The Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health are the results of those efforts. As explained in Chapter 1, this international legislative dynamic has led to a shift in the global markets in which developed countries have embraced high standards of patent protection to encourage originators to invest in R&D, whereas China and India have adopted TRIPs according to their own capacity in order to protect key industries, i.e. China has made every effort to increase capacity in its biotechnology industry and India has adopted a regulatory framework that largely benefits its generic industry. LDCs have also participated in this global shift by employing TRIPs flexibilities to manufacture, produce or import illegal generics in order to fill the gap left by countries such as India and China. Finally, Colombia has increased its capacity in manufacturing and distributing generics and originators under licence agreements, but has failed to encourage its local pharmaceutical industry to increase capacity by obtaining benefit sharing from the utilization of their own genetic resources for drug development.

This chapter complements the assessment of Chapters 1 and 2 as it contextualises how capacity, as an indicator, is a fundamental factor to analyse TRIPs and TRIPs-Plus provisions. Therefore, this chapter argues that, although TRIPs and TRIPs-Plus have given an important legal framework to originators in developed countries to extend patent protection for accessing new markets, there is still some room for manoeuvre for developing countries rich in biodiversity to implement such a legal framework to increase capacity according to the theoretical framework introduced in this thesis, which is based upon on social contract theory (Locke and Rawls) and the capability approach. In order to carry out this analysis, this chapter is divided into three parts. The first part studies how different industries in developed countries, particularly the chemical and pharmaceutical industries, campaigned for the creation of a patent treaty (the Paris Convention)[[467]](#footnote-468) that would secure patent protection in different jurisdictions in order to protect originators. The analysis of the Paris Convention provides an understanding of how some developed countries at the beginning of the 20th century employed mechanisms, such as compulsory licensing, to increase capacity in their chemical industry, and eventually in the pharmaceutical one; once these countries could master the technology, they became involved in campaigning to create international patent standards through the Paris Convention in order to secure markets ahead of local producers. This is in line with Locke’s labour theory, as analysed in this thesis, as the Paris Convention sought to protect originators’ intellectual labour, yet it left countries with the possibility of implementing patent protection according to their own capacity through mechanisms that limit patent protections (i.e. Locke’s proviso).

However, as originators became an important economic asset for developed countries after the second part of the 20th century, this section also explains that originators eventually found that the Paris Convention did not provide substantive protection. Originators, therefore, lobbied developed countries to link patents and trade in the WTO in order to create a bargaining approach that would compel developing countries, including those rich in biodiversity, to grant patents in all fields of technology including pharmaceutical inventions. These efforts eventually led to TRIPs. Developed countries have kept this policy as they signed up to FTAs with developing countries rich in biodiversity in which TRIPs substantive patent standards are expanded (i.e. TRIPs-Plus). As a consequence, this part also argues that the reason why originators in developed countries have campaigned for an international standardisation of patent legislation is to gain entrance into different markets away from developed countries; whereas developing countries rich in biodiversity seek to limit harmonisation in order to protect their interests in protecting their local industries and genetic resources, and increase capacity in the pharmaceutical industry.[[468]](#footnote-469) This has led developing countries rich in biodiversity to campaign with the WTO and the Council for TRIPs to bargain for reducing the scope of patent protection and delay implementation of TRIPs in LDCs. This means that despite the fact that Locke’s labour theory allows us to understand why there should be IPRs that protect the intellectual labour that adds value, there are circumstances in which such protection is not granted to protect innovation but it is rather the result of a bargain made of international trade for access to technology. Therefore, developing countries rich in biodiversity seek mechanisms to counterbalance the linkage of trade and IPRs, for a different trade-off that includes restricting the scope of patents on genetic resources and securing ownership control these resources in order to bargain with them for access to technology. This is particularly reflected in Rawls’ work. Rawls’ social contract theory highlights that developing countries rich in biodiversity are entitled to claim ownership control of genetic resources and restrict patents on them as a result of a bargain between developed and developing countries rich in biodiversity – despite the fact that developing countries rich in biodiversity do not carry out any intellectual labour that adds value to genetic resources.

The second part analyses the substantive provisions (patentable subject matter) and the exclusions from patentability that TRIPs created; this analysis is relevant since, despite the fact that the substantive provisions of TRIPs emerged as the result of the linkage between trade and IPRs, it offers a ground on which developing countries could limit patents on technologies that employ genetic resources and protect ownership control of genetic resources. The third part analyses the way in which developed countries have adapted patents for genetic resources in order to reward the intellectual labour of inventors. It also explains how and why developing countries rich in biodiversity have restricted patents on genetic resources. Yet, developing countries rich in biodiversity such as Colombia have implemented TRIPs and TRIPs-Plus provisions in order to gain benefits from international trade rather than with the aim of increasing capacity in the drug development process. Indeed, whereas Colombia has adopted high standards of patent protection in pharmaceutical products via TRIPs and TRIPs-Plus provision, it limits patent protection on genetic resources, even if the local industry adds value to genetic resources with the aim of increasing capacity. Therefore, this chapter concludes that Colombia should adopt tailored policies in the implementation of TRIPs and TRIPs-Plus provisions that take into account the country’s capacity.

However, before this analysis is carried out, it is important to clarify that from the study of the Paris Convention (especially in the 19th and beginning of the 20th century), this chapter will refer to developing countries that are and are not rich in biodiversity. This is because the interest in protecting biodiversity and maintaining control over genetic resources appeared towards the end of the 20th century as biotechnology emerged as a promising technology in the drug discovery area in the 1980s and TRIPs was enacted in 1994; hence, developing countries which are rich in biodiversity acquired particular prominence in the discussion on ownership control on genetic resources and patents, yet developing countries which are not rich in biodiversity have also raised concerns on TRIPs such access to medicines.

1. **Setting Up International Standards of Patents and International Trade: From Paris Convention to TRIPs**

Since the 19th century, the chemical industry, the predecessor of the pharmaceutical industry, has been one of the leading sectors in pushing for setting up international standards of patents. Analysis of the chemical industry and international standards of patent protection helps us to understand why patents are an important mechanism of protection for originators, i.e. they provide exclusivity protection to their inventions in new markets ahead of local producers which aim to manufacture and distribute those inventions without recognition of patent holders’ rights. This analysis also shows how some developed countries had assessed their own capacity as they implemented international standards of patent protection. Therefore, it equally points out how developing countries have adapted to new patent requirements in order to increase their capacity in the pre-TRIPs era.

Legislation on patents has been characterised by mechanisms that either restricted or excluded specific technologies, such as chemical synthesis, from patent protection. For instance, the 1888 Swiss Federal Patent Law (*Loi Fédérale Sur Les Brevets d’Invention, 1888*) required that invention had to be represented by mechanical models applicable to industry; this provision was intentionally created to exclude chemical inventions. [[469]](#footnote-470) This clearly reflects that even developed countries, in which most originators are currently located, did not grant absolute rights to those who carried out an intellectual labour that adds value, but also used to restrict or exclude inventions according to their own capacity. Indeed, there have been countries such as the UK that aimed to protect local industry and trade, and secure the transfer of technology in order to increase capacity. These countries employ mechanisms such as compulsory licensing, discriminatory treatment, importation and working requirements.[[470]](#footnote-471) However, the chemical industry found that such a situation affected them as its inventions could be replicated in a different country in which patent protection had been obtained. The chemical industry also found that foreign legislation on patent protection put them in a position in which the industry was vulnerable to the undue exploitation of their inventions. As a consequence, these companies campaigned for setting up minimum patent standards in an international treaty.

One of the first forums that they created to campaign for minimum standards in patent protection was the Paris Convention. This convention helped the chemical industry to harmonise the patent system among developed countries, especially in Europe. For instance, the German chemical industry expanded successfully into new markets in Europe thanks to the efforts of stakeholders from this sector to set up patent standards in different foreign legislation.[[471]](#footnote-472) Nevertheless, developed countries found that the Paris Convention did not succeed in stopping developing countries from using mechanisms that deter or limit patents on chemical and pharmaceutical inventions. The growing chemical and pharmaceutical industries did not only want to expand their activities in developed countries but also in developing countries. Under the pressure of large pharmaceutical companies and other important business sectors, developed countries (especially the US) shifted their policy of seeking patent standards of protection in a single international patent treaty towards the linkage between trade and IPRs. The result was TRIPs.

It is important to analyse: (1) how this shift occurred; (2) to what extent the interest of the pharmaceutical industry in developed countries in obtaining exclusivity protection in new markets in developing countries has influenced IPRs in the global context; and (3) developing countries’ approach to this process of standardisation.

* 1. **Paris Convention**

Increasing capacity by limiting or denying patent protection to the intellectual labour that adds value, has not been a unique effort by developing countries. Indeed, governments in Europe and the US encouraged local inventive activities by enacting legislation that discriminates foreign inventions. For instance, under the Statute of Monopolies of 1624 (one of the earliest British regulation on patents) it was permitted to grant patent protection to those who brought new technologies into Britain rather than the invention itself.[[472]](#footnote-473) Similarly, the American Patent Act of 1790 created the concept of ‘importation patents’ which allowed American importers to exploit patents in America without the authorisation of the overseas rights holder.[[473]](#footnote-474) This indicates that developed countries such as the UK and the US enacted normative provision that aimed to increase capacity in their local industries by circumventing patents’ rights, e.g. the national requirement in patents.

The national or local requirement (‘working’ requirement) in which different legislation demanded that inventions should be locally worked, or appropriately worked in order to maintain a patent, were common in Europe. If a patent was found that was not being worked, or not worked correctly, a governmental authority could issue a compulsory licence; hence the invention could be locally exploited without the patent holder’s consent.[[474]](#footnote-475)

Nevertheless, the chemical industry found that the measures that aimed to protect local industries in Europe would incentivise local industries to easily copy its inventions, even before patent holders had the chance to enter into the new markets.[[475]](#footnote-476) For instance, the French Patent Law of 1791 required inventors to work their inventions in France within two years of being granted, unless the patent holders could justify their inactivity, while Section 22 of the British Patents, Designs and Trade Marks Act of 1883 patent system provided even greater scope to the working requirement and compulsory licensing since it could be applied almost immediately if the patent was not worked.[[476]](#footnote-477) In particular, there was a worry that legislation on compulsory licensing and working requirements was widely interpreted to allow only local industries to work on an invention, regardless of the rights holders’ interests.[[477]](#footnote-478) This also meant that technologies, such as chemical inventions which required great investment and time, could be imitated or used in different countries without due recognition of patent holders’ rights.[[478]](#footnote-479) The chemical industry found that, although a patent granted exclusive rights to develop an invention, the protection was limited to a specific geographical area and to different rules in each jurisdiction. In other words, this enabled rights to be circumvented in countries where few or no patent rights exist. However, by the beginning of the 20th century, the chemical industry consolidated in developed countries which used to restrict patent protection (e.g. the UK and the US); as a result, it became fundamental for developed countries to campaign for exclusivity mechanisms that helped them to secure markets ahead of local producers.[[479]](#footnote-480)

Therefore, developed countries, which had already gained capacity in the industry, took on developing countries to demand patent exclusivity. Indeed, developing countries (such as India, Brazil, China) with growing economies began to mass produce inventions without due recognition of patent protection. It is for this reason that developed countries, led mainly by the US and especially influenced by the chemical industry, through different international treaties, tried to establish an international regime on IPRs.[[480]](#footnote-481) In the case of patents, the Paris Convention played a fundamental role in the setting up of an exclusivity mechanism that could secure markets for innovators ahead of local producers.

The Paris Convention’s success was the establishment of the principle of national treatment and the right of priority. Both mechanisms aimed at restricting the discriminatory treatment that patent holders underwent when they tried to obtain a patent overseas. For instance, Article 2 of the Paris Convention establishes that, in the process of granting patents, a non-national should have similar treatment to nationals as long as the non-national applicant meets all the requirements set up by the authorising body[[481]](#footnote-482) and he/she is a national from one of the members of the Paris Convention.[[482]](#footnote-483) However, the Paris Convention also extends the scope of national treatment to those applicants that are nationals from a non-member of the Paris Convention, but who are domiciled in a Signatory State.[[483]](#footnote-484) Additionally, the Paris Convention was successful in creating the right of priority in which an applicant that has filed a patent in a member country of the Convention has the right to apply for the same legal right in different countries within 12 months.[[484]](#footnote-485) This right gives the opportunity to ‘reserve’ markets in other countries where there is the fear that competitors or generic producers could enter important markets ahead of the patent holders.[[485]](#footnote-486)

However, the Paris Convention was also a scenario in which developing countries could still implement patent standards according to their own capacity, particularly when it came to reducing the scope of working requirements and compulsory licensing. In fact, the Paris Convention did not rule out the working requirement (or the ‘failure to work’ provision). Article 5 (a) (2) of the Paris Convention not only allowed Signatories to issue compulsory licences on the basis of working requirements, but also to prevent the abuse of the rights granted.[[486]](#footnote-487) Furthermore, the Convention did not provide a definition of ‘failure to work’; the interpretation of this concept leads to limited patent protection. Developing countries in particular were keen to adopt a wide interpretation of the ‘failure to work’ provision in order to impede patent importation on the grounds that the product was not produced locally.[[487]](#footnote-488) The implications of such a requirement for originators in developed countries would have been the obligation to establish labs and other research facilities in each country where the patented product or process was sold.[[488]](#footnote-489)

Another loophole of the Paris Convention was that it did not set up minimum requirements on patent protection, which means that Parties were able to create legislation which did not provide protection to specific technologies. This is despite the fact that those technologies obtained patents in developed countries by following the minimum patent requirements (novelty, inventive step and industrial application). This situation allowed Signatories to easily discriminate against specific fields of technology: for instance, not granting patent protection to pharmaceutical and agricultural chemical inventions. For example, Brazil did not allow patents on pharmaceutical inventions until 1996.[[489]](#footnote-490) As discussed, not granting patents on pharmaceutical products was an important element that led developing countries such as India to increase capacity in manufacturing illegal generics. For developed countries, the Paris Convention was not a comprehensive treaty and the ambivalence of the Convention’s wording permitted developing countries to adapt national legislation to manufacture and distribute illegal generics, so they could have access to technology regardless of any patent protection granted in developed countries.

Although there were further developments in implementing international rules in patents, the US government found this protection weak. For instance, Signatories of the Paris Convention joined efforts with the UN to create an international organisation in order to secure a more harmonised global patent legislation: WIPO.[[490]](#footnote-491) WIPO has created two treaties on patents: the Patent Cooperation Treaty (PCT) and Patent Law Treaty (PLT).[[491]](#footnote-492) However, WIPO’s treaties do not create substantive elements or requirements in patents. Although these treaties have standardised the procedures and rights of priority of the Paris Convention, the US was sceptical towards WIPO as this organisation did not demand a greater IPRs protection for its members.[[492]](#footnote-493) The US found that WIPO was not able to deal with developing countries’ interests in making use of the Paris Convention loopholes to gain access to technologies (regardless of developed countries’ patent protection) with the aim of increasing developing countries’ capacity in the drug development process. The developing countries’ stand was a barrier that impeded originators in securing exclusivity in new markets through patents.[[493]](#footnote-494) As a result, the US reallocated efforts to set up minimum patent standards in a different forum: the WTO’s TRIPs.

To sum up this section, the developments before and after the Paris Convention highlight the importance and relevance of Locke’s labour theory in understanding why countries grant patent rights in order to protect the intellectual labour that adds value. In other words, the Paris Convention aimed to provide patent protection to the intellectual labour of originators as they entered new markets. However, Locke’s labour theory also illustrates that the Paris Convention established mechanisms to limit patents, according to Locke’s proviso, in order to increase capacity. For instance, the sufficiency proviso can be reflected in the Paris Convention as it allowed countries to set up patent standards, so they could decide what technologies could or could not be considered patent subject matter. However, as the US reallocated efforts in a different forum to force developing countries to accept higher standards of patent protection via international trade, it is important to point out that Locke’s theory falls short in providing grounds on why the intellectual labour is rewarded against countries’ capacity and interest in protecting local industry. In order to complement Locke’s labour theory, this thesis has also highlighted the necessity to analyse TRIPs, TRIPs-Plus and the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health, in the light of Rawls’ theory and Nussbaum’s capability approach.

* 1. **Trade, Bilateralism, IPRs and TRIPs**

Nussbaum highlights that Rawls’ social contract theory fails to justify the existence of inequalities in the initial position (or Rawls’ veil of ignorance).[[494]](#footnote-495) Nussbaum rather points out that in the dynamics between States, there are participants that are economically and politically stronger (i.e. developed countries); as a consequence, they normally impose their own interests on other weaker participants (i.e. developing countries rich in biodiversity) in the social contract. James, in his work on fairness and social contract theory in international trade, also stresses the difficulty in employing Rawls’ veil of ignorance, since Rawls ‘suggests a parochial egalitarianism’ that does not reflect the economic, political and social differences between States.[[495]](#footnote-496)

Therefore, in order to provide a better understanding of the initial position or veil of ignorance in which countries are not equal, Nussbaum considers that capability operates as an indicator of what countries want and are actually capable of as they enter into an agreement.[[496]](#footnote-497) As mentioned above, the capability approach and capacity are terms that are articulated together in the scope of this thesis as the former does not only aim to increase capacity but also entitles countries to achieve different economical and social goals. Therefore, capacity should be taken into account in the process of the construction of international agreements between developed and developing countries rich in biodiversity. This subsection and the next analyse how TRIPs and TRIPs-Plus emerge as a bargain in which developing countries trade off access to international trade for higher standards of patent protection. This analysis is complemented by elements previously studied in Chapters 1 and 2 on developing countries rich in biodiversity’s capacity in order to assess the impact of TRIPs and TRIPs-Plus on technologies that employ genetic resources for drug development.

By the mid-1980s, developing countries managed to reduce the scope of patent protection. Developed countries were concerned that this situation was affecting originators’ market share in drugs as generic companies were delivering illegal generic versions in developing countries.[[497]](#footnote-498) Countries such as the US could not afford a situation in which industries with IPRs portfolios (which represented 2.8% of the US’s GNP) were not protected overseas.[[498]](#footnote-499)

However, working requirements and compulsory licensing, including pharmaceutical inventions, have remained an important mechanism of public policy in developing countries and even in developed countries such as Canada and the US, particularly to deal with the unmet demand of medicines.[[499]](#footnote-500) Indeed, between 1969 and 1992 Canada issued 613 compulsory licences for pharmaceuticals or patents that were against the public interest.[[500]](#footnote-501) Even though the US has never issued a general statute on compulsory licensing on public policy grounds, federal courts employed compulsory licensing to prevent misuse of patents or antitrust practices in most of the 20th century.[[501]](#footnote-502) Although the issue of working requirements and compulsory licensing, particularly in pharmaceutical inventions, is not studied in more detail in this thesis, it is relevant here because a key aspect of the failure to agree over TRIPs is centred on access to medicines. On the one hand, if compulsory licences are routinely issued in the health context, originators will cease to invest, or decrease in investing, in R&D.[[502]](#footnote-503) On the other hand, developing countries and LDCs have had a long battle to implement the compulsory licensing in order to supply the unmet demand for the medical treatment of HIV/AIDS.[[503]](#footnote-504) Certainly, developing countries and LDCs argue that the use of compulsory licensing is something that developed countries did with the chemical industry before the creation of the Paris Convention.[[504]](#footnote-505)

However, the rising pressure from important US economic sectors, such as the pharmaceutical industry, led the US government to change its strategy to set up international patent standards by connecting aspects of IPRs with international trade via bilateral agreements with other countries.[[505]](#footnote-506) This became a critical point for the pharmaceutical market for two reasons. First, during the 1970s and 1980s the pharmaceutical industry positioned itself as an important economic asset in developed countries and biotechnology emerged as a significant tool for originators in the drug development process.[[506]](#footnote-507) Second, the increase in international trade led to interdependency between developed countries and developing countries.[[507]](#footnote-508)

As a consequence, originators joined forces with other important business sectors to influence the US to abandon further changes to WIPO and to turn to international trade and bilateralism. This process started with the US trade partners and moved eventually into the negotiations of the General Agreements on Trade and Tariffs (GATT).[[508]](#footnote-509)

The US’s new approach to GATT was to include trade sanctions for countries that did not accomplish minimum requirements in IPRs.[[509]](#footnote-510) However, the negotiations in this aspect in the Tokyo Round, between 1973 and 1979, were in a deadlock.[[510]](#footnote-511) This stalemate was led by developing countries, such as India and Brazil, who attempted to rule out the US’s proposal to link GATT with a new international IPRs treaty. India and the Andean Community of Nations (ACN), were concerned about the economic burden patents would have for access to technology.[[511]](#footnote-512) Indeed, as analysed in Chapter 2, Vaitsos pointed out that the existence of a technological disparity between developed and developing countries justifies that the ACN created restrictions and limits to patent exclusivity on pharmaceutical products.[[512]](#footnote-513) This means that whereas developed countries were demanding greater protection for originators, countries such as India and ACN members prevented setting up patent standards and enacted patent legislation that ruled out patents on chemicals and drugs. In fact, Chapter 1 highlights how India assessed its capacity through different public policy documents in which it was recommended to India to limit patent protection on chemical and drugs in order to increase capacity.[[513]](#footnote-514) By excluding patent protection on these technologies, India turned its pharmaceutical industry into a sophisticated and important sector of India’s economy.[[514]](#footnote-515)

This means that, despite the fact that the US aimed to link international trade with IPRs in GATT, developing countries continued to limit and restrict patent protection in key industries in order to increase capacity. As a consequence, the US sought to strengthen its bargaining position through bilateral measures that involved trade sanctions on countries that did not protect IPRs. Section 301 of the US Trade Act conferred the right on the Office of US Trade Representatives (USTR) to carry out investigations in countries that did not protect US companies’ IPRs; if a US trade partner country failed to protect US IPRs, the USTR would be entitled to remove tariff privileges for imported products. Korea was the first country to face Section 301 as US companies complained about Korea’s weak IPRs legislation.[[515]](#footnote-516) The mechanism proved to be effective as Korea ultimately changed its IPRs.[[516]](#footnote-517) Consequently, other countries that had signed up for FTAs with the US strengthened their IPRs protection.[[517]](#footnote-518) As these bilateral measures proved to be successful in putting pressure on countries that did not secure IPRs, it was clear that developing countries did not have any alternative other than to accept the inclusion of IPRs within the negotiations of GATT.[[518]](#footnote-519) The result of these efforts was TRIPs.[[519]](#footnote-520)

By linking trade and IPRs, the US set up international minimum standards for the protection of pharmaceutical inventions, in particular limits on the use of compulsory licensing and working requirements.[[520]](#footnote-521) Therefore, TRIPs does not allow compulsory licences to be issued on the grounds of the category of inventions (e.g. pharmaceutical or chemical products). If a country is interested in issuing a compulsory licence, it has to be decided on a case-by-case basis and follow a series of rules set up in Article 31. This article establishes that negotiations with the patent holder should be carried out before issuing a compulsory licence; the compulsory licence should be limited to the purpose for which it was granted; the use of a compulsory licence should not be exclusive; the compulsory licence should only be to supply the local market; an adequate remuneration should be granted to the rights patent holder; and, a patent holder should also have the right to have the decision reviewed by a judicial authority. TRIPs also establishes that importation to local markets will be enough to honour any working requirement (Article 28).[[521]](#footnote-522)

* 1. **The Post TRIPs Era: TRIPs-Plus and Doha**[[522]](#footnote-523)

TRIPs is the result of developed countries’, particularly the US, campaign to link international trade and IPRs. This situation led developing countries rich in biodiversity to accept international minimum standards on patent protection. This means that TRIPs was not necessarily the result of countries’ capacity assessment or a reward for those who carried out intellectual labour, but rather a mechanism in which developing countries, including those rich in biodiversity, accepted a trade-off of access to international trade for higher IPRs standards. Yet, TRIPs is not the end of the bargaining process between developed and developing countries, including those rich in biodiversity, but it has rather created a forum in which those countries have continued to bargain trade for access to technology.

Although developed countries and developing countries reached an agreement on TRIPs on substantive aspects of IPRs and the limits of legal mechanisms that reduce the scope of patents (e.g. compulsory licensing), after the implementation of TRIPs a new set of issues emerged that created two different agendas: (1) developed countries, especially the US, have sought to extend the scope of the obligation established in TRIPs through bilateral agreements with developing countries such as Colombia, Panama and Peru. The most common trend of these bilateral agreements is to extend the scope of IPRs via bilateralism and FTAs. This is known as TRIPs-Plus; (2) developing countries and LDCs have found in TRIPs a legal framework in which they aim to broaden the discussion on IPRs (e.g. no patents on life forms) and link other issues to IPRs (e.g. access to medicines and public health, the relationship between TRIPs and the CBD) in order to strength their bargaining position.

* + 1. **TRIPs-Plus: the Revitalisation of Bilateralism**

For developed countries’ originators, TRIPs was not the end of the discussion about IPRs, but a prologue which has led to the expansion and creation of legal mechanisms that aim to amplify TRIPs obligations. Although TRIPs-Plus dispositions might be different, depending on the countries involved in it, there are two common trends: (1) TRIPs-Plus amplifies TRIPs substantive standards, and creates and extends current mechanisms of protection; and (2) it limits the scope of prerogatives which aim to ease the negative impact of patents such as compulsory licensing. This subsection analyses both trends and whether they actually aim to increase capacity in developing countries, particularly those rich in biodiversity.

* + - 1. **TRIPs-Plus Substantive Standards and Data Exclusivity**

As explained above, developed countries succeed in setting up minimum substantive standards in patent protection in TRIPs. However, this has not deterred developed countries from demanding developing countries to expand those substantive standards. For instance, in Article 27.3 (b), TRIPs allows countries to exclude plants from patentability; however, FTAs such as those issued by the US and Colombia stipulates that Signatories should issue similar legislation to the US patent protection over plants.[[523]](#footnote-524) Another example of modifications on substantive standards is second indications. This is a known composition or substance, which is employed to treat a disease that is different from the first indication. A second indication does not fulfil the patent requirement of novelty *per se*, but the US and EPO have granted patents on it. [[524]](#footnote-525) The US has included second indications in FTAs with developing countries such as Morocco, [[525]](#footnote-526) and even with Australia, a developed country.[[526]](#footnote-527)

On the other hand, originators have also explored other avenues in which they aim to provide further protection to pharmaceutical products. This has led to new mechanisms of protection, different from patents such as data exclusivity. This mechanism does not necessarily reward protecting intellectual labour but they are rather based upon product protection.[[527]](#footnote-528) However, TRIPs has already mentioned this mechanism in Article 39.3, i.e. data exclusivity, also known as the protection of the submission of undisclosed test or data of chemical and pharmaceutical products.

In this case, the protection is over the data or test which is employed to obtain an MA from governmental authorities such as the FDA in the US and EMA in the EU. Article 39.3 of TRIPs does not necessarily protect innovation itself, but it calls on States to protect from ‘unfair commercial use’ the effort employed to collect and organise specific data or test. Article 39.3 adds that such protection is on: (1) the information collected should be data or test whose aim is to obtain an MA in pharmaceutical or agro chemical products; (2) the data or test protected are those only related to new biochemical compounds; (3) the data or test submitted should be undisclosed; (4) there should be a considerable effort in collecting the data or test; and finally (5) States should protect the data against disclosure, except when the data go against the public interest, or to secure those data is to protect them against unfair commercial use. TRIPs only mentions data exclusivity (in a different Section) separately from other categories of IPRs. Indeed, the wording of Article 39.3 only offers general guidelines which do not necessarily involve an obligation for Members of the WTO to grant exclusivity rights but rather to protect data from unfair commercial use.[[528]](#footnote-529)

However, developed countries have employed data exclusivity as a mechanism to give further protection to originators since generic producers rely on previous data collected by originators to obtain an MA. Therefore, developed countries’ legislation on data exclusivity prevents generic companies from ‘cross-refer[ring] to the data in support of another marketing authorisation’.[[529]](#footnote-530) As a result, originators have also campaigned to include data exclusivity as a mechanism of exclusive protection in FTAs and patent legislation in developing countries, including those rich in biodiversity. Indeed, all the FTAs in which the US is a part (e.g. US-Peru FTA[[530]](#footnote-531)) have specific provisions demanding exclusive rights on data exclusivity. This protection has raised concerns in developing countries rich in biodiversity because Article 39.3 TRIPs does not necessarily create a mechanism of exclusivity but a mechanism to protect data from unfair commercial use.[[531]](#footnote-532) Yet, TRIPs-Plus provisions have transformed this provision into a mechanism of exclusivity protection.[[532]](#footnote-533) In fact, protection of the submission of undisclosed test or data extends the market exclusivity of a pharmaceutical product even if a patent has expired.[[533]](#footnote-534) This product and patent protection can overlap and/or extend the protection of new biochemical compounds as an MA can be obtained years after a patent is granted.

Another example of protection is the linkage between the process of obtaining an MA and patent status. The MA is an aspect that is not discussed in TRIPs, although there is a reference in Article 39.3 when the submission of undisclosed test or data is mentioned. However, an MA represents a problem for originators as the length of safety evaluation time for a drug could reduce the possibility of commercially exploiting the exclusivity that a patent provided.[[534]](#footnote-535) Indeed, after a patent has been granted to a new biochemical compound, it needs to undergo thorough technical and legal steps (e.g. clinical trials and MA), and can take up to 15 years to reach the market (see Annex I).

As this reduces the time of exclusivity to regain what has been invested in the development of a new drug, originators have campaigned to link the time that health authorities take to grant an MA with patent protection. Such protection has also been extended to delays in the process for granting a patent. Indeed, FTAs such as the US-Panama and the US-Peru have established that Signatories to FTAs shall compensate patent owners for any delays that occurred during the decision making process of the MA and patent issuance.[[535]](#footnote-536) Such a protection means that the length of protection will depend on the legal and technical capacity of each country to grant a patent or MA. As explained in Chapters 1 and 2, even developing countries rich in biodiversity with strong economies, such as China, have not completely managed to establish competent health and patent authorities. The corruption row in which the Chief of the Chinese State Food and Drug Administration was sentenced to death for his participation in situations which involved poor quality control on medicines, indicates that linkage might not be in the best interests of the local pharmaceutical companies. [[536]](#footnote-537)

* + - 1. **Further Minimum Standards in the TRIPs-Plus era**

TRIPs is an important mechanism in the setting up of minimum standards in which originators aim to secure exclusivity in new markets ahead of generic companies in developing countries. However, TRIPs has some exceptions and loopholes in which developing countries seek to deter patent protection, despite the fact that these countries have implemented most of the TRIPs provisions.

One of the main goals of TRIPs-Plus is to discourage developing countries from taking advantage of some of the prerogatives that TRIPs gives to States, especially compulsory licensing. This indicates that most of TRIPs-Plus provisions do not aim to protect an intellectual labour, but could instead lead to abuses from right holders by limiting mechanisms that reduce the negative effects of IPRs in developing countries. Although TRIPs-Plus provisions limit mechanisms that aim to ease the negative effects of exclusivity, they have played a central role in multilateral forums, particularly the Doha Round of WTO negotiations in which developing countries, including those rich in biodiversity, aimed to reduce some of the negative effects of TRIPs. The importance of analysing these mechanisms, not only within a TRIPs-Plus context but also in the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health, is to assess whether developing countries have found in TRIPs of the WTO a forum in which they could actually bargain for further reforms in the IPRs in order to increase capacity or instead to bargain for international trade for access to technology.

* + 1. **Doha and Beyond**

As discussed in section 1.2 of this chapter, developing countries decided to adapt developed countries’ patent style systems in order to obtain benefits from international trade. However, the creation of the WTO and implementation of TRIPs was not exclusively an international scenario in which developing countries accepted developed countries’ demands. The WTO and TRIPs emerged as a forum in which developing countries, including those rich in biodiversity, have not only accepted implementing patent protection, but have also pursued implementing an agenda that meets their interests.[[537]](#footnote-538) Indeed, Kapczynski points out that developing countries have come together as an answer to the hardening of IPRs in the WTO. Yu also argues that although developing countries were at first mere observers and did not actively participate in setting up international standards, these countries have become more involved in order to meet their own interests.[[538]](#footnote-539) However, as analysed in the previous section, developed countries have also employed TRIPs to construct new strategies to amplify exclusivity protection via TRIPs-Plus provisions.

Both points of view have shaped the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health, in which developed and developing countries have agreed to address some particular issues that concern the latter. In other words and following the analysis of subsections 1.2 and 1.3, from a Rawls point of view, developed and developing countries have come to bargain in the TRIPs of the WTO in order to address not only issues that benefit developed countries but also those of developing countries. However, this analysis is complemented by Nussbaum’s capability approach, which allows assessing whether developing countries could take advantage of this forum in order to increase capacity.

Although TRIPs has been the most comprehensive treaty on IPRs, both developed countries and developing countries have found that there were some issues that were not discussed in more detail during the negotiation of TRIPs. Gervais argues that the difficulty in reaching a consensus during the negotiations, and the technical and political events that emerged after TRIPs was enacted (e.g. discussion on access to medicines and scientific breakthroughs), were elements that made it impossible to create a legislation that would have covered all patent-related aspects.[[539]](#footnote-540) However, those loopholes left during the negotiations of TRIPs have served as a pivotal point in the post TRIPs era. This means that whereas developed countries aim to fill those loopholes through TRIPs-Plus dispositions, developing countries have tried to find ways to protect their own interests, particularly in their pharmaceutical industries, by campaigning in the WTO for amendments.

Article 71 of TRIPs allows members of the WTO to amend TRIPs dispositions. Article 71.1 establishes that the Council of TRIPs, the executive body of TRIPs, reviews the implementation of this treaty every two years; this leaves the possibility that the Council can carry out a review of the wording of the treaty in the light of ‘any new developments’ that might demand modifications to TRIPs. As a result, since TRIPs was enacted, this treaty has undergone considerable revision by Members of the WTO.

These discussions led to the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health.[[540]](#footnote-541) The fourth Session of the Ministerial Conference in 2001 issued a Ministerial Declaration (the Doha Ministerial Declaration) which set up a work programme on aspects related to trade negotiations and implementation issues of the agreements reached within the WTO, including TRIPs. Paragraphs 17 to 19 of the Doha Ministerial Declaration established a programme to work on three different issues which are relevant for this thesis: (1) the impact of patent protection on access to medicines and public health (including the delay of the implementation of TRIPs in LDCs and compulsory licensing);[[541]](#footnote-542) (2) the scope of Article 27.3 (b); and (3) the relationship between the ABS regime (especially the CBD) and TRIPs.[[542]](#footnote-543) The second and third points are studied in more detail in Section 2 of this chapter and Chapter 4 respectively.[[543]](#footnote-544)

* + - 1. **The Doha Declaration on TRIPs and Public Health**

As explained in subsection 1.2 of this chapter, it is beyond the scope of this thesis to analyse the relationship between TRIPs and public health.[[544]](#footnote-545) However, the negotiations and legal measures that emerged after this declaration have important consequences for the pharmaceutical industry and technologies that employ genetic resources in both developed and developing countries. The Doha Declaration on TRIPS and Public Health was established after developing countries and LDCs went through different problems in implementing compulsory licensing of pharmaceutical products in response to the increasing number of HIV/AIDS cases.[[545]](#footnote-546) As a result, these countries managed to set up a programme that aimed to amplify the scope of compulsory licensing and the deadline to implement TRIPs into national legislations of LDCs.[[546]](#footnote-547)

Article 31 of TRIPs did allow Members of the WTO to issue compulsory licences; however, countries must follow the guidelines established in Article 31, which aims to reduce the discretionary power of countries on this issue. For instance, if a government wishes to obtain a compulsory licence, it has to prove that it has already made efforts to reach an agreement with the patent holder and that this was not successful; this provision might be waived in cases that constitute a national emergency or other circumstances of extreme urgency (Article 31 (b) of TRIPs).

At the centre of the discussion has been under what circumstances Article 31 might apply. The Doha Declaration on TRIPs and Public Health confirms, clarifies and assures Members that they have the right to use compulsory licences and freedom to determine what constitutes a national emergency (Paragraph 5). However, the discussion is not only regarding the nature of what constitutes national emergency. Doha has also established two further prerogatives for LDCs: (1) a waiver for LDCs to delay the implementation of TRIPs in these countries; and (2) compulsory licensing for import.

First, TRIPs originally gave to all States a transitional period of one year after TRIPs was enacted (Article 65.1). However, developing countries, for the particular case of pharmaceutical products, could extend the transitional period up to 10 years (Article 65.4 of TRIPs); whereas, LDCs have a similar provision (Article 66), although they could extend the transitional period of 10 years not only to pharmaceutical products but also to the whole agreement. Such a period would have expired in 2004, but the Doha Declaration on TRIPs and Public Health extended the transitional period until 2016 in the case of pharmaceutical products for LDCs.[[547]](#footnote-548) As studied in Chapter 1, India and China, countries in which generic production of medicines is an important sector, have taken advantage of the LDCs’ waiver to implement TRIPS to set up labs and production facilities, and create trade links with LDCs; although India and China benefit from this provision, LDCs are also well placed to gain access to technology from India and China as they circumvent patents on pharmaceutical products, hence LDCs could increase capacity by setting up manufacturing facilities in order to produce illegal generics.

Second, as identified in subsection 1.2, the use of compulsory licensing is limited to the territory of the country in which it will be issued (Article 31 (f)(K) of TRIPs). This clearly means that a country should have the technical capacity to mass-produce a pharmaceutical product in order to issue a compulsory licence. As most LDCs lack capacity, Paragraph 6 of the Doha Declaration allows LDCs to issue a compulsory licence to import pharmaceutical products from a different country. Again, this situation does not only benefit LDCs but also other countries, such as India and China, as they could produce, export and distribute pharmaceutical products without the risk of being accused of infringing the patent rights of originators.

Even though LDCs and developing countries, such as Peru and Panama, have apparently gained autonomy to determine the scope of compulsory licensing, the Doha Round of negotiations not only served the interests of small and medium sized economies, but it has brought important flexibilities that benefit generic companies in India and China. The Doha Round is not only about access to medicines or public health, it is also the result of a bargain in which flexibilities are employed by India and China to set up labs and manufacturing facilities in LDCs and export medicines without infringing patents.

The outcome of Doha has been to create new opportunities for LDCs to create centres for the production of illegal generics, which could eventually increase capacity in these countries. In the meantime, TRIPs-Plus is not just about capacity in developing countries such as Panama, Peru or Colombia; authors such as Correa, Drahos, Frankel, Sell and Vivas all point out that TRIPs is merely the base for further bilateralisms in a post TRIPs era (or TRIPs-Plus era) which largely benefit the originators.[[548]](#footnote-549)

The use of flexibilities in patents (e.g. compulsory licensing, exclusion of pharmaceutical inventions from patentability or working requirements) according to countries’ capacity has even benefited developed countries. Indeed, as explained above,[[549]](#footnote-550) during the events that led to the Paris Conventions and the pre-TRIPs era, developed countries such as UK, France, US and Canada have obtained benefits from employing those flexibilities to increase capacity in their pharmaceutical industry. India and China have followed a similar approach in the pre-TRIPs and post-TRIPs eras.[[550]](#footnote-551) However, other developing countries could also benefit from Doha and even TRIPs-Plus if they were to implement them according to their own capacity.

Indeed, James even justifies that developing countries could ‘eviscerate TRIPs’ to level the playing field with developed countries regarding IPRs even if these countries have decided to participate within the rules of TRIPs.[[551]](#footnote-552) Maskus and Reichman have also called on countries to employ flexibilities in TRIPs and Doha, to encourage the transfer of technology according to countries’ capacity. Those recommendations have included reducing the scope of patent protection, no granting of patents on genetic resources, use of compulsory licensing and competition law.[[552]](#footnote-553) Nevertheless, developing countries are more concerned to trade with developed countries via FTAs rather than employing flexibilities of TRIPs and Doha. Indeed, Hermann has found that TRIPs and Doha have become a mechanism to further bargain in the negotiations of bilateral agreements that aim to obtain further access to markets in developed countries, rather than improving countries’ capacity to encourage their local pharmaceutical industries.[[553]](#footnote-554) For instance, there has been only one country that has employed Paragraph 6 of TRIPs.[[554]](#footnote-555) This means that developing countries such as Colombia, that could have employed patent flexibilities, are restricted in employing them. In other words, although TRIPs and Doha recognise prerogatives (e.g. compulsory licensing) that could give these countries enough manoeuvring room to implement TRIPs requirements in order to increase capacity, TRIPs-Plus deters and limits these countries from employing those flexibilities. TRIPs-Plus has even created exclusivity mechanisms (e.g. data exclusivity and patent linkage) that do not necessarily aim to reward the intellectual labour of inventors but rather to secure markets for originators ahead of local companies.

In the analysis of developing countries rich in biodiversity capacity, global markets and genetic resources, this thesis highlights the importance of providing patent protection to the intellectual labour that adds value and establishes limits to patents when they affect the access to technology and genetic resources, or third parties (e.g. access to medicines). Indeed, in Locke’s labour theory the intellectual labour that adds value allows inventors to appropriate from the commons; but there are also limits of IPRs which are based upon Locke’s provisos, i.e. the sufficiency proviso and spoiled or no waste proviso. In principle, TRIPs could reaffirm this approach as it creates a set of patent requirements that does not discriminate inventions and mechanisms that aim to entitle countries to limit patents, such as compulsory licensing in case patent holders’ rights affect other interests (e.g. access to medicines).

However, the relationship between TRIPs (including TRIPs-Plus) and international trade has actually limited developing countries from implementing patents according to their countries’ capacity. This means that even if flexibilities (i.e. Locke’s proviso) are in place, they are inoperable because countries such as Colombia do not assess capacity as they implement TRIPs and TRIPs-Plus provisions. These countries rather trade off access to technology for international trade. Despite the fact that international trade remains an important mechanism to set up minimum standards in patents in developing countries, and for the scope of this theses developing countries, there are some aspects of TRIPs agreements in which developing countries, particularly those rich in biodiversity such as Colombia, still have room to manoeuvre in implementing TRIPs according to their own capacity, especially in technologies that employ genetic resources. These are the substantive elements in TRIPs that could define the scope of patent protection on genetic resources. This is because the substantive elements offer common ground for both developed and developing countries rich in biodiversity which the latter could employ in order to increase capacity in technologies that employ genetic resources.

1. **Patentable Subject Matter and Article 27 of TRIPs**

Up to this point, this chapter has focussed specifically on how, from the Paris Convention to TRIPs, developing countries, including those rich in biodiversity, have been reducing their autonomy to determine important aspects of patent legislation as they aim to obtain benefits from international and bilateral trade. This applies, for instance, to the limits and scope of issuing compulsory licences. In this case, developing countries have had to balance, on the one hand, the benefits of securing international trade, while, on the other hand, protecting local industry from the cost of paying for licences on patents.

This indicates that despite the fact that IPRs (particularly patents) are created to protect the intellectual labour that adds value to what is in nature or the commons, the dynamics between countries, international trade and IPRs respond necessarily to a bargain in which developing countries, including biodiversity ones, trade off access to technology for access to international trade.

As a result, TRIPs and TRIPs-Plus provision does not only establish significant changes to compulsory licensing and working requirements, but also sets up minimum standards on patentable subject matter in TRIPs. Without doubt this is where TRIPs stands apart from the Paris Convention.[[555]](#footnote-556) This Convention did not establish a definition of patentable subject matter or the requirements of patents which has led Signatories to exclude categories of inventions (e.g. pharmaceutical and agriculture inventions) which allowed them to increase capacity. In contrast, TRIPs demands that countries grant patent protection in all fields of technology and secure minimum standards for granting patents.[[556]](#footnote-557) However, TRIPs also provides flexibilities to countries so they can adopt an interpretation through which their interests might be protected. In other words, although TRIPs, and even TRIPs-Plus, have been the result of a trade-off of access to technology for access to international trade (rather than an incentive innovation), developing countries rich in biodiversity still have mechanisms to limit patents in order to increase capacity, particularly in technologies that employ genetic resources.

The substantive minimum standards of TRIPs are stated in Article 27, which is titled Patentable Subject Matter. Article 27 is divided into three main parts: Article 27.1 establishes the patent requirements and the scope of patent protection; Article 27.2 refers to the morality clause; and Article 27.3 sets up a list of inventions that might be excluded from patentability, despite the fact that they fulfil the requirements of Article 27.1.

Article 27.1 states that any invention should enjoy patent protection in all members of the WTO, regardless of the place and category of an invention. It also establishes that a patent can be granted if an invention fulfils the requirements of novelty, inventive step and industrial application, and is not excluded from patentability (e.g. for being immoral or an excluded category). Although the scope of these requirements is usually established by statute in each country, taking into account different grounds (economic, ethical[[557]](#footnote-558) or social value[[558]](#footnote-559)), TRIPs identifies the minimum standards that member states of the WTO should meet, as well as what category of inventions might be excluded from patentability (Article 27.3).

Articles 27.2 and 27.3 were the result of intensive negotiations during the process of negotiations of TRIPs in which the tension can be observed between the countries that supported either wide or narrow exclusions. At the end, developed countries in the Uruguay Round (1986-1994) of negotiations accomplished two important goals. First, they managed to remove most of the exclusions proposed by developing countries and some European countries. For instance, the 1990 Brussels draft mentioned that it was up to Members of the WTO to decide whether or not patents on biotechnology, pharmaceutical and chemical inventions were patentable subject matters.[[559]](#footnote-560) Second, Article 27 states that an invention could not be excluded on the grounds of its category of technology. This also illustrates that originators succeeded in removing any exclusion which refers directly to its inventions after intensive lobbying in the negotiation rounds of TRIPs.[[560]](#footnote-561)

However, it is important to mention that Articles 27.2 and 27.3 do not permit exclusions *per se*, but set up limits on the scope of exclusions. For instance, Article 27.3 (b) permits the exclusion of plants and animals but does not exclude all the biotechnological inventions. Similarly, Article 27.2 allows countries to exclude inventions on stated grounds. Article 27.2 also stipulates that if the commercial exploitation of an invention acts against *ordre public* or morality, the patent could be excluded from patentability. The article further provides examples which might be considered to be acting against *ordre public* and morality, such as inventions which threaten human life, health and the environment. However, the scope and meaning of *ordre public* and morality has brought some controversy, since these two concepts need a highly elaborated conceptualisation.

The concept of *ordre public* comes from continental law and does not have an exact translation into English. *Ordre public* might be understood as public policy in common law. However, public policy might refer more to public safety, whereas for continental law traditions, *ordre public* is a condition that society imposes on citizens to recognise rights and obligations.[[561]](#footnote-562) There are not only problems in the concept of *ordre public* and morality, but also in the way to assess them. For instance, the EPO has been criticised for applying different standards to assess morality that have created extreme confusion about how to apply this provision within Europe.[[562]](#footnote-563) Although TRIPs limits the exclusions, member states of WTO are entitled to interpret Article 27 in any way that enables them to protect their own interests. In the case of technologies that employ genetic resources, developing countries rich in biodiversity have employed these exclusions in order to rule out or limit patents on genetic resources.

This two-dimensional approach of TRIPs indicates that patents in these technologies have not met originators’ expectations of setting up a standard for patents in an international legislation. Although developed countries have taken a bargaining position by linking IPRs and trade, developing countries rich in biodiversity can still manoeuvre to exclude inventions that might affect their interests by implementing Articles 27.2 and 27.3 according to their own capacity. However, before any conclusion can be drawn, it is necessary to analyse how developed countries have adapted and standardised their patent legislation to secure patent protection on genetic resources. Naturally, it is also important to study the different mechanisms and interpretations that developing countries rich in biodiversity have employed to reduce or exclude patent protection on genetic resources.

# Patents and Genetic Resources

As explained in the introduction of this chapter, Locke provides an analytical framework in which the intellectual labour that adds value to genetic resources is rewarded via patent exclusivity. This is particularly reflected in the academic scholarships of Merges[[563]](#footnote-564) and Mossoff[[564]](#footnote-565) who recognised the importance of Locke’s labour theory in justifying patents on intangibles. This particularly agrees with developed countries’ approach to technologies that employ genetic resources.[[565]](#footnote-566) Indeed, developed countries have created a legal fiction to remove problems with property rights in natural occurring genetic resources. From the developed countries’ perspective patents on genetic resources are allowed as long as there is something that makes them different from genetic resources *in situ*.

Evidently, this perspective not only comes from the fact that usually developed countries do not host most of world’s biodiversity, but also from the fact that they hold the technology that could make genetic resources different from genetic resources *in situ* by adding value to what is in nature (or the commons). Nevertheless, this does not necessarily apply to developing countries, particularly those rich in biodiversity, since they view such a division as mechanisms to create monopolies on natural genetic resources without receiving any benefits (e.g. transfer of technology) from the exploitation of those resources (biopiracy).[[566]](#footnote-567) In fact, as pointed out in the introduction of this thesis, there is a difficulty in applying Locke’s labour theory (including his proviso) to genetic resources *in situ* since sovereignty ownership control on those genetic resources does not fit into an intellectual labour that adds value.[[567]](#footnote-568) Sovereignty ownership on genetic resources is rather, as also explained in the introduction of this thesis, a way in which developing countries rich in biodiversity are entitled to control access to genetic resources.[[568]](#footnote-569) Such an ownership control has emerged as a result of an international bargain, i.e. the ABS Regime in which developing countries rich in biodiversity seek to obtain benefit sharing from the utilization of genetic resources. As a result, developing countries rich in biodiversity have employed a twofold strategy in two different forums.[[569]](#footnote-570) Regarding patents on genetic resources, developing countries rich in biodiversity have used the flexibilities and exclusions of Article 27 of TRIPs to remove or reduce the scope of these from being patentable subject matter. Regarding the aspects of sovereignty control on genetic resources, developing countries have set up limits on the accessing of genetic resources located in their own soil. This last aspect is studied in more detail in Chapter 4.

However, the interpretation of TRIPs by developing countries rich in biodiversity could be against Article 27 which states that Member States of the WTO should grant patents to any field of technology. Indeed, as explained above, Article 27 and 27.3 (b) in particular, set up limits to avoid exclusion on technologies *per se*.[[570]](#footnote-571) As a result, it is important to analyse three aspects: (1) the way in which developed countries have interpreted their legislation to adopt patents on genetic resources; (2) whether developing countries rich in biodiversity’s interpretations fall within the meaning of Article 27; and (3) whether such an interpretation has effectively entitled developing countries rich in biodiversity to trade off access to genetic resources with access to technology in order to increase capacity.

* 1. **Patentable Subject Matter**

Article 27 includes both patent requirements and patent exclusions as a part of what can be considered to be an invention, but it does not actually establish a definition of invention. Therefore, the same product or process could be interpreted in two opposite ways. For example, with regard to the particular interest of this chapter, developed countries deem that genetic resources are patentable subject matter, whereas developing countries rich in biodiversity have a restrictive view on whether or not those resources are inventions. In this sense, developed countries and developing countries rich in biodiversity have clashed over whether genetic resources are inventions.

* 1. **Inventions and Discoveries**

While patent legislation in both developing countries rich in biodiversity and developed countries does not have a clear definition of invention, these countries do mention what cannot be considered to be an invention.[[571]](#footnote-572) In that sense, most regional and national patent legislation considers that discoveries are not inventions. For instance, Article 52 (a) of the European Patent Convention, Article 5.1 of the Directive 94/44/EC on the Legal Protection of Biotechnological Inventions (Biotech Directive),[[572]](#footnote-573) Article 15 (a) of Decision 486 of the ACN and Section 1 (2) (a) of the UK Patent Act[[573]](#footnote-574) all mention that discoveries are not inventions. [[574]](#footnote-575)

It is important to discuss the difference between discovery and invention since natural occurring genetic resources are considered as mere discoveries by both developed countries and developing countries rich in biodiversity. Indeed, discovery of a naturally occurring phenomenon is something that does not represent any intellectual labour that adds value to what is in nature, unless an inventor made an invention based upon genetic resources different from the naturally occurring one. For instance, Article 3.2 of the Biotech Directive states that ‘biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature’. Article 5.2 of the Biotech Directive also establishes that ‘an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute patentable inventions’. In other words, the Biootech Directive establishes that although an invention based upon genetic resources could be identical to the naturally occurring one, it is patentable if there is a technical process involved.[[575]](#footnote-576) On the other hand, developing countries rich in biodiversity do not usually consider that a mere technical intervention could make genetic resources patentable; hence both might be discoveries. In order to understand this discussion, both points of view are explained.

* 1. **Early Developments**

Before biotechnology emerged as a technology that employs genetic resources, courts and patent offices in developed countries had already adapted patent legislation to technologies that employ natural resources through chemical means. The problem that they faced was whether chemically purified (extracted) natural resources were different from their natural version. Early developments on this issue were characterised by two main trends: (1) extracted natural resources had to demonstrate different characteristics that made them different from the natural product; and/or (2) the extracted natural product had to have a significant value that made it different from the naturally occurring one.[[576]](#footnote-577)

In *American Wood-Paper Co. v. Fibre Disintegrating Co.,* [[577]](#footnote-578)the US Supreme Court had to decide whether a pulp for the production of paper extracted from wood by chemical means was a discovery. Justice Strong dismissed the possibility of granting patent protection over the chemically extracted or purified natural products by arguing that ‘the extract is the same, no matter from what it has been taken.’[[578]](#footnote-579) He added that the natural product itself, ‘when obtained [or purified] cannot be called an invention’.[[579]](#footnote-580) What is even more relevant for the current analysis is that Justice Strong, citing the UK case *Young v. Fernie*,[[580]](#footnote-581) found that the product resulting from the purification of chemicals from natural products was no different from the existing natural product; for Justice Strong the claim was nothing more than a discovery.[[581]](#footnote-582) However, a detailed interpretation of the Supreme Court ruling led to the conclusion that a patent for natural resources could be granted as long as it is proved that the characteristics of the purified product are considerably different from the original source. In other words, the Supreme Court did not rule out the patent on natural resources but set up a technical bar in which purified natural resources needed to prove that they were different from the natural version.

Years later, the Circuit Court of New York in *Parke-Davis & Co. v. H.K. Mulford,*[[582]](#footnote-583) recognised patent protection on a chemical substance purified and isolated from a living organism as an invention (i.e. adrenalin). Such a statement might lead to the conclusion that this contradicts *American Wood-Paper Co. v. Fibre Disintegrating Co.* as the Circuit Court argued that the isolated and purified natural product was distinctive ‘not in degree, but in kind’ and ‘even if it were merely an extracted product without change, there is no rule that such products are not patentable’. In other words, the court extends patent protection to products that were merely extracted. However, Harkness considers that the decision in *Parke-Davis* misunderstood *American Wood-Paper Co. v. Fibre Disintegrating Co.* since the chemical substance (adrenalin) ‘was something other than a purified version of the naturally occurring hormone’. [[583]](#footnote-584) Nevertheless, Harkness does not give any credit to what *Paper Co. v. Fibre Disintegrating Co.* actually contributes to the interpretation of *American Wood-Paper Co. v. Fibre Disintegrating Co.*, i.e. that the former helps to understand what could be the bar set up by the latter. Indeed, the Circuit Court did not only recognise the patent on an isolated chemical product derivate from a living organism, but also the fact that the inventor ‘was the first to make it available for any use by removing’ from a naturally occurring organism. The term ‘use’ in *Paper Co. v. Fibre Disintegrating*  refers to ‘every practical purpose of a new thing commercially and therapeutically’.[[584]](#footnote-585)

This indicates that the inventor did not only have to prove that the naturally based product was isolated but also to demonstrate a therapeutic or commercial value.[[585]](#footnote-586) Similarly, it was also possible to demonstrate a significant value when a natural resource (Vitamin B2) was identified and isolated for the first time.[[586]](#footnote-587)

Nevertheless, developing countries took a different approach. Instead of creating a division between non-patentable natural resources as such and patentable natural resources, developing countries did not consider inventions from technologies that employ natural resources to be patentable subject matter. For instance, Article 9 (b) and (c) of the 1971 Brazilian Patent Act[[587]](#footnote-588) and Section 5 of the Indian Patent Act 1971 excluded purified natural resources from patentability. Certainly, these measures were not restricted by the international patent framework at that time (Paris Convention).[[588]](#footnote-589) This reflected what developing countries were concerned about at that time: protecting local industry and securing the transfer of technology, rather than ownership control over genetic resources.[[589]](#footnote-590)

However, developing countries’, and particularly those rich in biodiversity, perspectives changed because of two important facts: firstly, the boom of biotechnology in the 1980s, as this new technology was aiming to enhance the functional value of genetic resources through patents;[[590]](#footnote-591) and secondly, developing countries rich in biodiversity could not exclude inventions on the grounds of the technological field, as established by Article 27 of TRIPs.[[591]](#footnote-592) Even though developed countries did not adapt immediately to patents on genetic resources, they were more prepared as scientific developments had already occurred in their countries and they had also granted patents on natural products. For instance, it took 10 years for the EU to pass the Biotech Directive. Although the aim of the European Commission was only to clarify how to grant patents on biotechnological inventions rather than making substantive changes to local patent legislations, the Commission faced different challenges that impeded them from passing a directive any faster.[[592]](#footnote-593)

However, despite the fact that the application of Article 27 of TRIPs in developing countries’ legislations led those countries to abolish any mention of factors that would discriminate against technologies, developing countries, particularly those rich in biodiversity, have employed new mechanisms to limit technologies that employ genetic resources from patentability.

* 1. **Patents on Genetic Resources**

Developed countries have been willing to provide similar protection to genetic resources copied from naturally occurring resources if them are significantly different from the natural product and also have a significant value.

In *Diamond v. Chakrabarty*, [[593]](#footnote-594) the Supreme Court decision was the affirmation of what courts and the USPTO had affirmed before over chemicals extracted from natural products. The case referred to a patent application regarding a microorganism derived from the *Pseudomonos* genus bacteria that was modified by using molecular technology. Although the Supreme Court used the (in)famous expression that anything ‘under the sun’ can be patentable, the core of the decision was that an invention could attract a patent if it could be proved that the invention has ‘markedly different’ characteristics from its natural version.

In the case of DNA sequences, Justice Lourie in *Amgen, Inc v. Chugai Pharmaceutical Co., Ltd*, [[594]](#footnote-595) concluded that a claim on a DNA sequence could be granted a patent if the patent applicant could distinguish an isolated DNA from the natural version of the DNA sequences. The claim referred to an isolated and purified protein (Erythropoietin), which ‘stimulate[s] the production of red blood cells’.[[595]](#footnote-596) Justice Lourie also stated that DNA sequences are ‘chemical compound[s]’.[[596]](#footnote-597) By considering isolated and purified genetic resources as chemicals, Justice Lourie opened the path to follow what had been established not only in *Diamond v. Chakrabarty*, but also in previous rulings regarding purified chemicals: once natural resources have been made different from the natural version, they could be considered to be patentable.[[597]](#footnote-598)

Indeed, as has occurred with natural resources, developed countries have also interpreted their patent law in such a way that genetic resources should not only be ‘markedly different’, but also have a significant value. For example, the EPO in *Relaxin* [[598]](#footnote-599) deemed that isolated sequences of DNA were chemicals in order to consider them as an invention. The patent was based on the isolated DNA sequence of H2-prepro Relaxin, a protein that helps to reduce the need for Caesarean section deliveries. The Opposition Division (OP) of the EPO pointed out that a DNA sequence is not a living organism but: ‘a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be **medically useful**’ (emphasis added).[[599]](#footnote-600) The significance of this is that the EPO recognised the commercial and therapeutic value of isolated DNA sequences that could be artificially mass produced. It was the first time that such a sequence was available outside the body, regardless of whether the isolated DNA sequence was similar to the naturally occurring one or not. The *Relaxin* and its medical usefulness would not have been available and been understood to humankind if it had not been isolated.

However, the problem of identifying the commercial or therapeutic value of a DNA sequence is also contested. For instance, in the 2002 Nuffield Council Report in the UK, the Council considers that patents on DNA sequences should be ‘the exception rather the norm’.[[600]](#footnote-601) The Council divides the use of DNA sequences in order to define which type of use should obtain a patent. However, this division has been criticised as it is considered that it creates a new set of superficial and unjustified patent rules for biotechnology and establishes a new business practice. [[601]](#footnote-602)

For instance, for the Council, patents on DNA sequences which are employed as research tools, should be discouraged by making the requirement of industrial applicability stringent.[[602]](#footnote-603) The Council defines research tools as gene sequences that are used in research but do not have a therapeutic or diagnostic value.[[603]](#footnote-604) Since these gene sequences do not have an actual therapeutic or diagnostic value, the Council considers that they do not fulfil the requirements of utility or industrial application. The Gowers Review of Intellectual Property in the UK also highlights the importance of not extending patents on genes beyond current limits unless there is evidence that they could actually incentivise innovation.[[604]](#footnote-605) For authors such as Warren-Jones, patents on DNA sequences, in particular research tools, should be granted as they are fundamental to the process of innovation (or the ‘chain of innovation’).[[605]](#footnote-606) Not granting patents on research tools could eventually affect the commercialisation of final products or processes; hence society has the most to lose.[[606]](#footnote-607) Although this discussion analyses whether patents on genetic resources will deliver further research and innovation, it also provides valuable information on how to adapt patent legislation to genetic resources.[[607]](#footnote-608)

Indeed, developed countries’ patent policy is not static, but evolves to try to find a balance between encouraging patent holders to keep delivering further R&D, and secure the flow of information and technology via disclosure. This was an important element that in 2013 the US Supreme Court of Justice faced when it decided whether isolated DNA genes and “synthetically created DNA” or complementary DNA (cDNA) were patent subject matter. [[608]](#footnote-609) cDNA is created and only contain exons, rather than both exons and introns as a DNA sequences does.[[609]](#footnote-610) The US Supreme Court of Justice invalidated patents on isolated BRCA1 and BRCA2 (i.e. DNA sequences employed to determine whether or not a woman is vulnerable to breast cancer) on the grounds that the patent holder ‘did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes’ but rather its contribution was to uncover ‘the precise location and genetic sequence’ of the BRCA1 and BRCA2 genes. This means that an isolated gene did not represent anything particularly different from the naturally occurring ones; yet, the Supreme Court of Justice maintains patents on the cDNA version of BRCA1 and BRCA2 since the creation of a cDNA is the result of genetic engineering techniques ‘not naturally occurring’.[[610]](#footnote-611) However, this decision does not mean that the Supreme Court will not recognise further patents on genetic resources. This decision demands that stakeholders deliver further R&D in technologies that employ genetic resources in order to grant patent protection, as well as allowing access to already existing scientific techniques (e.g. gene sequencing) without infringing patents on specific genes.[[611]](#footnote-612)

Despite the evolving nature of patents on genetic resources, developed countries still consider it to be important to provide patent protection on genetic resources. Cooperative agreements between patent offices in developed countries prove not only the importance of developed countries promoting patent protection on genetic resources, but also encourage further standardisation in this field. Since 1983 the USPTO, EPO and Japanese Patent Office (JPO) have worked together to harmonise patent practices and exchanges of information through the Trilateral Co-operation Project.[[612]](#footnote-613) For instance, in 1988 the project issued a statement which stated that natural resources which have been purified by chemical means are inventions rather than discoveries.[[613]](#footnote-614) The Trilateral Co-operative Project has also issued an important number of guidelines and reports regarding common patent practices in genetic resources.[[614]](#footnote-615)

Drahos finds that this cooperative project has provided an important platform for the developed countries, not only to secure standardisation and favourable common patent practices within patent offices in developed countries, but also to developing countries.[[615]](#footnote-616) For instance, Drahos mentions that different agreements, for example, between the EPO and patent offices from Mexico and Malaysia, have been signed, in which the EPO provides technical assistance to make developing countries adopt developed countries’ perspectives on pharmaceutical inventions. However, this approach does not necessarily observe countries’ capacity to add value to what is in nature or the commons.[[616]](#footnote-617) That is why it is important to assess developing countries rich in biodiversity’s capacity as they implement TRIPs and TRIPs-Plus standards.

As a consequence, it has been suggested that developing countries rich in biodiversity should explore discussions, such as the one carried out by the Nuffield Council, as they could employ similar elements to increase capacity. For instance, Correa and Dutfield consider that developing countries could take greater advantage of high standards in the requirements of novelty, inventive steps and industrial applicability without breaching TRIPs.[[617]](#footnote-618) Similarly, the Commission on IPRs has encouraged these countries to set up high minimum standards in granting patents over genetic resources.[[618]](#footnote-619) Also multilateral organisations such as the UNCTAD point out that ‘IPRs should be geared to the technological capacities of the [developing] country in question to the extent that the policy space under the TRIPS Agreement allows in order to maximize incentives to invent’.[[619]](#footnote-620) Similarly, a trilateral report carried out by the WHO, WIPO and WTO has highlighted the importance of providing capacity building resources for policy makers, including a better understanding of patent flexibilities to meet developing countries’ demand for medicines at affordable prices.[[620]](#footnote-621) This illustrates how these countries could also adapt their legislation according to their capacity without banning patents over genetic resources *per se*.

Indeed, developing countries rich in biodiversity have enacted restrictive patent legislations that either limit or exclude genetic resources from patentable subject matter, regardless of any technical intervention or significant value, with the aim of gaining access to technologies. For instance, Decision 486 of the ANC does not give patent protection to ‘any living thing’ partial or complete, even if it is isolated, including ‘the genome or germ plasma’.[[621]](#footnote-622) Similarly, Brazil in Article 9(ix) of the Brazilian Industrial Property Act, does not recognise patents over living things, including partially or totally isolated genomes or germ plasma. Yet, Brazil grants patent protection to microorganisms (Article 18(ii)). However, the wording of Decision 486, and the Brazilian Industrial Property Act, is not far from the US Supreme Court’s decision on BRCA1 and BRCA2, as this ruling precisely establishes that genes that have only been isolated cannot be subject to patent protection.

Nonetheless, this issue remains conflictive in TRIPs. The African Group of the WTO has proposed (based on Paragraphs 17 to 19 of the Doha Ministerial Declaration) to re-examine the exclusion of Article 27.3 (b) (this article establishes that countries could exclude from patentability living organisms such as plants and animals)[[622]](#footnote-623) and prohibit any patent over living organisms, including microorganisms, as a means to protect biodiversity from misappropriation by companies located in developed countries.[[623]](#footnote-624) As expected, developed countries have refused to review Article 27.3 (b). The EU rejected this idea in 2004 as it claimed that this article gives enough ‘flexibility to modulate patent protection as a function of their needs, interests or ethical standards’.[[624]](#footnote-625) In other, words the EU is proposing that developing countries rich in biodiversity should adapt their patent legislation on genetic resources according to their capacity to deliver technologies that employ genetic resources for drug development. For instance, developing countries could eventually narrow down the scope of patents by raising the technical bar in the requirements of patents rather than excluding *per se* genetic resources from patentability.[[625]](#footnote-626)

Nevertheless, this discussion also brings up ethical considerations that can play against biotechnology and justification might be found in Article 27.2 of TRIPs. Developing countries rich in biodiversity might find, in this article, sufficient grounds to exclude genetic resources from patentability. For instance, the Andean Tribunal of Justice (ATJ) (the judicial body of the ACN) in an opinion regarding the scope of Decision 486 on biotechnological inventions, mentions that a patent on a human DNA sequence used for the production of pharmaceutical products derived from bile, although isolated and purified, was not allowed in the ACN for ethical reasons.[[626]](#footnote-627) Moreover, the ATJ does not give further reasons or explain the scope of what could be considered an unethical invention, which means that other biotechnological inventions could also be excluded from patentability. As has happened in Europe, developing countries rich in biodiversity could eventually face a very difficult task in interpreting the scope of and imposing boundaries to Article 27.2 of TRIPs.[[627]](#footnote-628)

Developing countries rich in biodiversity have also restricted patents through the ‘disclosure of origin’ requirement. During the process of granting a patent, it is usually required that the applicant describes his invention, so an ordinarily skilled person can replicate it. In order to do so, the patent holder has to disclose information relevant to the invention. Developing countries rich in biodiversity have added an extra requirement within the disclosure. Legislation in countries such as Colombia demands that whoever uses genetic resources should disclose all information related to the origin of the genetic resources and demonstrates that such information was extracted following the legislation on access to genetic resources and benefit sharing. In this way, developing countries rich in biodiversity aim to link patent requirements with the regulation of access to genetic resources and benefit sharing of the ABS regime. Although some developed countries have similar dispositions, failing to meet these requirements does not affect the grant of a patent on genetic resources. For example, Recital 27 of the Biotech Directive states that ‘the patent application should, where appropriate, include information on the geographical origin of such material, if known’, but this requirement should not be contrary to ‘the processing of patent applications or the validity of rights arising from granted patents’.

Since disclosure of origin has been considered in the Conference of Parties of the CBD,[[628]](#footnote-629) this issue has triggered disagreements within the Council for TRIPs and WIPO, particularly because developed countries have been emphatically opposed to any inclusion of extra requirements in patent protection that could weaken patent holders’ rights. Authors such as Straus have given opinions on how to unlock the stalemate on this issue based on a national approach in which it is up to each country to adopt the disclosure of origin according to their capacity.[[629]](#footnote-630) There are also other voices such as those of Correa and De Carvalho that argue that disclosure of origin is indeed a mechanism not only to create a bridge between TRIPs and the ABS regime, but also a way to improve credibility and trust between developing countries rich in biodiversity and patent holders.[[630]](#footnote-631) However, disclosure of origin has not been an effective mechanism and represents a burden not only for patent holders but also developing countries rich in biodiversity as these countries’ patent offices need to cross-examine an extra requirement in patent protection and ABS. Chapters 4 and 5 identify that disclosure of origin has created more difficulties to ensure that patent holders comply with ABS requirements rather than being an effective mechanism in which developing countries rich in biodiversity actually trade off genetic resources for access to technology.

To sum up, the question of whether or not to provide patent protection to genetic resources has resulted in a twofold discussion. First, developed countries have created a legal framework that protects technologies that employ genetic resources for drug production. The aim is to ensure originators are able to enter new markets by providing exclusivity on the technologies that employ genetic resources ahead of local producers. Article 27 of TRIPs seeks to encourage this perspective by providing patent protection to any field of technology.

However, the exclusions and extra requirements made by developing countries rich in biodiversity illustrate that these countries do not perceive that patents could lead them to increase capacity; instead, they find that patents on genetic resources incentivise biopiracy.[[631]](#footnote-632) Murphy finds that these countries not only fear that biopiracy will affect their sovereignty ownership control over genetic resources, but also that even if they provide patents on genetic resources they will not be able to have access to technology since they could not afford the licences involved in those patents, hence, it is better for them to exclude or limit patents for them.[[632]](#footnote-633) As a result, these countries aim to amplify mechanisms that restrict patents over genetic resources.[[633]](#footnote-634)

Despite the fact that there are decisions made in cases such as BRCA1 and BRCA2, which narrow down the scope of patents on genetic resources, developed countries will not give up granting patents on genetic resources as a mechanism to encourage the intellectual labour that adds value to genetic resources. A recent report that evaluates IPRs insensitive to biotechnology in more than 50 different countries mentions that developed countries such as the US, Denmark and UK will increase their patent activity in biotechnology; whereas developing countries such as India and Brazil had low patent activity.[[634]](#footnote-635) Furthermore, as discussed in subsection 1.3, developed countries, particularly the US, have maintained the policy of employing the trade-IPRs approach to demand patent protection on genetic resources in developing countries rich in biodiversity’s patent legislation via TRIPs-Plus provisions, as these mechanisms aim to restrict the latter’s ability to employ TRIPs flexibilities.

As a consequence, developing countries rich in biodiversity should adopt a more pragmatic and discriminatory approach that increases capacity. Therefore, it is important that these countries assess their own capacity as they implement or interpret patent provisions. In the case of Colombia, which is a member of ACN, it should embrace more patents on genetic resources in order to encourage its pharmaceutical industry to take a more active role in the first stages of the drug development process. This is particularly important as Colombia is setting up higher levels of exclusivity in IPRs via TRIPs-Plus provisions which are forcing Colombian pharmaceutical generic companies to comply with developed countries’ competitors’ patents.

TRIPs-Plus has led Colombia to amplified protection on pharmaceutical inventions, including data exclusivity and linkage between patent status and the MA, as well as restricting the use of compulsory licensing. As a result, Colombia is obliged to give patent protection to originators but restricts patents on genetic resources which could benefit Colombia’s pharmaceutical industry, particularly small labs and publicly funded research institutes. In other words, Colombia does not effectively trade off access to genetic resources for access to technology because it lacks a clear policy towards the implementation of TRIPs and the ABS regime. Furthermore, recent developments in the ABS, and the way that developing countries rich in biodiversity perceive TRIPs, indicate that developing countries rich in biodiversity will keep restricting patents on genetic resources from patent eligibility and limiting access to genetic resources located in developing countries rich in biodiversity. Chapter 4 explains in more detail this second aspect, whereas Chapter 5 contextualises the analysis and conclusions of Chapter 3 (i.e. TRIPs and TRIPs-Plus) and Chapter 4 (the ABS regulation) in Colombia.

**Conclusions**

Although there were commercial interests of the chemical industry and originators to create international standards that protected their inventions ahead of local producers in the Paris Convention, this international instrument rewarded the intellectual labour that adds value. Furthermore, there were loopholes in the Paris Convention which allowed developing countries to employ flexibilities, such as limiting the scope of patent protection to some technologies (e.g. chemistry and pharmaceutical), compulsory licensing and working requirements, in order to increase capacity in drug development. For instance, India employed those flexibilities to transform its pharmaceutical industry into an important stakeholder in the global market. As a result, this chapter points out that Locke’s labour theory provides grounds to justify the Paris Convention scope, i.e. it recognises the intellectual labour that adds value as well as allowing countries to employ flexibilities (e.g. compulsory licensing) to implement the Paris Convention according to their own capacity.

However, as the US linked international trade with IPRs in the WTO, Locke’s analysis fall short of giving enough ground to justify IPRs because TRIPs, and eventually TRIPs-Plus, did not necessarily aim to reward the intellectual labour but they rather represent how developed countries bargain access to trade for access to technology with developing countries, including those rich in biodiversity. Therefore, this could undermine countries’ capacity as they implement higher standards of exclusivity protection without taking into account their own necessities.

As a result, the analysis of Locke’s labour is studied along that of Rawls. In Rawls’ social contract theory, there could be inequalities. However, Rawls points that although there might be inequalities, they can be solved through agreement. This means that in Rawls’ theory it is possible to justify flexibilities on IPRs and ownership on genetic resources as a result of a ‘fair agreement’ between developed countries and developing countries rich in biodiversity. Rawls also points out that participants in the initial bargaining position are equal as they are under a veil of ignorance. However, it is difficult to find that in relationships between countries, participants are equal. This is because there are developed countries which could strengthen their economic and political power by validating their interests against those of developing countries. That is why Nussbaum’s capability approach complements this analysis because it points out that in international agreements countries are not equal, but have different capacities. Therefore, by employing the capability approach, it is possible to assess countries’ capacity, which serves to establish what they want and are capable of.

Following this analysis, TRIPs has trigged inequalities because developing countries, including those rich in biodiversity, agreed to implement higher standards of patent protection as a way to access international trade rather than increasing capacity. Therefore, the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health sought to fix this by enabling countries to implement flexibilities that reduce the negative effects of TRIPs. This has allowed countries such as India, China and even LDCs to increase capacity, and shape the global market. The global market is reflected in developed countries employing exclusivity mechanisms of protection, especially patents, to encourage originators to invest in further R&D on genetic resources, while India and China, which have transformed from illegal generics to generic producers, are promoting and taking over generic production globally, and potentially bringing new medicines into the market, especially China. However, China and India limit access to genetic resources, so they can trade off access to genetic resources with access to technology via disclosure of origin in patents and the ABS regulation. In the meantime, LDCs aim to fill the gap for illegal generics as they can delay implementation of TRIPs patent protection on pharmaceutical products up to 2016 because of its lack of capacity. However, Colombia has continued to bargain access to technology for trading with developed countries, as they have implemented higher standards of patent protection via TRIPs-Plus which limits the use of compulsory licensing and creates new mechanisms of exclusivity protection.

That is why it is important to pay special attention to the substantive standards since developing countries rich in biodiversity such as Colombia have already compromised with higher standards of patent protection with TRIPs-Plus. Therefore, developing countries rich in biodiversity should implement and interpret substantive standards in line with countries’ capacity.

As observed in Chapter 2 and this chapter, Colombia’s pharmaceutical capacity dwells in manufacturing generics or originators’ medicines under licensing agreements, and the availability to provide genetic resources for drug development. Yet, the higher standards that come from TRIPs-Plus go against Colombian generic companies’ access to technology. Furthermore, Colombia has a restrictive approach to the patenting of genetic resources as it limits patent protection on these resources by creating higher standards and implementing disclosure of origin. As a result, developing countries rich in biodiversity, in particular Colombia, should consider a tailored policy as they implement and employ TRIPs substantive standards on patents on genetic resources in order to increase capacity. This means that Colombia should consider patent protection on genetic resources in more comprehensive way since this country already grants not only patent protection to pharmaceutical inventions but also data exclusivity, which benefits originators. As observed in the next chapter, the ABS regime grants property rights on genetic resources to developing countries rich in biodiversity in order to entitle these countries to obtain benefit sharing from the utilization of genetic resources. By restricting patents on genetic resources, Colombia undermines the efforts of local users of genetic resources (e.g. publicly funded institutions) to obtain patents on intangibles in order to trade off those resources for technology. In the case of extra requirements on patents, such as disclosure of origin, developing countries rich in biodiversity should also reconsider whether or not this mechanism facilitates access to technology by creating a link between patent legislation and access to genetic resources; otherwise, these countries will reject gaining access to technologies that could add value to their own genetic resources and, hence, increase capacity in technologies that employ genetic resources for drug development. The next chapter analyses whether the ABS regime provides mechanisms for developing countries to effectively obtain benefits from the utilization of genetic resources in order to increase capacity.

Chapter 4: Looking Beyond Access: Capacity and Benefit-Sharing

**Introduction**

Chapters 1 and 2 analyse the capacity of developing countries rich in biodiversity in technologies that employ genetic resources for drug development, particularly in India, China and Colombia. Both chapters identify that although India and China are rich in biodiversity, these two countries have not been successful in obtaining benefit sharing from the utilisation of genetic resources in order to increase capacity in their pharmaceutical industry. However, China has recently delivered a policy to boost innovation on technologies that employ genetic resources, especially biotechnology and traditional Chinese medicine. [[635]](#footnote-636) Chapter 2 also identifies that despite Colombia’s availability of genetic resources and the fact that authorities have pointed out that the utilization of genetic resources is an important element for the Colombian pharmaceutical industry, there has been a lack of capacity to develop a pharmaceutical industry able to compete even with countries such as India and China in terms of market size, exports and expenditure on genetic resources.[[636]](#footnote-637) Instead, Colombia has rather focused on manufacturing and distributing generic medicines.

As a result, there has been a shift in the global pharmaceutical market in which developed countries have created legal mechanisms of exclusivity, such as patents, to promote and encourage originators to carry out R&D for drug development. India and China, which used to be production centres of illegal generics, have adapted to comply with TRIPs; this has led these two countries to increase their global share in generic medicines. However, India is not delivering policies and legislation to become a more innovative country, instead it has protected its generic industry and aimed to keep expanding to other markets, including developed countries. China, on the other hand, has paid particular attention to its biotechnology industry and Chinese traditional medicines to encourage a more innovative country; this has led China to increase the number of patents locally and globally. In the meantime, LDCs, with low or no capacity, aim to fill the market gap left by other countries such as India and China as TRIPs grants them a transition period of time to implement TRIPs and even to issue compulsory licences for import. Finally, Colombia, a biodiversity rich country, has adopted TRIPs-Plus standards, which has led this country to provide stronger exclusivity protection to originators than those granted by TRIPs. As a result, the pharmaceutical industry in Colombia primarily produces and distributes generics or originators under licensing agreements, but has not improved R&D on technologies that employ genetic resources for drug development.

Therefore, Chapter 3 analyses that the global market shift has been reflected in the negotiations and implementation of TRIPs, Doha and TRIPs-Plus provisions. However, this legal framework has not focused on improving the capacity in developing countries for drug development. Rather, it has centred on discussing whether to protect originators’ inventions in developing countries markets and access to international trade.

As a result, Chapter 3 points out that TRIPs and TRIPs-Plus provisions do not necessarily seek to incentivise the intellectual labour that adds value to genetic resources (i.e. capacity), but they are rather the result of bargaining access to markets for access to technology. This means that although the interpretation of Locke’s theory on intellectual property rights justifies the existence of patents on genetic resources and creates limits to those exclusivity rights, the linkage between international trade and IPRs in TRIPs and TRIPs-Plus have led developing countries, including those rich in biodiversity, to expand exclusivity rights on pharmaceutical products as a bargain for access to markets rather than as a mechanism to increase capacity.

However, Rawls’ social contract theory provides a framework in which it is possible to justify flexibilities and limits to IPRs since developing countries, including those rich in biodiversity, could address the inequalities (lack of capacity or access to technology) that emerge from TRIPs and TRIPs-Plus provisions. This is particularly reflected in the Doha Ministerial and the Doha Declaration on the TRIPs Agreement and Public Health Declaration, which have entitled countries to use flexibilities (e.g. compulsory licensing) in order to reduce the negative effects of TRIPs. Nonetheless, Chapter 3 also concludes that the use of those flexibilities should be employed according to countries’ capacity. This means that distributive measures that emerge from Rawls cannot be interpreted in strictly equal terms to all parts involved in the contract (i.e. TRIPs and Doha), but they should respond to countries’ capacity in order to entitle developing countries rich in biodiversity, to determine what they are capable of in technologies that employ genetic resources for drug development (i.e. the capability approach).

Chapter 4 assesses to what extent the regulation on access to genetic resources and benefit sharing of the CBD has served the interests of developing countries rich in biodiversity, in accessing technologies that employ genetic resources in order to increase their capacity for drug development. Therefore, Chapter 4 also employs Rawls’ social contract theory and the capability approach in the ABS regime. The reason why Chapter 4 focuses primarily on Rawls social contract theory and the capability approach is because Locke’s labour theory falls short of explaining why developing countries rich in biodiversity are entitled to claim ownership control on genetic resources as they do not carry out any intellectual labour that adds value.[[637]](#footnote-638) Instead, the distributive nature of Rawls’ social contract theory and the capability approach provides a better understanding of the dynamics between developed and developing countries rich in biodiversity in the bargain process that has resulted in the ABS regime. Such a bargain grants ownership control on genetic resources to developing countries rich in biodiversity, despite the fact that they do not carry out any intellectual labour on genetic resources. This is despite the fact that the ABS regime was intended to be about conservation of biodiversity and the sustainable use of its components.[[638]](#footnote-639) As a result, the ABS regime entitles developing countries rich in biodiversity to trade off access to genetic resources for access to technology in order to counterbalance the lack of technology in developing countries rich in biodiversity. In this way, the ABS regime aims to encourage developing countries rich in biodiversity in protecting that biodiversity by providing them with control over access to genetic resources in order to secure benefit sharing from the exploitation of genetic resources, particularly the transfer of technology.

The CBD is the international instrument upon which the ABS is based. In addition, there are two further international instruments that have clarified the content of the CBD: the Bonn Guidelines and the NP.[[639]](#footnote-640) These two legal instruments do not derogate or amend the CBD; instead both clarify the CBD’s wording. The Bonn Guidelines, however, is not a legally binding instrument but rather is an international instrument that assists States and users of genetic resources to implement and comply with the CBD. However, the NP is a legally binding instrument that creates obligations to States in the way that the CBD should be implemented at the national and regional level. It is also important to note that most of the issues that the NP regulates are those that have emerged after the implementation of the CBD at the regional and national level. These three legal instruments constitute what has been called the ABS regime. [[640]](#footnote-641)

Although the ABS regime aims to encourage developing countries rich in biodiversity in protecting biodiversity by providing them with control on access to genetic resources in order to secure benefit sharing from the exploitation of genetic resources, developing countries rich in biodiversity and developed countries disagree in the way that such a trade-off should take place.

As users of genetic resources (e.g. pharmaceutical and biotechnological companies, universities, labs, museums and botanical gardens) are mainly located in developed countries and hold IPRs on the technology that employ genetic resources, developed countries expect that the trade-off between access to genetic resources and access to technology is the result of bilateral agreements between users and developing countries rich in biodiversity, rather than obligations between States. Bioprospecting initiatives or projects reflect this policy. In bioprospecting initiatives, users of genetic resources carry out the activities of scanning and scoping of biodiversity in order to collect new biochemical compounds for drug production based on genetic resources in developing countries rich in biodiversity. Before a bioprospecting initiative takes place, users of genetic resources seek to reach an agreement on mutually agreed terms (MATs) in which users and developing countries rich in biodiversity agree the terms and conditions for access to genetic resources and benefit sharing, including the transfer of technology and how IPRs will be handled.

However, developing countries rich in biodiversity aim to create international compromises in which developed countries are obliged to transfer technology, regardless of whether the technology is protected by IPRs, to developing countries rich in biodiversity in order to encourage the protection of biodiversity. If developed countries are to comply with ABS regulation (particularly the transfer of technology) within their own territory on similar terms that developing countries rich in biodiversity have done, the impact on the global pharmaceutical market would be considerable since originators’ patents could be undermined by ABS regulation. As developed countries have secured the flow of technology from originators by granting patent rights, the ABS implementation in developed countries’ legislation could rather discourage originators from investing in R&D on genetic resources as it creates extra requirements for them in developed countries. Indeed, Chapter 1 points out that the shape of the global market is that originators address R&D resources in developed countries as these countries encourage R&D through exclusivity in patents, orphan drugs legislation, etc.[[641]](#footnote-642)

Chapter 4 analyses how this discussion on access to genetic resources and access to technology has shaped the ABS regime. Therefore, Chapter 4 assesses to what extent the regulation on access to genetic resources and benefit sharing of the CBD, the ABS regime, has served the interests of developing countries rich in biodiversity, in accessing technologies that employ genetic resources in order to increase their capacity for drug development.

This chapter is divided into four parts: the first part discusses the wording of the ABS regime (i.e. the CBD, Bonn Guidelines and the NP) including capacity in the ABS regime, the issue of sovereignty, the nature of genetic resources, PIC and MATs. The second part analyses the policy behind the ABS regime. The third part assesses the impact of the ABS regime in the pharmaceutical industry in developing countries rich in biodiversity. Finally, the fourth part examines some lessons from the implementation of the ABS regime and the challenges ahead for developing countries rich in biodiversity. This analysis illustrates that although the ABS has brought important elements to provide the transfer of technology to developing countries rich in biodiversity, its implementation at the national and regional level have indicated that the lack of capacity of developing countries rich in biodiversity for the exploitation of their own genetic resources have not encouraged innovation in technologies that employ genetic resources for drug development. As a result, this chapter suggests that since the ABS regime entitles developing countries rich in biodiversity to trade off access to genetic resources for access to technology, these countries should implement the ABS regime in a way that creates mechanisms that facilitate benefit sharing from the utilisation of genetic resources for drug development in order to increase capacity in these countries.

1. **The Wording of the ABS Regime: From the CBD to the NP**

The cornerstone of the ABS is Article 1 of the CBD which establishes three objectives. Two of them contemplate the responsibility that States have for the conservation of biodiversity and the sustainable use of its components. The third principle asserts that users of genetic resources are also obligated to share the benefits from the utilisation of genetic resources. This third objective is what has been called the ‘grand bargain’ as developing countries rich in biodiversity accepted a conservation and sustainability treaty in exchange for benefit sharing; yet there are authors such as Schroeder and Pisupati, and Cabrera and Garforth who have mentioned that despite the inclusion of the third objective being a bargain, this has provided a legal framework in which developing countries rich in biodiversity aim to counterbalance the economic and technological advantages of the exploitation of genetic resources in developed countries.[[642]](#footnote-643)

Additionally, Article 1 of the CBD provides three further elements to comply with the third objective of the CBD: (1) sovereignty control on access to genetic resources; (2) access to relevant technologies; and (3) funding.[[643]](#footnote-644) Therefore, Article 1 of the CBD establishes the general parameters which are developed in more detail by the rest of the wording of the CBD, Bonn Guidelines and the NP.

The following subsections analyse (1) the general obligations created by the CBD to both developing and developed countries, particularly conservation and sustainability as well as other important issues relevant to achieve Article 1 of the CBD, including transfer of technology, funding, technical and financial mechanisms of cooperation and capacity; and (2) this section also analyses Articles 2, 3 and 15 of the CBD (the nature of genetic resources, PIC, and MATs) and focuses on developing the scope of the third objective of the CBD, i.e. the share of benefits that arise from the exploitation of genetic resources. This section also studies what aspects of the CBD have been clarified by the Bonn Guidelines and the NP.

* 1. **Conservation of Biodiversity and Sustainable Use of its Components in the ABS Regime**

As the CBD establishes that conservation of biodiversity and sustainable use of its components is a ‘common concern’ of the Parties,[[644]](#footnote-645) the CBD creates two different sets of obligations for developing countries rich in biodiversity and developed countries based on Article 1: first, developing countries rich in biodiversity, as stewards of biodiversity and providers of genetic resources, should create policies that aim to protect biodiversity (i.e. conservation and sustainable use of biodiversity) and to facilitate access to genetic resources; [[645]](#footnote-646) second, developed countries have an obligation to facilitate financial and technical cooperation, transfer of technology to developing countries rich in biodiversity, and to comply with access to genetic resources and benefit sharing legislation in developing countries rich in biodiversity.

For developing countries rich in biodiversity, the CBD recognises in Article 3 that the only principle of the CBD is the sovereign right that States have over their biodiversity (Article 3) and genetic resources (Articles 3 and 15.1) to decide their own policies of conservation of biodiversity and sustainable use of its components, and access to genetic resources and benefit sharing. Sovereignty sets the CBD apart from the concept of ‘common heritage’, which has prevailed through other international instruments and was particularly supported by developed countries during the process of negotiation of the CBD.[[646]](#footnote-647)

However, the stewardship obligations of developing countries rich in biodiversity in the CBD mean that, despite the CBD having granted sovereignty rights over biodiversity, this treaty also creates obligations to protect biodiversity. Indeed, under the mandate of Article 6 of the CBD, developing countries rich in biodiversity should develop a national biodiversity strategy which includes programmes and policies to comply with the measures set up in the CBD, such as identification and monitoring of biodiversity and its components (Article 7), conservation of *in situ* areas (e.g. rain forest) (Article 8) and *ex situ* collections (e.g. botanical gardens, genetic banks) (Article 9), and allowing access to genetic resources (Article 15). For instance, the ACN has developed a regional strategy on the conservation and sustainable use of their biodiversity and natural resources which creates a general policy framework for the Andean (Bolivia, Colombia, Ecuador and Peru) region on the implementation of the CBD.[[647]](#footnote-648)

In the case of developed countries, the CBD provides different measures of cooperation and financial assistance to support developing countries rich in biodiversity in the implementation of the CBD. For example, Article 5 of the CBD requires Signatories to provide cooperation through international organisations in the implementation of measures of the CBD, such as those described in Articles 7 to 10 of the CBD. For instance, since 1910 the British-based organisation CABI has led taxonomy initiatives in different countries, particularly former British colonies.[[648]](#footnote-649)

Taxonomy initiatives are important for developing countries rich in biodiversity as they could help those countries to understand the potential of their own biodiversity in different areas such as drug discovery, tourism and agriculture. [[649]](#footnote-650) The CBD is also leading the Global Taxonomy Initiative which has the support of developed countries and developing countries rich in biodiversity organisations such as national museums and botanical gardens.[[650]](#footnote-651)

The CBD also calls on developed countries to support the implementation of the CBD in developing countries rich in biodiversity by providing financial assistance (Articles 20 and 21) and technical and scientific cooperation (Article 18) such as the Clearing-House Mechanism (CHM) which provides a platform for the exchange of information on aspects related to the implementation of the CBD.[[651]](#footnote-652) Additionally, the CBD not only created a broad mandate in technological and financial cooperation between developed countries and developing countries rich in biodiversity (e.g. Articles 5 and 18 of the CBD) but different parts of the CBD (e.g. Articles 16 and 19) also call for developed countries’ users of genetic resources to transfer technology, particularly biotechnology, to developing countries rich in biodiversity in exchange for access to genetic resources.

Taxonomy initiatives, and technical and scientific cooperation highlight the importance of the synergy between developed countries and developing countries rich in biodiversity to understand the value of genetic resources and design national and regional strategies that could boost capacity in developing countries rich in biodiversity in technologies that employ genetic resources in order to achieve the objectives of the CBD. However, technical cooperation has not been the only mechanism with which developing countries rich in biodiversity aim to access technology. The ABS regime entitles developing countries rich in biodiversity to an entire legal framework in order to capitalise on access to technologies that employ genetic resources for drug development via control to access to genetic resources and benefit sharing. Such a legal framework is based upon the sovereignty that the CBD recognises in developing countries over access to genetic resources and, in particular, Articles 2, 3 and 15 of the CBD.

Nevertheless, the ABS regime, and particularly the NP, has also developed another important element that countries should take into account as they implement the ABS into national and regional legislation: capacity. Capacity, in the context of the ABS, aims to create the right conditions (legal and technical) to take advantage of benefits that arise from the exploitation of genetic resources, particularly in the transfer of technology. Although the original wording of the CBD did not mention capacity, it establishes that Parties of the CBD should take into account their ‘conditions’ and ‘capabilities’ (e.g. Articles 6 and 20 of the CBD) to implement the CBD at the national and regional level. This was further developed in the 2004 Action Plan on ABS in which its primary objective is to support the development of developing countries rich in biodiversity and the consolidation of the capacities of their national institution as well as individuals in order to implement the objectives the CBD. [[652]](#footnote-653) The Action Plan also calls for the assessment of developing countries rich in biodiversity’s ‘needs, priorities, mechanism of implementation and sources of funding’ to achieve capacity.[[653]](#footnote-654)

Eventually, Article 22 of NP adopted most of the Action Plan’s elements. [[654]](#footnote-655) Article 22 highlights that capacity is an important element that should be taken into account as countries implement the ABS regime. Indeed, this Article calls on countries to carry out ‘self-assessment’ on capacity. Particularly, the NP requires countries to address, *inter alia*, capacity to implement and to comply with the obligations of the NP; capacity to negotiate MATs; capacity to develop, implement and enforce domestic legislative and administrative measures on access and benefit sharing; and capacity to develop their own endogenous research (Article 22 (4)). Article 22 (5) of NP also lists a series of measures which users of genetic resources located in developed countries could provide, that aim to transfer relevant skills and technology to developing countries rich in biodiversity, particularly via bioprospecting, associate research and taxonomic studies.

As a result, Article 22 of the NP indicates that the ABS regime highlights the importance of assessing countries’ capacity as the ABS is implemented. Therefore, it is now important to define the most relevant aspects that countries should take into account as they have implemented Articles 2, 3 and 15 of the CBD. Therefore, the next subsection analyses the complexity of this regulation and the more relevant issues that developing countries rich in biodiversity and developed countries should be taking into account in order to implement this legislation at the national and regional level according to their own capacity; it also provides essential elements to assess whether or not ABS has facilitated developing countries rich in biodiversity in obtaining benefits from the utilisation of genetic resources in the drug development process in order to increase capacity in these countries. The next subsection is divided as follows: (i) the definition of the nature of genetic resources; and (ii) the legal and administrative mechanisms for access to genetic resources and benefit sharing (PIC and MATs).

* 1. **The Nature of Genetic Resources**

The role of the nature of genetic resources within the CBD is twofold. First, it narrows down the concept of biological resources with the aim of distinguishing the obligations of sustainability and conservation, and access to genetic resources and benefit sharing. Second, it defines whether or not technologies that employ genetic resources are included in the nature of genetic resources. This means, for instance, if a definition of genetic resources includes the technology that synthesises them, users of genetic resources should transfer the technology to developing countries rich in biodiversity as these countries have the sovereignty rights over genetic resources according to Articles 3 and 15.1 of the CBD; but if it does not include the technology, users of genetic resources and developing countries rich in biodiversity should negotiate the transfer of technology in MATs according to Article 15.2-7. For that reason, it is important to analyse in detail Article 2 which defines the nature and scope of genetic resources.

Article 2 of the CBD defines genetic resources as ‘genetic material of actual or potential value’, while genetic material means ‘any material from plant and animal, microbial, or other origin containing functional units of heredity’. In the context of Article 2, functional units of heredity refer to genetic elements that contains DNA and RNA such as seed, cutting, individual organism, DNA extracted from plants, animals or microorganism, but a biochemical extract, for instance, that do not contain any functional units of heredity is not considered to be genetic material;[[655]](#footnote-656) whereas, potential or actual value is the element that helps to distinguish genetic resources from genetic material and refers to ‘a use that can be ascribed to or is likely’.[[656]](#footnote-657) Article 2 also defines biological resources as including ‘genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity’. In other words, biological resources refer to ‘real entities’ that goes from animal to genes and ecosystems that have a value for humanity.[[657]](#footnote-658) However, biological resources involve mainly an obligation to conservation and sustainable use.[[658]](#footnote-659) Instead, genetic resources are linked to the regulation of access to genetic resources of Article 15 of the CBD. Therefore, the role of the term ‘genetic resources’ is to limit the application of the CBD’s regulation of access to genetic resources to genetic materials (with potential or actual value) and to exclude biological resources from access and benefit sharing requirements.

Another important element, in order to understand the importance of the nature of genetic resources, is the division naturally occurring genetic resources or genetic resources *in situ* and the technologies that makes genetic resources different from the natural one. Chapter 3 observes that Article 27 of TRIPs prompts a discussion between developed countries and developing countries rich in biodiversity on the scope of patents on genetic resources; it particularly analyses the division between naturally occurring genetic resources and technologies that employ genetic resources for drug development.[[659]](#footnote-660) This division is relevant in patents, TRIPs and the implementation of this treaty since developed countries give patent protection to the latter rather than the former. In this way, developed countries protect technologies that make invention based upon genetic resources different from naturally occurring ones. The approach of developing countries rich in biodiversity is different as they seek to either not provide patent protection or to reduce the scope of patent protection on technologies that employ genetic resources. By adopting such an approach, these countries aim to gain access to the technology that employs genetic resources.

This division is again relevant to understand what ‘genetic resources’ mean in the context of the CBD. In other words, the definition of the nature of genetic resources defines whether the ABS regime includes only naturally occurring genetic resources or also the technology that employ genetic resources. In the context of the ABS regime, naturally occurring genetic resources are those genetic resources defined by Article 2 of the CBD. This is because there is no mention in Article 2 of genetic resources that have gone through, for instance, any technical intervention, which in turn makes them different from naturally occurring ones; hence, extracted compounds from genetic resources such as natural oils or products could be excluded from the definition of genetic resources in Article 2 and the requirements of Article 15.[[660]](#footnote-661)

In order to extend Article 2 to technologies that employ genetic resources, the Bonn Guidelines and the NP have helped to clarify the content of Article 2 by employing the term ‘derivatives’ and a standard of utility. The use of these terms aim to include not only functional units of heredity but also the products that are derived from genetic resources such as chemical compounds that are modified, created or synthesised from genetic resources and the different uses given to them.[[661]](#footnote-662) The Bonn Guidelines do not extend the scope of the definition of genetic resources in Article 2 of the CBD, but suggest that derivatives and products that arise from the utilisation of genetic resources should be part of the negotiation of MATs. [[662]](#footnote-663) Furthermore, the Bonn Guidelines highlight the importance of Articles 1 and 15 of the CBD’s term ‘utilisation of genetic resources’ from the exploitation of genetic resources in order to focus on a standard of utility over the use of genetic resources.[[663]](#footnote-664) However, the Bonn Guidelines do not aim to extend the definition of Article 2 over technologies that employ genetic resources, but rather the definition clarifies that those technologies should be included in MATs. This means that the Bonn Guidelines clarify that genetic resources should require appropriate access, but the technology that employ them should be defined in MATs.

However, the NP seems to extend the scope of Article 2 of the CBD in technologies that employ genetic resources. The discussion centres on the use of the term ‘utilisation of genetic resources’ in Article 2 (c) and the term ‘derivatives’ in Article 2 (e). The former focuses on the different uses or utilisation given to genetic resources, for instance, in the drug development process. The NP’s definition of ‘utilisation of genetic resources’ amplifies the nature of genetic resources not only to the actual or potential value of genetic material (with functional units of heredity) but also to genetic resources employed in research and development activities, including biotechnology. By focusing on the utility criteria of access to genetic resources in a binding instrument, the NP covers the different technologies that are employed in the exploitation of genetic resources, including genetic modification and DNA synthesis or biochemical techniques employed within the pharmaceutical industry. [[664]](#footnote-665) Furthermore, there is not a list of uses or technologies, which would have helped to exemplify the scope of the term utilisation, because it was agreed within the negotiations that led to the NP, that an open-ended term would cover new uses and technologies that were not discussed there.[[665]](#footnote-666)

On derivatives,[[666]](#footnote-667) the NP states that derivatives are ‘naturally occurring biochemical compound(s) resulting from the genetic expression or metabolism of biological or genetic resources’ even if they do not have functional units of heredity (Article 2 (e) of NP). The definition of derivative is extended, therefore, to biochemical compounds such as aromas, resins and biochemicals in cells employed in pharmaceutical products. Although this could mean that the NP actually extends the nature of genetic resources of Article 2 of the CBD to technologies that employ genetic resources with the terms derivatives and utilisation of genetic resources, the discussion is far from being over. Particularly, because the NP seems to contradict what is established by the Bonn Guidelines which mention that the terms derivatives and utilisation of genetic resources should be negotiated within MATs rather than being a condition to access genetic resources.

Scholars are already disagreeing in this contradiction of terms and what this could mean for technologies that employ genetic resources. For instance, authors such as Buck and Hamilton argue that the definition of the NP does not transform the nature of the definition of genetic resources in Article 2 of the CBD, i.e. technologies that employ genetic resources are not included in the definition of Article 2 of the CBD, but rather should be defined by developing countries rich in biodiversity and users in MATs.[[667]](#footnote-668) However, Greiber et al. consider that the NP is not clear on whether technologies should be included in the nature of genetic resources of Article 2 of the CBD; hence, it depends on Parties of the NP to interpret Article 2 of the CBD and Article 2 of the NP to either include technologies that employ genetic resources within the nature of genetic resources or allow users of genetic resources and developing countries to include them within the scope of MATs.[[668]](#footnote-669)

For developing countries rich in biodiversity, despite the fact that there is a technical intervention, genetic resources as such remain an important source for drug development; hence, they should be entitled to obtain benefit sharing, including the transfer of technology, to meet the objectives of conservation and sustainability of Article 1 of the CBD. Indeed, authors such as Tvedt and Swanson claim that the reason for having an obligation to protect biodiversity is not necessarily linked to an individual and identified genetic resource, but gives the opportunity to users of genetic resources to research and test large samples of biodiversity in a territory via bioprospecting initiatives.[[669]](#footnote-670) In other words, the value of genetic resources extends to the information that these sources provide and to the biodiversity itself as users of genetic resources have the chance to exploit extensions of biodiversity rather than a single component.

This perspective from developing countries rich in biodiversity has led them to enact legislation that includes terms, such as ‘derivatives’ and ‘utilisation of genetic resources’, to include the technology that employs genetic resources within the nature of genetic resources – even before the NP was under negotiation. For instance, the 2001 Decision 391 of the ACN includes synthesised products (i.e. products based on the artificial processing of genetic information or biological molecules), and by-products (e.g. crude extracts from live or dead organisms). Developing countries rich in biodiversity have also already included the interpretation of the utilisation of genetic resources within the definition of the nature of genetic resources. Section 2 of the 2002 Indian Biological Diversity Act defines commercial utilisation, as the ‘end uses of biological resources for commercial **utilization** such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts’ (highlighted by the author). This means that developing countries rich in biodiversity such as India and the ACN have employed the term ‘utilisation of genetic resources’ in Article 15.7 and derivatives to include technologies that employ genetic resources. However, originators represented by the Biotechnology Industry Organisation (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have argued to define concepts such as derivatives and utilisation of genetic resources in MATs in a case-by-case approach with countries.[[670]](#footnote-671)

In conclusion, the NP aimed to define utilisation of genetic resources and derivatives in order to clarify the scope of genetic resources in Article 2 of the CBD, but the apparent contradiction of terms between the NP and Bonn Guidelines keeps the scope of the nature of genetic resources open to interpretation by countries. Either way, developing countries rich in biodiversity should increase capacity to identify and distinguish genetic resources and the technology involved in the utilization of genetic resources as this division brings different obligations and/or could conflict with IPRs.

* 1. **The Legal and Administrative Mechanisms for Access to Genetic Resources and Benefit Sharing**

Articles 3 and 15(1) of the CBD give States the sovereign right to determine who can access their genetic resources and under what conditions. However, Article 15 also sets up the minimum requirements that Members of the CBD should take into account when they decide to implement the CBD into their national or regional legislation: (1) PIC; and (2) how to reach an agreement with developing countries rich in biodiversity; these agreements are called MATs, which include among other things the sort of benefit sharing that will take place. However, Article 15 also allows countries not to adopt any of these requirements. For instance, developed countries such as Germany and the UK have decided not to implement these requirements at the national level;[[671]](#footnote-672) this disposition is ratified in Article 6 (1) of the NP.

* + 1. **Prior Informed Consent (PIC): from Administrative Measures to Traditional Knowledge Associated with Genetic Resources and Beyond**

Article 15.5 of the CBD establishes that access to genetic resources should be subject to PIC from the country that provides the genetic resources, unless Members of the CBD regulate otherwise. In order to exercise their sovereignty, the CBD conditions users of genetic resources to require consent from States before they can actually have access to those resources. This necessarily means that States determine the legal procedures and requirements to consent to access to genetic resources located in their own territory. Moreover, an obligation to obtain PIC also means that users of genetic resources provide all the necessary information regarding those resources.

Although the CBD does not create a procedure for obtaining PIC, the Bonn Guidelines have set up guidelines for legal administrative steps to obtain PIC which can be divided into three categories: (1) the establishing of a national authority that gives consent on behalf of the State (usually the national Ministry of the Environment) (Guidelines 14) and a national focal point in which States provide relevant information on procedures to obtain PIC and share that information through the CHM of the CBD (Guideline 13); (2) an administrative procedure (e.g. administrative fees, registration, etc.), in which the Bonn Guidelines also recommend to countries that provide genetic resources (developing countries rich in biodiversity) to deliver legal certainty (e.g. deadlines, timing, etc.), and reduce the cost of obtaining the granting of access and transparency in any procedure (Guideline 16); and (3) the duty of users to disclose all relevant information regarding the scope of the research activity on genetic resources (e.g. whether it is commercial or not). This means that developed countries, in which usually users of genetic resources are located, should create mechanisms to ensure that users of genetic resources comply with access and benefit sharing, for instance, by providing information to users of the origin of the genetic resources by disclosing information in patents (Guideline 14 (d)). Disclosure of origin, as discussed in Chapter 3, mandates the users of genetic resources to disclose all the information related to the origin of genetic resources when a patent application is filed.[[672]](#footnote-673)

The NP regulates in more detail what the Bonn Guidelines establish and creates two sets of obligations: Provider Measures and User Measures. This is because the NP requires users of genetic resources to fulfil the requirement of PIC as they access genetic resources; and providers of genetic resources to create transparent and clear rules of how to access genetic resources, including PIC procedures and MATs.

On user measures, Article 15 of the NP recommends States to adopt mechanisms of compliance to ensure that genetic resources utilised within their territory have been lawfully accessed according to the ABS in developing countries rich in biodiversity. Therefore, Article 17 of the NP decides what those mechanisms are in order to monitor the compliance of users of genetic resources. These include (1) checkpoints and (2) an international certificate of compliance. First, Article 17.1 states that Members should designate one or more checkpoints which collect and receive information relating to the access and utilisation of genetic resources, PIC and MATs, in order to address the situation of non-compliance by users of genetic resources in both developed countries and developing countries rich in biodiversity. The designation of checkpoints and the procedure to collect and receive information should be regulated at the national level. Second, Article 17 of the NP also adopted the Internationally Recognized Certificate of Compliance (IRCC) which can also be employed by the designated checkpoint.[[673]](#footnote-674) This is a mechanism to track and monitor the flow of genetic resources. Such a certificate is issued at the moment that access has been granted and MATs issued (Articles 6.3 (e) and 17.2 of NP). The issuance of an IRCC should be notified to the CHM of the CBD via national focal points. The design of checkpoints and IRCC was proposed by developing countries rich in biodiversity with the original purpose of including patent offices as checkpoints; hence patent offices might have required disclosure of origin of genetic resources at the time a patent application was filed;[[674]](#footnote-675) then, the IRCC would verify the origin of those genetic resources and whether there were PIC and MATs. However, developed countries have always opposed any mention of disclosure or patent offices in the NP as these countries consider that this could create an extra burden to obtain patent protection on technologies that employ genetic resources.[[675]](#footnote-676)

In the case of providers’ measures, Article 6.1 of the NP limits the scope of ABS to genetic resources that are from countries that regulate access. This means that genetic resources that are located in *ex situ* collections should not require PIC, for example. Regarding PIC and MATs, Article 6.3 states that countries that require PIC should provide legal certainty, transparency and clarity in the implementation of the CBD as well as securing the flow of information regarding those legal and administrative measures through the CHM of the CBD (Article 14 of the NP). Equally, the NP also calls on States, particularly developing countries rich in biodiversity, to encourage non-commercial research on genetic resources (Article 8) by easing rules on access, including PIC. Indeed, for instance, Section 7 of the Indian Biological Diversity Act does not require PIC and MATs for institutions and individuals that do not carry out commercial research on genetic resources. Similarly, Colombia has recently enacted new legislation that facilitates access to genetic resources for non-commercial research by easing the requirements of PIC and MATs.[[676]](#footnote-677)

However, PIC does not only refer to States, but also to indigenous and local communities, particularly on the issue of traditional knowledge associated with genetic resources. The CBD only refers to indigenous and local communities in Article 8 (j) which calls on States to respect, preserve and maintain traditional knowledge relevant for conservation and sustainability, and to involve indigenous and local communities in benefit sharing. Yet, Article 8 (j) does not mention that PIC from them is required. However, Guideline 31 of the Bonn Guidelines and especially Article 7 of the NP require States to take measures to ensure that PIC of indigenous and local communities is obtained when there is access to traditional knowledge associated with genetic resources.

Yet, the issue of traditional knowledge associated with genetic resources is not only limited to the CBD and the NP, but has also been at the centre of discussion in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (ICG) of the WIPO.[[677]](#footnote-678) Regarding traditional knowledge associated with genetic resources, the ICG seeks to address concerns from developing countries rich in biodiversity on the misappropriation of ancient knowledge and practices on genetic resources. Nonetheless, this ancient knowledge on the use of genetic resources has been proved difficult to document since indigenous and local communities have passed this knowledge mouth-to-mouth rather than in patents or scientific journals. As a result, there are working documents from ICG’s negotiation that have recognised that ‘traditional knowledge associated with genetic resources have important economic, scientific and commercial value to a wide range of stakeholders’ including the pharmaceutical industry.[[678]](#footnote-679)

Although parties in the ICG, including developed countries, have recognised the important value that traditional knowledge adds to genetic resources, it remains problematic regarding what sort of measures should be taken to avoid misappropriation and secure benefit sharing to indigenous and local communities. However, there are already national initiatives such as the TDKL in India that seek to put traditional knowledge associated with genetic resources in the public domain through Internet databases with the aim that patent offices and courts dismiss patent protection to inventions on the basis that the invention does not fulfil the patent requirement of novelty and non-obviousness.[[679]](#footnote-680)

Duffield has also indicated that courts and patent offices in developed countries have already taken into account traditional knowledge to deny or revoke patent protection on genetic resources.[[680]](#footnote-681) For instance, Duffield points out that Lord Hoffman, from the British House of Lords, highlighted that despite the fact that an Amazonian Indian was not able to describe in chemical terms the therapeutic value of quinine in treating fevers, he knew that ‘the bark has a quality which makes it good for fever and that is one description of quinine’.[[681]](#footnote-682) Another important example that Duffield describes is the rejection of a claim on a ‘method of treating erectile dysfunction’ based upon four references to the use of a traditional medicine Ying Yang Hou (horny goat weed) that anticipate the claim, despite the fact that those four references did not describe the claim in chemical terms.[[682]](#footnote-683) Both examples indicate that there are patent examiners and courts in developed countries that consider relevant traditional knowledge associated to genetic resources in order to dismiss the novelty of a patent, regardless of such information not having been presented in scientific or technical terms.

Although employing an approach such as the Indian database or USPTO and House of Lords’ decisions could prevent misappropriation, this does not ensure that there would be PIC from indigenous and local communities or that they could obtain benefit sharing from the utilisation of genetic resources. Therefore, it remains imperative that States, including providers and users, implement Article 7 of the NP to ensure that PIC of indigenous and local communities is obtained.

Finally, the NP also contemplates the scenario in which genetic resources are located in different countries (trans-boundary situations) and where it is difficult to obtain PIC. For those situations, Articles 10 and 11 of the NP call for the creation of a global multilateral benefit sharing in which the benefits that arise from the utilisation of those genetic resources should be directed at conservation and sustainability globally. As this issue is only mentioned in the NP and does give any details (particularly how to obtain PIC in these situations) the Executive Secretary of the CBD has opened an online broad discussion to clarify the wording of Articles 10 and 11 of the NP, particularly what constitutes trans-boundary situations, situations in which it is difficult to obtain PIC, and how a global multilateral benefit sharing mechanism can be employed to support conservation and sustainability.[[683]](#footnote-684)

PIC has different elements that vary depending on where the genetic resources are located (e.g. trans-boundary situations and *ex situ* collections), the kind of research that is carried out on genetic resources (Article 8 of the NP), if there are holders of traditional knowledge associated with genetic resources (Article 8 (j) of the CBD and 7 of the NP), and the legal and administrative procedures to obtain PIC (including national authority, IRCC, disclosure of origin in patents, etc.). As a result, users of genetic resources and developing countries rich in biodiversity have to observe each of these situations in order to ensure that there is no breach of national and regional legislation on PIC. This clearly demands that developing countries rich in biodiversity accompany local authorities and users of genetic resources on each step of the legal ladder towards obtaining PIC.

* + 1. **Mutually Agree Terms (MATs) and Benefit Sharing**

MATs are agreements (or contracts) that need to be reached by users of genetic resources (e.g. labs that carry out bioprospecting initiatives) and the designated national authority (Article 15.4 of the CBD). MATs set up the terms and conditions for the use of genetic resources and the way that users should share the benefits derived from the utilisation of those resources; this is also proof that there is PIC from a national authority. Reaching MATs means that the users of the genetic resources have successfully obtained PIC and benefit sharing. However, MATs might differ from each other as there might be, for example, different benefit sharing agreements – i.e. economic benefits such as royalties and upfront payments or non-economic benefits such as the transfer of technology. This makes MATs particularly flexible mechanisms in the negotiations for benefit sharing as they follow the contractual rules and legislation of each country. [[684]](#footnote-685)

The Bonn Guidelines also provide suggested definitions of elements of MATs, particularly the kind of benefit sharing that can take place. For instance, Guidelines 43 (c) and (d) give recommendations on the management of IPRs (e.g. licensing) in joint research between developing countries rich in biodiversity’s institutions and users of genetic resources, and the possibility of joint ownership of IPRs between countries and users of genetic resources. Other types of benefit sharing mentioned in the Bonn Guidelines include milestone payments, licence fees, joint ownership in IPRs and share of research results training. Similarly, the NP establishes a similar list of possible benefit sharing that can be negotiated in MATs.[[685]](#footnote-686)

The importance of MATs is the legal mechanism that materialises and defined benefit sharing. It is also important to note that (as mentioned in subsection 1.2.) it is in MATs in which users of genetic resources and developing countries rich in biodiversity are able to define what technologies that employ genetic resources will be part of the agreement. This particular element in MATs requires developing countries to actually understand the scope of the nature of genetic resources and their value in drug development. Additionally, the obligation of reaching MATs in order to grant access to genetic resources also requires that developing countries rich in biodiversity gain negotiation skills in order to decide how benefit sharing could lead them to improve their technological capacity.

To this point, the wording and scope of the ABS regime, which includes the CBD, the Bonn Guidelines and the NP, have been analysed. It has been observed that there are different requirements and mechanisms which users of genetic resources should take into account before engaging in a bioprospective initiative in developing countries rich in biodiversity. The following section takes a step further away from the literal wording of the CBD and analyses the policy implications of the ABS regime for both developed countries and developing countries rich in biodiversity in technologies that employ genetic resources.

1. **Trading off Access to Genetic Resources with Access to Technologies**

Section 1 identifies the ABS as a mechanism to encourage developing countries rich in biodiversity to protect their biodiversity by granting property control on genetic resources and securing benefit sharing, including transfer of technology. This is because the protection of biodiversity necessarily involves a burden on developing countries in their role of stewardships of biodiversity. Developed countries have not opposed the inclusion of mechanisms of economic and technological cooperation to encourage conservation of biodiversity and sustainable use of its components for developing countries rich in biodiversity. For instance, developed countries have founded initiatives to protect biodiversity through international organisations such as the Global Environmental Facility (GEF), a US-based organisation that grants funding to protect biodiversity in developing countries rich in biodiversity.[[686]](#footnote-687)

This gives an important value to biodiversity, particularly genetic resources, for technologies that employ genetic resources for drug development. As explained in the introduction of the thesis, the ABS granted property rights to States over genetic resources in order to ensure that developing countries rich in biodiversity could obtain the benefit sharing that arises from the utilisation of genetic resources. This indicates that the ABS does not aim to reward the intellectual labour that adds value to genetic resources but it is rather a ‘fair agreement’ or ‘bargain’ in which developed countries and developing countries rich in biodiversity address the latter’s concerns on their own limits to exploit their own genetic resources and their lack of technology development. The distributive nature of the ABS indicates, according to Rawls’ social contract theory, in which parties seek to counterbalance inequalities (e.g. the lack of technology development in developing countries rich in biodiversity), that developing countries rich in biodiversity are entitled to obtain benefits that arise from the use of technologies on genetic resources.

Therefore, the ABS turns biodiversity and its components (e.g. genetic resources) into important assets for the economic development of developing countries rich in biodiversity. [[687]](#footnote-688) This is partially based on studies analysed in previous chapters, that pointed out that genetic resources are important sources for drug development. For example, Cragg et al.’s research on the importance of genetic resources for the pharmaceutical industry highlights that only 36% of the small molecules that have led to new biochemical entities between 1980 and 2010 were purely synthetic or free from any natural inspiration genetic resources.[[688]](#footnote-689) This trend is reflected in the pre-CBD bioprospecting deal between a developing country rich in biodiversity and a multinational pharmaceutical company, i.e. Costa Rica’s National Biodiversity Institute (INBio – Spanish acronym) and the US Merck. The agreement included that Costa Rica allowed access to their genetic resources to Merck in exchange for training, scientific infrastructure and payment of royalties by Merck.[[689]](#footnote-690)

However, developing countries rich in biodiversity seized the opportunity not only to demand economic and technological cooperation, but also to obtain transfer of technology, as established in Articles 5, 16, 18 and 19 of the CBD. Furthermore, Article 20 (4) of the CBD explicitly mentions that the implementation of the CBD in developing countries depends on developed countries’ commitment to transfer technology to the former in order to achieve the objectives of the CBD. Equally, Article 23 of the NP also calls on developed countries to transfer technology to developing countries rich in biodiversity. In other words, the ABS clearly entitles developing countries rich in biodiversity to trade off access to genetic resources for access to technologies and the share of other benefits that arise from the exploitation of genetic resources by granting property rights on those resources, despite the fact that developing countries rich in biodiversity do not carry out any intellectual activity on those genetic resources.[[690]](#footnote-691)

However, developed countries, especially the US, have considered that the transfer of technology should come from a free market perspective since it depends on holders of IPRs to negotiate the terms of transfer technology rather than between States.[[691]](#footnote-692) As studied in Chapter 3, since it is originators located in developed countries that protect their technologies through patents to access to markets ahead of local producers, developed countries campaigned to include safeguards on IPRs in the CBD (e.g. Articles 16 and 22) to protect technologies that employ genetic resources. The inclusion of transfer of technology and IPRs within the CBD has been particularly relevant as it was the issue that led the US to refuse to ratify the CBD, despite the fact that it took part in the negotiation process as US’s originators raised concerns over the implications of the CBD in their commercial and R&D initiatives.[[692]](#footnote-693)

Furthermore, the ABS regime has served developing countries rich in biodiversity as a platform from which to demand further changes in different forums in order to complement the ABS regime with other international treaties on IPRs. Indeed, developing countries rich in biodiversity have introduced issues related to the ABS regime in WIPO and TRIPs of the WTO. In the case of WIPO, [[693]](#footnote-694) developing countries rich in biodiversity succeeded in creating a specific body within WIPO that negotiates aspects related to the ABS regime, such as disclosure of origin and traditional knowledge associated with genetic resources: the IGC.[[694]](#footnote-695)

Developing countries have managed to discuss ABS-related provisions since Colombia, supported by the ACN and other developing countries, presented in 1999 a submission before the Standing Committee on Patents (SCP)[[695]](#footnote-696) which proposed that patent procedure for members of WIPO should guarantee protection of countries’ biological and genetic resources by proving that if a patent application was related to genetic resources, the applicant should demonstrate that those resources were acquired legally.[[696]](#footnote-697) Albeit, the Colombian’s submission was not specific and clear on how to protect biological and genetic resources through patents, it raised for the first time in WIPO the issue of the relationship between the regulation on genetic resources and patents.[[697]](#footnote-698) Colombia removed the submission on the condition that WIPO would create an international committee to discuss this issue, i.e. the IGC.[[698]](#footnote-699) In 2001 the IGC began negotiations for the creation of an international instrument related to IPRs and access to genetic resources.[[699]](#footnote-700) The negotiations ended in 2013 with a draft of a ‘consolidated document’.[[700]](#footnote-701) Despite the fact that some progress was made in the consolidated document, parties have not reach any compromise in key aspects, such as the nature of genetic resources and disclosure of origin. Furthermore, as the General Assembly of WIPO in 2014 did not make a decision on the work of the IGC, the WIPO agenda for 2015 did not include any IGC sessions.[[701]](#footnote-702)

In the case of the WTO and the Council for TRIPs, developing countries were those members of the WTO that campaigned more to relax IPRs’ dispositions in Doha.[[702]](#footnote-703) Although access to medicine was the most noticeable discussion during the Doha negotiations,[[703]](#footnote-704) developing countries rich in biodiversity have also included traditional knowledge and the relationship between the CBD and TRIPs, including definitions of genetic resources and disclosure of origin in patents, in the agenda of negotiations. However, the US (supported by other developed nations such as Japan) has refused to implement any measures that might create binding obligations and amendments in TRIPs, and has maintained the position that a perfect synergy between IPRs and the ABS regime could only occur through national legislation and bilateral agreements that facilitate that users of genetic resources and developing countries could reach MATs.[[704]](#footnote-705) These conflicting views on this issue have led to a stalemate in the negotiations in TRIPs. Indeed, the Director of the WTO issued a report in 2011, which highlights that conflicting views remain from developed countries and developing countries rich in biodiversity on the relationship between the CBD and TRIPs, in particular the implementation of the disclosure of origin.[[705]](#footnote-706)

Although the inclusion of provisions related to the ABS regime in negotiations within the WTO and WIPO have led to a stalemate, Helfer[[706]](#footnote-707), Safrin,[[707]](#footnote-708) Raustiala and Victor[[708]](#footnote-709) consider that the ABS regime has given the opportunity to developing countries, including those rich in biodiversity, to counterbalance provisions in TRIPs which restrict access to technology, patents in particular, by creating an alternative regime based on the three objectives of Article 1 of the CBD.

However, a trade-off between access to genetic resources and access to technology still depends on developed countries’ (especially users of genetic resources that hold IPRs) determination to transfer technology to developing countries. Certainly, the pharmaceutical industry in developed countries and representatives from this sector, such as Finston, point out that more changes in the ABS regime that undermines IPRs lead necessarily to the reduction of R&D on genetic resources.[[709]](#footnote-710) This situation is problematic since large pharmaceutical companies have important technology that could be transferred to developing countries rich in biodiversity via bioprospecting initiatives. Indeed, Cragg et al. have recently expressed concerns that the pharmaceutical industry is losing interest in genetic resources located in these countries for drug development.[[710]](#footnote-711) Legislative efforts in WTO, WIPO and the Conference of Parties of the CBD will be fruitless if developing countries rich in biodiversity do not engage with IPRs holders to access technologies that employ genetic resources.

Following Nozick’s critique on the distributive nature of Rawls’ theory, the ABS regime could lead researchers and inventors to ‘redistribute activities’ in which they are obliged to carry out activities that deter their capacity to innovate.[[711]](#footnote-712) In other words, the distributive nature of the ABS could impose administrative and legislative burdens on users of genetic resources, a situation that could lead them to reduce their capacity on technologies that employ genetic resources.

That is why this thesis focuses on ensuring that distributive mechanisms, such as benefit sharing of the ABS regime, do not create further burdens on developing countries rich in biodiversity, but rather entitle countries to assess their own capacity and create legal mechanisms accordingly. As a result, the capability approach is employed to define what developing countries rich in biodiversity are capable of and how they can actually increase capacity in technologies that employ genetic resources for drug development. This means that access to technology not only requires that developing countries rich in biodiversity issue legislation to trade off technology for genetic resources, but also have the capacity to actually employ those technologies in these countries.[[712]](#footnote-713) Chapter 2 points out, for instance, that the lack of capacity of Colombia in its pharmaceutical industries has limited it to manufacture and distribute generic medicines with little or no regard to R&D. This means that developing countries rich in biodiversity’s efforts should focus on delivering policies that create the legal and technical conditions to adopt the ABS provisions on benefit sharing (particularly transfer of technology) according to countries’ capacity. In other words, countries should implement the ABS according to what countries are actually able to do and to be.[[713]](#footnote-714) That is why it is important to assess whether or not the implementation of ABS regime in developing countries rich in biodiversity is leading these countries to effectively trade off genetic resources for technology.

1. **Implementation and the Impact of the ABS Regime for the Pharmaceutical Industry in Developing Countries Rich in Biodiversity**

Sections 1 and 2 both conclude that the current ABS regime aims to provide developing countries rich in biodiversity with a legal framework that facilitates their access to technology in exchange for access to genetic resources. Section 1 illustrates that the different mechanisms and legal procedures established by the ABS regime require that countries carry out a ‘self-assessment’ of their own capacity (Article 22 of the NP) so this international legal instrument can be implemented at the national and regional level. Sections 1 and 2 find that developed countries consider the transfer of technology should be designed from a free market perspective as it is users of genetic resources that hold IPRs who should negotiate terms of transfer technology through MATs, while developing countries rich in biodiversity have demanded the transfer of technology as part of a broader mandate established by the three objectives of the CBD. This section analyses the impact of the current ABS regime on the pharmaceutical industry in technologies that employ genetic resources by taking into account the elements provided in sections 1 and 2.

The first part of this section discusses the impact that the implementation of ABS at the national and regional level in developing countries rich in biodiversity has on the pharmaceutical industry; in particular, this part analyses the difficulties that have been created by the establishment of different property regimes on genetic resources and procedures to obtain PIC and reach MAT. The second part explains how the ABS regime is framing developed countries’ policy towards access to genetic resources and transfer of technology, especially how developed countries are trying to fence off their originators from the ABS regime, particularly the NP.

* 1. **The Implementation Problem**

The implementation of Articles 3 and 15 of the CBD in developing countries rich in biodiversity has created two issues that have an impact on the pharmaceutical industry: (1) as Articles 3 and 15.1 of the CBD give sovereign right to States to control access to genetic resources according to their own policies, the implementation of these two norms have led to the creation of multiple property regimes over genetic resources, which depend entirely on where the genetic resources are located; this situation has equally created a clash with IPRs; and (2) since there are different property regimes on genetic resources, there are also different rules regarding access to genetic resources and to reach MATs. These two issues require further analysis.

* + 1. **The Sovereignty and IPRs dilemma**

First, the implementation of Articles 3 and 15.1 at a regional and national level has led developing countries rich in biodiversity to adopt different approaches to deal with sovereignty. For instance, Articles 5 and 6 of the Central American Protocol on Access to Genetic Resources and Bio-Chemicals and Related Traditional Knowledge establish that although this protocol recognises sovereignty over genetic resources, parties to the protocol are entitled to define the legal status of their own genetic resources.[[714]](#footnote-715) Costa Rica, one of the parties to the Central American protocol, has enacted the Biodiversity Act in which it is established that this country has sovereignty over genetic resources, but those resources are part of the public domain. Hence, in principle, there is no ownership over them,[[715]](#footnote-716) yet access to those resources is regulated by the State;[[716]](#footnote-717) whereas, El Salvador (another party to the Protocol) has not even clarified in its national legislation the legal status of genetic resources and access measures.[[717]](#footnote-718)

Furthermore, the ACN states that under sovereign rights,[[718]](#footnote-719) genetic resources are the property of the State,[[719]](#footnote-720) but the ACN legislation on access to genetic resources leaves each State Member to adopt their own property rules over genetic resources.[[720]](#footnote-721) This means that, despite the fact that the four countries are members of the ACN (Bolivia, Colombia, Ecuador and Peru) and have adopted the same legal status of genetic resources (sovereignty), each country could apply different property rules to genetic resources.

Conversely, developed countries such as France, the UK and the US have not implemented legislation that mentions sovereignty over their own genetic resources. Instead, European countries such as the UK and France only provide property rights (patents) to genetic resources which go through a technical intervention that makes them different from the naturally occurring.[[721]](#footnote-722) Indeed, Article 3.2. of Biotech Directive establishes that ‘biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature’. Norway, a non EU member, is one of the few developed countries which clarifies that genetic resources are the common heritage of Norway, access to which is controlled by the State.[[722]](#footnote-723)

Therefore, the implementation of Articles 3 and 15.1 of the CBD has created a multiplicity of property regimes over genetic resources, which depend entirely on where the genetic resources are located. This situation creates two problems. First, there is the case of trans-boundary situations in which genetic resources are in border countries; hence a lab or pharmaceutical company could be obligated to require access to each country under different rules for property on genetic resources. The case of the Council for Scientific and Industrial Research (CSIR), a South African research institute and the plant hoodia, illustrates the problem of trans-boundary issues. The CSIR carried out a research on hoodia (a traditional plant employed and developed to stave off hunger) which can be found in three different Southern Nations of Africa (i.e. Namibia, South Africa and Botswana).[[723]](#footnote-724) This case also involves the use of traditional knowledge, as the hoodia is a traditional plant employed by the San people; they are located also in different territories including Namibia, South Africa and Botswana. The CSIR required access to South Africa and Namibia to carry out research on the hoodia.[[724]](#footnote-725) However, the CSIR did not require access from Botswana’s authorities since this country has yet to even establish a regulation on access to genetic resources and benefit sharing.[[725]](#footnote-726) Although Article 10 of the NP calls Parties to explore a global multilateral mechanism for the case of trans-boundary situations, there has not been consensus among State Members of the CBD on the scope of this article and how this operates in cases in which it is difficult to identify where genetic resources are located.[[726]](#footnote-727)

Additionally, there can be situations in which property regimes in developing countries, which implemented the CBD, clash with IPRs. Again, the case of CSIR illustrates this problem. The CSIR obtained a patent for the hoodia; this institution eventually reached an agreement with Pfizer for the possible commercialisation of the patented product.[[727]](#footnote-728) At first, the CSIR did not recognise any benefit sharing over the patented product to South Africa and the San people, but pressure from the South African authorities and other organisations led the CSIR to renegotiate over the possible commercialization of the product with Pfizer and share benefits with the San people.[[728]](#footnote-729) However, Wynberg considers that the final agreement did not provide the right benefits to the San people because the CSIR exclusively owned the patent and the indigenous communities would receive only a percentage of the royalties.[[729]](#footnote-730) This is a troublesome situation, since developing countries rich in biodiversity consider that the granting of patent rights over genetic resources is biopiracy and does not recognise their sovereign rights and the value that traditional knowledge adds those resources, while developed countries’ patent legislation is designed to grant property rights not over the genetic resources located in areas rich in biodiversity but over the technology employed on those genetic resources.[[730]](#footnote-731)

* + 1. **The Legal (un)Certainty**

The implementation of the ABS regime into national and regional levels has not only created a multiple regime on property rights in which it is difficult to decide the legal status of genetic resources, but also the legal and administrative measures to obtain PIC and reach MATs.

In the case of PIC, developed and developing countries have adopted different approaches towards PIC which can be summarised as follows: on the one hand, most developed countries have adopted an approach to PIC that facilitates access to genetic resources. For instance, the Supreme Court of California prioritised the interests of users of genetic resources over PIC in *Moore vs. Regents of the University of California*.[[731]](#footnote-732) Although the case is related to human genetic resources (cells employed for genetic research), it indicates a stance in the US on balancing property on genetic resources and PIC. In this case, the University of California (UCLA) extracted cells without PIC from a patient (Moore) who had undergone leukaemia treatment; the UCLA obtained patent protection and licensed the genetic resources isolated from Moore to obtain commercial benefits. The Supreme Court of Justice of California pointed out that although the UCLA did breach the duty of PIC, Moore could not obtain ownership control or joint ownership on patents over the cells as they were ‘factually and legally distinct from’ Moore’s original cells. The Court also highlighted that PIC cannot obstruct access to genetic resources or ‘raw material’ as the value of genetic resources takes place only if there is an ‘inventive effort’ by, for example, research institutions or labs. [[732]](#footnote-733) Granting patents rights, according to the Court, rewards such an inventive effort.[[733]](#footnote-734) However, scholars remain sceptical towards this issue in the US and other developed countries, although they recognise that developed countries aim to maximise the benefits that emerge from biotechnology. [[734]](#footnote-735) For instance, Lin points out that the Moore case ‘grants free reign to the biotechnology industry’ and does not ‘protect a patient-donor's individual liberties and further fails to provide patients with any incentive to allow research’.[[735]](#footnote-736) In other words, despite the fact that there are concerns in developed countries regarding legal decisions, such as the Moore case, developed countries seek to benefit from the inventive activity rather than PIC.

On the other hand, developing countries regulate PIC in more detail and aim to increase and create legal and technical mechanisms in order to keep control over genetic resources. Indeed, as explained in section 1, whereas most developed countries have not enacted legislation or delayed implementation of the ABS in order to create legal and administrative procedures to obtain PIC, developing countries rich in biodiversity have designed, via the ABS regimes, regional and national legislation detailed PIC procedures and mechanisms. These include a national authority, an administrative procedure and the duty of users to disclose all relevant information regarding the scope of the research activity on genetic resources.[[736]](#footnote-737) Again, although the Bonn Guidelines and the NP seek to create legal certainty on this legal and administrative procedure, there is no uniformity among these countries in this matter. For instance, whereas India demands that Indian citizens might be exempted from PIC,[[737]](#footnote-738) if it carries out non-commercial activities over genetic resources, the ACN legislation does not exempt from this requirement any organization or individual;[[738]](#footnote-739) yet Colombia, a member of the ACN, has just enacted a law that allows more flexibility in obtaining PIC for non-commercial activities.[[739]](#footnote-740)

Originators have already criticised the division between commercial and non-commercial as it brings difficulties in defining the nature of each type of use and when there is actually a transition from non-commercial uses to commercial uses. Representatives of this sector who have participated in the Conference of Parties highlight that countries that opt to create two different systems to comply with PIC and MATs need to properly define each of type of research (i.e. commercial or non-commercial) and how PIC and MATs should be obtained in the case that a non-commercial use develops into a commercial one.[[740]](#footnote-741)

Furthermore, the design of checkpoints and IRCC (which has not been fully implemented yet) aims to link regulation on access to genetic resources, disclosure of origin and patent protection, rather than simplifying and creating legal certainty for users of genetic resources.[[741]](#footnote-742) Indeed, there are a few cases reported on disclosure of origin in the ACN which indicate that this legal mechanism has added more legal uncertainty to users of genetic resources in the process of obtaining PIC as it was the lack of clarity in administrative procedures and scope of the MATs that led to users of genetic resources to breach PIC requirements.[[742]](#footnote-743)

That is why users of genetic resources, including originators, and leading scientists such as Cragg and Newman consider that the regulation of access to genetic resources and benefit sharing have overcomplicated R&D activities on genetic resources due to the legal uncertainty of the implementation of the ABS regime in developing countries rich in biodiversity.[[743]](#footnote-744) Indeed, there is evidence that illustrates these difficulties. Eli Lilly and Company claimed that it withdrew a large bioprospective initiative from Cameroon as a result of the overcomplicated process of obtaining PIC from local authorities.[[744]](#footnote-745) The difficulties mainly involved the lack of legal capacity from local authorities on how to obtain PIC and uncertainty of what information should be disclosed. After three years (2007-2009) of legal and administrative procedures, Eli Lilly decided to abandon the initiative due to the legal complications in obtaining PIC.[[745]](#footnote-746) Furthermore, this case has not been the only one in which users of genetic resources complained of the difficulty in obtaining PIC and negotiating MATs with local authorities. Laird and Wynberg reported in a study involving seven different cases of access to genetic resources and benefit sharing, that users of genetic resources face problems in going through PIC and MATs procedures.[[746]](#footnote-747) As there is no legal certainty on PIC and MATs requirements, users of genetic resources could easily end up breaching national or regional legislation on access to genetic resources and benefit sharing (i.e. biopiracy).[[747]](#footnote-748)

Although the lack of implementation of the ABS regime in developed countries is of great concern for developing countries rich in biodiversity and one of the most recent issues that developed countries are facing after the NP, the former has failed to provide any regulation on access to genetic resources and benefit sharing that gives legal certainty to users of genetic resources. As analysed in this section, the implementation of the ABS in developing countries rich in biodiversity has provided evidence of the difficulties of complying with the ABS’s requirements on access and objectives. However, the way that developed countries aim to implement the NP into their national and regional legislation indicates that these countries are trying to fence off their pharmaceutical industry from the ABS regime. The next subsection analyses this aspect.

* 1. **Implementation and Impact of ABS in Developed Countries: Reducing the Impact of ABS Measures through ‘Best Practices’**

One of the outcomes of the Bonn Guidelines was the participation of different stakeholders including originators in the elaboration of those guidelines (see Guidelines 17-21). Ever since the introduction of the guidelines, users of genetic resources (particularly pharmaceutical companies) have demonstrated an interest in taking part in the design of the ABS regime. Indeed, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)[[748]](#footnote-749) and the Biotechnological Industry Organisation (BIO)[[749]](#footnote-750) enacted guidelines for their bioprospecting initiatives in developing countries rich in biodiversity. For instance, the Guidelines for BIO Members Engaging in Bioprospecting makes recommendations on how to conduct bioprospecting initiatives, e.g. identify and contact the focal point before engaging in any research activity in these countries.[[750]](#footnote-751) Although such guidelines are non-binding but rather a catalogue of recommendations on what the best practices are for accessing genetic resources and benefit sharing, they have become a mechanism to influence the design of developed countries’ legislation on access in the light of the obligation to implement the NP in developed countries. For instance, EU has recently enacted a Regulation on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, [[751]](#footnote-752) which implement the NP’s user measures in the EU.[[752]](#footnote-753) However, this regulation did not create any providers measures, hence it is up to each EU country to decide whether or not to adopt separate provider measures. Only a few EU countries are considering implementing provider measures according to the CBD and NP (Bulgaria, France and Spain); yet these countries have not enacted or enforced any legislation or administrative measures.[[753]](#footnote-754)

During the drafting process of the EU Regulation, users of genetic resources (including pharmaceutical companies such as Novartis) submitted comments, which stressed the need to take into account pharmaceutical and biotechnology companies’ best practices. [[754]](#footnote-755) As a result, the EU Regulation has created two important elements based on the industry’s best practices: (1) users and due diligence; and (2) measures of monitoring users’ compliance.

First, on the user and due diligence element, the regulation requires users of genetic resources to exercise due diligence in order to comply with the requirements of the CBD and NP on access to genetic resources and benefit sharing (Article 4). Due diligence is a mechanism to demonstrate that users of genetic resources have made the necessary effort to comply with the regulation on access to genetic resources and benefit sharing. Although Article 4 of the EU Regulation states that users of genetic resources should exercise due diligence in accordance with ABS regulation, users can prove that they have complied with the EU Regulation through best practices set up by users, such as the Guidelines for BIO Members Engaging in Bioprospecting (Article 8).[[755]](#footnote-756)

Although the EU Regulation does not distinguish between users when it demands due diligence to comply with the regulation on access to genetic resources of third party countries, there are different levels of due diligence which depend on the type of user of genetic resources. For instance, Article 5 states that country Members of the EU should consider the registration of collections, which includes institutions such as universities and botanical gardens that collect genetic resources, following the requirements of Article 5.3, e.g. standardise procedures for verification and collection of information on genetic resources. Collections should request EU Members to include a register of the collection in the Union (‘the register’), which is established and maintained by the EU Commission (Article 5.1). The importance of registered collections is the role that these will play in the drug development process. By acquiring genetic resources through a trusted collection, users (that are towards the end of the drug development process) can prove their due diligence (Article 4.7). This indicates that the EU is centralising compliance with the ABS regime through users that interact directly with developing countries rich in biodiversity; hence, users that are at the beginning of the drug development process will have to take the administrative and economic burden of complying with PIC and MATs. Those users are usually botanical gardens, universities or publicly funded organisations.

Second, Articles 6, 7 and 9 of the EU Regulation establish the mechanisms to monitor the compliance of users of genetic resources. Each Member State of the EU should establish a competent authority to oversee that users of genetic resources comply with the Regulation and the NP (Article 6.1.). Moreover, each State should create a national focal point that provides information on PIC and MATs. In order to monitor user compliance, the EU Regulation suggests two mechanisms: (1) Article 7.1 requires Member States and the Commission to request publicly funded researches to comply with due diligence as established by Article 4 of the EU Regulation; and (2) Article 7.2 demands that users should declare to the competent authorities their compliance with due diligence ‘at the stage of final development’.

However, the EU Regulation does not define what is ‘at the stage of final development’ and delegates the EU Commission to ‘determinate the stage of final development of a product in order to identify the final stage of utilisation in different sectors’ such as the pharmaceutical industry (Article 7.6). Yet the EU Commission has not enacted the rules for the implementation of the EU Regulation, therefore the EU has not defined what is the final stage of utilisation in the drug development process. This point is particularly sensitive for originators since this article could indicate what could be the EU Commission policy towards disclosure of origin. This is because the EU has already rejected the inclusion of disclosure of origin in patents as mandatory for patent applicants. In fact, the European Court of Justice has made it clear that EU Members should prioritise EU legislation on patents over CBD dispositions. The controversy lies in whether Recital 27 of the Biotech Directive, which establishes that ‘the patent application should, where appropriate, include information on the geographical origin of such material, if known’, could indicate an obligation to EU Members to adopt disclosure of origin in patents. As the ECJ rules that patentability of genetic resources does not affect the interests of developing countries rich in biodiversity in monitoring and tracking their own genetic resources, Members of the EU should not take those interests into account in the implementation of the Biotech Directive in their national patent legislation.[[756]](#footnote-757) As a result, the applicability of the disclosure of origin should not go against ‘the processing of patent applications or the validity of rights arising from granted patents’.[[757]](#footnote-758)

However, European countries have not consolidated a common position on disclosure of origin. For instance, Belgium, Denmark, Germany and Sweden (all EU Members) as well as Norway and Switzerland (non-EU Members) have implemented disclosure of origin in their national patent legislations.[[758]](#footnote-759)In the case of Germany[[759]](#footnote-760) and Sweden,[[760]](#footnote-761) they have implemented a similar wording to Recital 27 of the Biotech Directive, i.e. disclosure of origin is not mandatory, and neither affects the processing of patent applications nor the validity of rights arising from granted patents. In the meantime, Belgium, in theory, has implemented a formal disclosure of origin,[[761]](#footnote-762) i.e. if the requirement is not met, it will result in the patent not being processed. However, the Belgium patent office, in practice, does not check that applicants meet this requirement.[[762]](#footnote-763)

Nonetheless, Denmark, Norway and Switzerland have not only implemented disclosure of origin in patents but also established administrative fines or criminal sanctions when disclosure of origin is not met.[[763]](#footnote-764) For instance, the Switzerland Patent Act establishes that if there is not a disclosure of the “source” of an invention based upon genetic resources or traditional knowledge associated with genetic resources, the applicant is liable to a fine.[[764]](#footnote-765) Furthermore, Switzerland has even proposed to include disclosure of origin in the PCT of the WTO.[[765]](#footnote-766) In the PCT, a patent applicant can fill one international patent application, and simultaneously seek patent protection in one of the 148 members of the PCT. Switzerland proposes that countries could require the patent applicant to disclose the origin of an invention related to genetic resources and traditional knowledge, when or after the applicant seeks patent protection in one of the members of the PCT; in the event that a patent applicant does not comply with the requirement, members of the PCT would not process the patent application until the requirement has been fulfilled.[[766]](#footnote-767) Yet the PCT has not been amended to include this requirement, and current negotiations on disclosure of origin in the IGC of the WIPO are at a stalemate.[[767]](#footnote-768)

Additionally, the 2009 Norwegian Nature Diversity Act[[768]](#footnote-769) also states that failure to disclose the origin of the source[[769]](#footnote-770) could trigger administrative remedies,[[770]](#footnote-771) coercive fines[[771]](#footnote-772) and criminal sanctions (e.g. imprisonment up to three years).[[772]](#footnote-773) However, the implementation of coercive and binding measures does not mean that those measures are necessarily effective. Indeed, Tvedt and Fauchald have pointed out that in the case of Norway, despite the fact that disclosure of origin is compulsory and there are criminal and administrative sanctions, no cases have been taken before Norwegian authorities.[[773]](#footnote-774)

Therefore, even though there are countries in Europe that have included disclosure of origin in patents, the non-compliance of this requirement does not effectively affect the processing patent application in cases such as Germany, Sweden, and even Belgium. In the cases of Norway, Denmark and Switzerland, there are criminal and administrative sanctions, or fines, but there are no records of cases that have been taken before these countries.

Nevertheless, as established in Article 7.2 of the Regulation, users should prove that they comply with the Regulation by providing information related to the origin of genetic resources ‘at the stage of final development’; Recital 25 of the EU Regulation suggests that the final stage of development could occur in MA. Disclosure of origin in MA offers three elements that are important to discuss: first, the EMA is the EU agency that oversees compliance with user measures when MA is required.[[774]](#footnote-775) This could bring all EU Members to comply with a centralised disclosure of origin in the Union on pharmaceutical products, rather than in EPO (a non-EU organisation). Second, it provides an alternative to the discussion of disclosure of origin in patents that has taken place in different international organisations (IGC, Council for TRIPs and Conference of Parties of the CBD). This has led to a stalemate in the negotiations.[[775]](#footnote-776) If the EU Commission defines MA as the stage of final development, it could provide a common ground for developed countries and developing countries rich in biodiversity to move forward. Third, it will be users of genetic resources, which are towards the end of the drug development process, who will be required to demonstrate compliance. As a result, users that are at the beginning of the drug development process will reduce the burden of disclosure of origin in patents.

However, a great difficulty of the requirement of a disclosure of origin in MA is that it could delay the entry of new medicines that would eventually put at risk patients’ health and life as they could not have access to those medicines, for instance, if there is a claim from a third country on the compliance of the EU Regulation. Although, according to Article 7.6 of the EU Regulation, the EU Commission has to determine what is the final stage of development for medicines based on genetic resources in order to decide whether disclosure might occur, it will be adverse towards public health to consider disclosure of origin in any stage of the drug development if that leads to delay the entry of new medicines into the market.

Finally, the EU Regulation designs a procedure which enables the competent authority to carry out checks to verify if users comply with the Regulation (Article 9). These procedures can take place in two situations: first, the competent authority should carry out periodical checks following a risk-based approach in which States should take into account the best practices to reduce users’ risk of non-compliance; second, the competent authority can also carry out checks when it is in position of having relevant information of non-compliance, which might be provided by a third party, and if such information is provided by a providers country (developing countries rich in biodiversity) ‘special consideration shall be given’ (Article 9.3 (b)) .

On the aspect of mechanisms to monitor the compliance of users of genetic resources, it is important to highlight two elements: (1) again, the EU Regulation does not directly divide users of genetic resources, but it establishes a distinction between publicly funded institutions, which are usually users that collect genetic resources in developing countries rich in biodiversity, and users that aim to commercialise natural-based products according to Article 7; (2) rather than securing compliance with developing countries rich in biodiversity’s legislation on PIC and MATs, the checks of Article 9 of the EU Regulation aim to protect users of genetic resources because Article 9 seeks to reduce the risk of non-compliance based on best practice, which is designed by users of genetic resources themselves. Although third parties might provide information of non-compliance, it is the Commission who will decide whether or not there is non-compliance based on best practices. Although the EU Regulation indicates that States should accept the IRCC as proof of compliance of national legislation, it does not make it compulsory.

The EU has designed a regulatory framework in which users, which are at the beginning of the drug discovery process, bear the administrative and economic burden of complying with the CBD and the NP.[[776]](#footnote-777) The creation of registered collections indicates that users such as originators will comply with due diligence by accessing genetic resources through those collections. Although this regulation will centralise user measures in the EU, it indicates that it will be the first stages of the drug development process in which the user measure of the NP will have more impact.

The EU’s implementation of the NP in Europe indicates that developed countries are focusing on users that are in the first stage of a drug development (e.g. universities and small and medium size companies) to comply with the ABS requirements. This means that the developed countries are trying to fence off users of genetic resources that are towards the end of the drug development process, such as Novartis, from ABS requirements since they will need to prove that they acquired the genetic resources from registered collections and according to the best practices that they have created. This could significantly reduce the interests of users, such as botanical gardens, small labs and universities, to carry out R&D activities on areas rich in biodiversity.

1. **Lessons: Going Forward?**

Section 3 demonstrates that the implementation of the ABS regime is having a greater impact on the first stages of drug development in which developing countries rich in biodiversity could contribute further as these countries are creating different requirements and procedures that overcomplicate access to genetic resources and benefit sharing. Section 3 also indicates that developed countries, such as EU countries, are making users of genetic resources, such as labs, botanical gardens, small biotech companies and universities, comply with ABS, while originators will opt to access genetic resources via registered collections and according to industry’s best practices. This could lead the EU Regulation to jeopardise the EU policies to encourage R&D within the Union. This means that the regulation of ABS will have a larger impact on users such as universities, small labs, botanical gardens, etc.

However, the recent inclusion of provisions that aim to increase capacity building in the NP (Article 22) could provide a different perspective on achieving the objectives of the CBD,[[777]](#footnote-778) particularly the share of the benefits that arise from the utilisation of genetic resources. As concluded in sections 1 and 2, transfer of technology to developing countries rich in biodiversity does not only depend on developed countries’ interest, but also the capacity of the former to adopt legal mechanisms that create the right conditions to access and take advantage of technologies that employ genetic resources for drug development. By focusing on increasing capacity rather than securing control on genetic resources, developing countries rich in biodiversity could improve their capacity to develop their own pharmaceutical industry being able to take advantage of genetic resources. As analysed in Chapter 2, Colombia has only engaged in manufacturing and trading generic medicines rather than taking a more active role in the other stages of the drug development process. This section analyses what the elements are that developing countries rich in biodiversity should observe in order to increase capacity.

* 1. **Facilitating Access and delivering Benefit Sharing**

This chapter identifies that the lack of capacity is an important barrier to developing countries rich in biodiversity having access to technology. However, the increasing levels of legal complexity in these countries has deterred users of genetic resources from transferring technology. This subsection argues that there are some cases in which rules are made more flexible for access (PIC and MATs) have delivered benefit sharing to these countries that have contributed to capacity, yet there are important challenges that need to be taken into account.

The case of Costa Rican INBio provides a significant example of challenges and opportunities to increase capacity for research based on genetic resources. Since Costa Rica pioneered in 1989 with the creation of INBio, this developing country rich in biodiversity has benefited from the interest of users in the exploitation of Costa Rica’s genetic resources.[[778]](#footnote-779) Some of the most important outcomes of INBio have been to identify more than 28% of genetic resources located in Costa Rica, to sign up more than 20 projects with users of genetic resources (e.g. the US pharmaceutical company Merck) (which include transfer of technology, taxonomic activities, etc.) and to ensure that more than 50% of revenues come from bioprospecting projects.[[779]](#footnote-780) In addition, Costa Rica’s government has designed a national strategy on access to genetic resources and benefit sharing which includes a framework of MATs for public universities and research centres in order to facilitate and speed up PIC and MATs procedures. [[780]](#footnote-781)

However, some challenges still remain: first, although INBio has not been able to deliver a commercial product so far, this organisation has already signed up MATs in which have been established different types of benefit sharing that emerge from IPRs, such as royalties or milestone payments; these could only be effective when a product gets into the market.[[781]](#footnote-782) Second, INBio has recently been bailed out by the Costa Rican government as it was unable to self-sustain; yet this was triggered by the fact that INBio amplified its portfolio to activities alien to bioprospecting, such as managing natural parks and educational programmes.[[782]](#footnote-783) Although the lack of commercial breakthroughs and financial viability of INBio could lead to the conclusion that Costa Rica’s policy on access to genetic resources and benefit sharing has failed, it is rather better to take into account the transferable skills, knowledge, and legal and scientific infrastructure that bioprospecting projects have provided to Costa Rica.

Another example of easing rules on PIC and MATs to increase capacity is the agreement between the International Cooperative Biodiversity Groups (ICBG) (a US programme funding) and Panama.[[783]](#footnote-784) The programme was launched with the aim of screening the Panamanian ecosystem and supporting the transfer of technology and knowledge. The project has encouraged capacity with the intention of providing Panama with high quality training and equipment to exploit its own genetic resources.[[784]](#footnote-785) Although this project has not delivered a commercially new biochemical compound yet, the ICBG is carrying out more than eight different projects in Panama in association with universities, museums and research centres in the US;[[785]](#footnote-786) scientists from the US and Panama institutions have also been able to publish more than 82 papers in different journals.[[786]](#footnote-787) The fact that the ICBG has been carrying out R&D on Panama’s biodiversity since 1998 reflects the long-term commitment of both the ICBG and Panama in increasing capacity in this country. The ICBG has also participated in different bioprospective initiatives in other developing countries rich in biodiversity, such as Costa Rica and Indonesia.[[787]](#footnote-788) In Colombia, the Institute Alexander Von Humboldt (a public-private partnership) carries out conservation and sustainability activities (e.g. taxonomy) with the aim of understanding Colombia’s biological and genetic resources; yet the Institute is not legally entitled to perform bioprospecting activities in Colombia.[[788]](#footnote-789)

It is also important to recognise the significance of taxonomy initiatives in developing countries rich in biodiversity. Even though taxonomy initiatives do not necessarily lead to activities related to drug discovery, these countries will benefit enormously from identifying and classifying their own biological and genetic resources, so they can then decide which policy to adopt for improving their capacity.[[789]](#footnote-790)

Developing countries rich in biodiversity should facilitate bioprospecting initiatives’ access to genetic resources as these projects require as many areas as possible to screen and explore. The possibility of obtaining genetic resources, which could lead to important breakthroughs, will therefore be maximised. Such an endeavour would involve the transfer of technology that improves developing countries rich in biodiversity’s capacity by providing training and equipment to local scientists and universities. Indeed, Kursar,[[790]](#footnote-791) Artuso,[[791]](#footnote-792) and Grajal[[792]](#footnote-793) argue that although economic benefits from bioprospecting do not materialise immediately, these initiatives play a key role in increasing capacity, so developing countries rich in biodiversity should make efforts to facilitate access to genetic resources. MATs is also an important tool for bioprospecting initiatives, particularly for issues which are related to the protection of IPRs and benefits that arise from those rights; the next subsection analyses this element.

* 1. **Patenting Genetic Resources and Alternatives in MATs**

Users of genetic resources that access those resources through bioprospecting initiatives pay very close attention to IPRs in MATs. Although issues such as the legality and nature of genetic resources or disclosure of origin remain conflictive as they clash with IPRs provisions in other international treaties such as TRIPs, users of genetic resources aim to frame IPRs within MATs with the aim of (1) establishing clear rules in MATs of how to handle the transfer of technology to developing countries rich in biodiversity; and (2) setting up the conditions for benefit sharing that emerge from the exploitation of genetic resources, particularly IPRs, such as joint patent ownership, milestone payments, share of royalties and licensing of technologies.

For instance, the ICGB has set up a series of principles regarding MATs and IPRs.[[793]](#footnote-794) Principle 2 mentions that bioprospecting projects sponsored by the ICBG should be clear on what information, knowledge and technology is to be shared with developing countries at the moment to obtain PIC and negotiate MATs. In the same way, Principle 3 establishes that users and developing countries rich in biodiversity should negotiate terms and conditions of IPRs that emerge from the utilisation of genetic resources case-by-case. Similar principles have been established by other organizations such as BIO and PhRMA.[[794]](#footnote-795)

It is clear that users of genetic resources, such as the ICBD, BIO and PhRMA, will not give up on securing exclusivity via patent protection on technologies that employ genetic resources for the exchange of genetic resources. These users of genetic resources would rather not access genetic resources in a specific country if their IPRs are not protected. This points out that developing countries rich in biodiversity are better off opting to trade off access to genetic resources with access to technology via MATs, rather than creating legal obligations in ABS legislation. This necessarily requires that developing countries rich in biodiversity protect users’ patents on technologies that employ genetic resources and grant patents on these technologies as they could set up agreements in the same way that benefit sharing can be obtained through the exploitation of patents, as has occurred with INBio.

The lessons are, therefore, that access and benefit sharing should be negotiated on a case-by-case approach, securing transparency and legal certainty in each step to obtain PIC and negotiate MATs. In the case of Costa Rica, it is worth mentioning that its national strategy on biodiversity is in accordance with its policy on access and benefit sharing which identifies countries’ capacity in technologies that employ genetic resources. On IPRs, these countries should consider approaching patents in a more constructive way by granting patent rights and obtaining their protection locally. This also demands that developing countries rich in biodiversity ensure that they reach clear terms and conditions in MATs on how to access technology through the drug development process (e.g. licensing, joint ownership, etc.).

Therefore, this section identifies that developing countries rich in biodiversity should increase capacity in technologies that employ genetic resources by (1) making policies on access to genetic resources more flexible, including how to obtain PIC and reach MATs; and (2) allowing and facilitating patents on genetic resources as well as developing negotiation skills in MATs.

**Conclusions**

Under the umbrella of the conservation of biological diversity and sustainable use of its components, the ABS has entitled developing countries rich in biodiversity to trade off access to genetic resources for access to technology. This trade-off is the result of a bargain between developing countries rich in biodiversity and developed countries as the former is granted property rights over genetic resources, despite the fact that they do not carry out any intellectual labor. As a result, the wording of ABS has provided different mechanisms in which developing countries rich in biodiversity link access to genetic resources with benefit sharing. Indeed, developing countries rich in biodiversity have implemented at the national and regional level different procedures and mechanisms to secure control over access to genetic resources, such as the nature of genetic resources and PICs’ procedures as well as demanding benefit sharing, including the transfer of technology.

This requires that developing countries develop capacity in different areas. For instance, developing countries rich in biodiversity should increase capacity to identify and distinguish naturally occurring genetic resources and the technologies that employ those genetic resources in order to define whether users of genetic resources should go through PICs in order to access genetic resources or negotiate in MATs instead. In the case of PIC procedures, the different situation and requirements (e.g. trans-boundary situations, traditional knowledge associated with genetic resources, non-commercial research) demand that developing countries rich in biodiversity create clear and transparent legislation that provides legal certainty to users to carry out R&D in their territory. Finally, developing countries rich in biodiversity should also gain capacity in how to negotiate benefit sharing that will lead them to encourage a pharmaceutical industry able to take a more active role in the different stages of the drug development process.

However, users of genetic resources and developed countries do not compromise on technology transfer as a mandate established by the ABS. They highlight that access to genetic resources and benefit sharing should be exclusively the result of negotiations between IPRs, holders of technology and developing countries rich in biodiversity. For developed countries and users of genetic resources, the ideal mechanism to reflect this policy is through MATs, which offer enough flexibility to decide the terms and conditions required to negotiate how the transfer of technology can take place and how IPRs should be handled.

The impact of the implementation of the ABS regime on developing countries rich in biodiversity illustrates that this international framework has affected R&D on genetic resources in developing countries rich in biodiversity, reducing the possibility that these countries could obtain the benefits that arise from the utilization of genetic resources in order to increase capacity in their own pharmaceutical industry. This means that it is the lack of capacity which is a barrier for these countries to obtain the benefits that arise from the utilization of genetic resources, rather than patents. The distributive nature of the ABS regime seems to have created a burden on developing countries rich in biodiversity because they do not assess their own capacity in order to create legal mechanisms that increase it.

In the case of developed countries, although users still consider that genetic resources are a very important source for drug development, the recent EU Regulation of the implementation of the ABS regime in Europe and different ‘best practices’ set up by users indicate that developed countries are setting up a policy in which it is the users that interact directly with developing countries rich in biodiversity through, for instance, bioprospecting initiatives, who will incur the economic burden by complying with developing countries rich in biodiversity’s legislation. This situation is problematic as these users are usually publicly funded organisations, universities and small companies rather than large pharmaceutical companies. Indeed, the landscape in Europe is that pharmaceutical companies such as Novartis or AstraZeneca will gain access to genetic resources via registered collections rather than taking a more active role in bioprospecting initiatives in developing countries rich in biodiversity.

Yet, the inclusion of articles related to capacity in the NP and the examples of flexible legislation and institutional strength in developing countries rich in biodiversity, such as Costa Rica’s INBio and Panama’s ICBG, highlight the importance of facilitating access to genetic resources and engaging users of genetic resources with these countries via MATs, so that it can be decided using a case-by-case approach, how the transfer of technology and IPRs should be handled. This will increase capacity according countries’ strengths and weaknesses in the utilisation of genetic resources. Nevertheless, such a policy demands that both developing countries and developed countries become involved in long-term policies that provide legal certainty to users of genetic resources and adequate access to technology to boost capacity.

However, developing countries rich in biodiversity should not only face the challenge to facilitate and encourage R&D on genetic resources, but also to implement patent legislation that could lead to the involvement of local pharmaceutical companies, universities and laboratories in the drug development process. On the issue of disclosure of origin in patents, although disclosure of origin in MA provides an important alternative to unlock the stalemate in the ICG and the Council for TRIPs, the EU Regulation is unclear on the scope of disclosure and how this could eventually lead to delay to the entry of new medicines in the Union; yet, as the EU Commission will implement the EU Regulation, there will be more opportunity to analyse the actual scope of disclosure of origin in MA or any other stage of the final development. Another mechanism to unlock the stalemate is to implement a formal requirement of disclosure of origin in patents, as proposed by Switzerland in the PCT and Belgian legislation, which would not lead to criminal and administrative sanctions, or fines, but instead uphold the processing of a patent application until the requirement is met. However, the EU, in Recital 27 of the Biotech Directive, along with EU Members that have already implemented this Recital (Germany and Sweden), has created a non-mandatory requirement that does not affect the patent application or processing.

Having analysed the ABS regulation and concluded that developing countries rich in biodiversity have faced different problems in the implementation of the ABS into national and regional legislation, the next chapter analyses in particular how the implementation of both TRIPs and the ABS regime in Colombia has reduced the interest of users of genetic resources, including publicly funded institutions, to take a more active role in technologies that employ genetic resources rather than increase capacity in the utilization of those resources.

Chapter 5: Lessons for Colombia

**Introduction**

This thesis analyses the regulation on access to technology (i.e. IPRs) and access to genetic resources (the ABS regime) of developing countries rich in biodiversity, particularly China, India and Colombia, in the light of technologies that employ genetic resources for drug development. In order to carry out such an analysis, three elements have been considered: the capacity of the selected developing countries rich in biodiversity in the drug development process, the pharmaceutical global market, and genetic resources. These three elements are in line with the thesis’ theoretical framework, i.e. an analysis of the ABS regime and IPRs on genetic resources according to Locke’s and Rawls’ social contract theories. This framework is complemented by an assessment of countries’ capacity which is based upon Nussbaum’s capability approach.

As a result, Chapters 1 and 2 assess countries’ capacity on their pharmaceutical industry. Such an assessment allows us to understand the global market shift in the pharmaceutical industry in which developed countries employ exclusivity protection, especially patents, to incentivise originators to invest in further R&D.[[795]](#footnote-796) In the meantime, India and China, which used to produce and distribute illegal generics, are promoting and taking over generic production globally. These two countries have employed IPRs’ flexibilities (e.g. compulsory licensing) for protecting their generic industries. IPRs, including patents, do not give absolute rights to the intellectual labour that adds value, but patent legislation does allow countries to use IPRs’ flexibilities in particular situations, such as access to medicines.

However, China’s increased investment in R&D on genetic resources, particularly in traditional Chinese medicine, and in patent filings locally and abroad, illustrates that this country aims to take a share of the generic market, but also to participate more actively in R&D on genetic resources. It is also important to note that as China and India have a large availability of genetic resources, they also create legal mechanisms to control access to them in order to obtain the benefits that arise from their utilization. LDCs are not studied in depth, but analysis of these countries’ capacity illustrates how they are filling the gap for illegal generics left by China and India, as they can waive TRIPs on pharmaceutical products up to 2016 due to their economic and social conditions.

Chapter 2 highlights that the importance in analysing Colombia dwells in its availability to provide genetic resources for drug development and the interest of this country to employ genetic resources for drug development in order to increase capacity. Indeed, Colombian authorities have highlighted the importance of employing genetic resources for drug development in increasing the country’s capacity.[[796]](#footnote-797) For instance, the government has pointed out in a White Paper that biodiversity is important in order to develop a pharmaceutical industry capable of taking advantage of Colombia’ biodiversity for drug development.[[797]](#footnote-798) Additionally, Chapter 2 finds that international trade is also a crucial point for Colombia’s pharmaceutical industry as this country does not only aim to implement TRIPs standards, but it also provides higher standards of exclusivity protection via TRIPs-Plus. This means that although Colombia has accepted implementing TRIPs and TRIPs-Plus provisions, which deny this country the possibility of producing and distributing illegal generic resources, it cannot compete on similar terms with countries such as China and India for a share of the global market. Indeed, the Colombian pharmaceutical industry is insignificant when compared with, for example, that of India. The Colombian generic pharmaceutical companies in 2011 exported around US$ 380,000 million, compared with Indian generic pharmaceutical companies that exported US$ 7.2 billion in the same year.[[798]](#footnote-799) This situation makes Colombian pharmaceutical companies vulnerable not only to developed countries’ originators, but also those pharmaceutical companies located in China and India. This is due to the fact that Colombia has created contradictory policies on access to technology and access to genetic resources since it is in the interests of Colombia to gain access to developed countries’ markets via TRIPs and TRIPs-Plus provisions, rather than obtaining benefits that would arise from the utilisation of genetic resources in order to increase capacity. As a result, Colombia’s generic industry has focused on distributing and manufacturing generics and originators under licensing agreements with little regard given to increasing R&D on genetic resources for drug development.

Consequently, Chapters 3 and 4 have studied the international legal framework that has an impact on developing countries rich in biodiversity’s capacity for drug development, especially Colombia, and how these countries implement that international framework locally. Chapters 3 and 4 focus, therefore, on TRIPs and the ABS regime respectively. Chapter 3 concludes that, for the particular case of Colombia, this country has prioritised access to international trade over access to technology as it has already compromised on high standards of protection via TRIPs and TRIPs-Plus, which restrict the use of flexibilities such as compulsory licensing. Therefore, Colombia should implement and employ TRIPs substantive standards on patents (e.g. patent requirements) comprehensively on genetic resources in order to increase capacity. This is because Colombia already provides greater exclusivity via patent protection and data exclusivity to originators, but it creates barriers to obtaining patents on genetic resources and to local users of genetic resources who access genetic resources. For instance, Chapter 3 finds that the ATJ has denied patent protection on isolated and purified DNA sequence as this is excluded from patentability according to Article 15 (b) of the Decision 486; additionally, the ATJ also denied patent protection based upon ethical considerations since the invention was an isolated gene from a human.[[799]](#footnote-800) Chapter 4 goes on to point out that, despite the ABS regime having entitled developing countries rich in biodiversity such as Colombia to trade genetic resources for access to technology, they have failed to do so because they have failed to create legal certainty to users of genetic resources. In other words, Colombia has enacted legislation that affects the users of genetic resources, including local institutions, rather than securing a trade-off of genetic resources for access to technology.

Therefore, the analysis in Chapter 5 centres on Colombia’s implementation of TRIPs, TRIPs-Plus and the ABS regime. It includes a legal assessment of the ACN’s IPRs and regulation of access to genetic resources (Colombia is part of this regional organisation and ACN’s legislation is enforceable within its territory) in order to analyse their impact on Colombia’s capacity. Therefore, it focuses on the way that the ACN, and particularly Colombia, has implemented TRIPs and the ABS regime (i.e. Decisions 391 and 486, respectively). By discussing the strengths and weaknesses of the Colombian legal framework, it is possible to identify scope for a more effective approach to regulating which will meet the capacity of Colombia’s pharmaceutical industry. This approach is in line with those conclusions on Colombia’s capacity studied in Chapter 2.

Indeed, Chapter 2 suggests that if Colombia aims to increase capacity through the utilization of genetic resources for drug development, then it ought to centre on the following three important aspects: since Colombia has enacted legislation which aims to provide patent protection to pharmaceutical products and processes, it should facilitate further patent protection on genetic resources in order to encourage R&D with local users of genetic resources; Colombia should also facilitate access to genetic resources for both local and overseas R&D activities in order to attract, for instance, bioprospecting initiatives which might lead to the transfer of technology; and, Colombia should clarify its policy on R&D on genetic resources by implementing an ABS legislation that creates legal certainty to users of genetic resources.

As a result, this chapter is divided into two parts. The first part analyses two main points: current Colombian patent legislation (Decision 486), and the implementation of TRIPs and TRIPs-Plus standards, and the implications of this legal framework for the Colombian pharmaceutical industry and R&D on genetic resources. This part concludes that since originators are granted patent protection on pharmaceutical products and other forms of exclusivity protection (e.g. data exclusivity), they have gained a competitive advantage over local generic pharmaceutical companies. However, the implementation of TRIPs and TRIPs-Plus provision has not led to increase R&D on drug development in Colombia. The second part focuses on the legislation on access to genetic resources (Decision 391), and how its implementation has created legal uncertainty, particularly within local labs, publicly funded institutes, universities and research centres. This chapter identifies that such a situation has occurred because this Andean country has not articulated a legislation that could lead it to encourage an innovative activity based on Colombia’s genetic resources.

On the one hand, the ACN sought to create a common and unified position on patents that could have protected the local industry. Colombia used to grant patents on technologies, such as chemical synthesis of natural resources. For instance, the Act of 15 May of 1848 and eventually Act 35 of 1869 granted patent protection to machinery, industrial processes and applications that were not merely a variation of an object (Articles 1 and 2 of Act 35 of 1869). The patent term was between 5 and 20 years (Article 3).[[800]](#footnote-801) However, patenting on chemical inventions was amended by the ACN which enacted Decision 85 of 1974. This Decision restricted patents on pharmaceutical products and introduced flexible mechanisms that reduce patent exclusivity (e.g. compulsory licensing) in order to encourage and protect its members’ pharmaceutical industries (Articles 4 (b) (c), 28, 30 (a) and 34). Although this position remained during the 1980s, Member States of the ACN (particularly Colombia) opened their economies to international trade under the regulation set up by the WTO. Such a situation led the ACN to modify its patent legislation according to TRIPs,[[801]](#footnote-802) rather than keep restrictions over patents on pharmaceutical products and flexibilities, as was originally established by the ACN itself. Even though at first ACN patent legislation aimed at protecting the local pharmaceutical industry, the ACN renounced the restriction of patents on pharmaceutical products as its members sought to enter into developed countries’ markets via international trade. Moreover, Colombia has already signed up to FTAs with the US and the EU which expands the scope of patent protection and limits the use of TRIPs’ flexibilities. [[802]](#footnote-803) These bilateral trade agreements are known as TRIPs-Plus.[[803]](#footnote-804)

On the other hand, Colombia, as well as the ACN, has set up a policy over its biodiversity that consists of the ‘strategic value’ of genetic resources that could lead to obtaining benefit sharing from the exploitation of genetic resources.[[804]](#footnote-805) As a result, the ACN has created the first regional legislation (Decision 391) on access to genetic resources. Decision 391 underlines the strategic value of genetic resources as a legal mechanism that does not only aim to obtain benefit sharing from the exploitation of genetic resources, but also should strengthen Andean countries’ bargaining position on patents over technologies that employ natural genetic resources.[[805]](#footnote-806) Indeed, although Decision 391 implements the ABS regime, it has gone beyond in terms of extending the scope of the regulation on access to genetic resources in patents by, for instance, implementing disclosure of origin.[[806]](#footnote-807)

However, both approaches have failed to encourage R&D on genetic resources in Colombia. Although Colombia has developed a pharmaceutical industry capable of manufacturing generic medicines, thanks to the lack of patent protection before the country joined the WTO, Andean regulation on access to genetic resources and patents has not had a major impact on R&D on technologies that employ natural genetic resources for drug production. Indeed, as analysed in Chapter 2, innovation in the pharmaceutical industry has not grown, despite the fact that Colombia and the Andean region controls 20% of the world’s biodiversity.[[807]](#footnote-808) Universities, research institutions and publicly funded institutions have also failed to take advantage of Colombian genetic resources because of the complexity of the legislation on access to genetic resources and patents. In fact, one Colombian public university has been in breach of the Andean regulation on access to genetic resources as a result of the extensive and complicated process of obtaining that access, and has had a patent revoked.[[808]](#footnote-809) This is particularly worrying since the Colombian pharmaceutical industry is not capable of competing with developed countries in the same way that China and India have done.[[809]](#footnote-810)

Decisions 391 and 486, concerning patents and access to genetic resources, are part of the ACN legal system. The ACN is a regional organisation which aims to form a common Latin-American market in order to compete with other countries (particularly developed countries) and to negotiate *en bloc* within international institutions such as the WTO.[[810]](#footnote-811) The ACN is currently comprised of Bolivia, Colombia, Ecuador and Peru.[[811]](#footnote-812) The ACN Acts or Decisions are legally and automatically binding to ACN State Members and do not require further local legal procedures to be enforceable, but they might need to be harmonized with national legal systems by State Member authorities (e.g. the President or local parliament).[[812]](#footnote-813)

The organisation of ACN is led by the State Members and the Andean System of Integration or SAI (Spanish acronym).[[813]](#footnote-814) The SAI is comprised of different Andean institutions that promote the integration of the Andean region as a whole or key industry or sectors (e.g. banking, agro industry, etc.).[[814]](#footnote-815) The institutions of the SAI that define policies and legislation on IPRs and access to genetic resources are: (i) the Andean Presidential Council (led by the Presidents of each State Member), the top decision making body of ACN which sets up the policies of integration;[[815]](#footnote-816) (ii) the Andean Council of Ministers of International Affairs that coordinates the common international agenda on issues that affect the common market, such as the negotiation of international trade with the WTO;[[816]](#footnote-817) (iii) the Commission, the Executive body of the SAI, whose main role is to implement through Decisions the policy of integration of the common market;[[817]](#footnote-818) and (iv) the ATJ that interprets the Andean legislation to ensure that it is applied uniformly by Member States via the following: pre-judicial interpretation; actions for annulment against an Andean law that might be in opposition to the Andean legislation; actions against Member States or SAI institutions for failure to act according to the Andean legislation and labour actions; as well as serving as an arbitral tribunal for SAI institutions and contractual disputes among parties that employ Andean legislation in private contracts.[[818]](#footnote-819) Having defined the main features of the ACN, the legislation which has an impact on the capacity of the Colombian pharmaceutical industry requires analysis.

1. **The Patent Legislation for Pharmaceutical Products in the ACN and Colombia**

Although Colombia has large areas rich in biodiversity, patent legislation does not play a fundamental role in rewarding the intellectual labour that adds value to genetic resources for this country. Chapter 2 highlights that patents and IPRs in general are part of a list of requirements that Colombia has to fulfil in order to gain trade with developed countries. For instance, in 2012 before the US-Colombia FTA was implemented, Colombia’s President Juan Manuel Santos passed through the Colombian Congress different reforms on IPRs (including copyright provisions and plant variety protection) in a record time of less than one month.[[819]](#footnote-820) In contrast, any Bill introduced by the Government to the Colombian Parliament usually takes at least one year.[[820]](#footnote-821) The influence of US in IPRs is due part that this country is Colombia main trade partner (25.7 % of Colombian exports goes to the US);[[821]](#footnote-822) and as it was analysed in Chapter 3, the US has influenced IPRs legislation through international trade.[[822]](#footnote-823) This means that patent legislation is not decided by Colombia itself but by multilateral organisations such as the WTO and developed countries, especially the US. Furthermore, as explained in Chapter 2, Colombia (under pressure from the US) has paid more attention to the improvement of the safety and quality of generic medicines than encouraging R&D on genetic resources for drug production.[[823]](#footnote-824) The influence of international organisations and countries on the ACN has diminished the possibility of creating a coherent and comprehensive patent legislation that could take advantage of Andean biodiversity. This is because, despite the fact that the ACN has aimed to consolidate a common position in IPRs in multilateral organisations such as the WTO,[[824]](#footnote-825) the implementation of TRIPs has led to the dilution of the Andean common position on patents. For example, as analysed in the next subsections, Andean countries have conflicting ideas on how to implement some legal mechanisms, such as second indications on pharmaceutical products.

Yet, the local generic pharmaceutical industry, which has been greatly affected by TRIPs, has still campaigned to reduce the scope of patent protection in Colombia. However, Colombian generic pharmaceutical companies do not lobby to obtain a legal framework in which they could be encouraged to invest in R&D, but rather to reduce the competitive advantage that a patent provides to developed countries’ pharmaceutical companies. Indeed, as discussed in the following subsections, although patent reforms in the ACN have not had a positive impact on encouraging R&D on technologies that employ genetic resources, they have led patent legislation to become a competitive battleground between Colombians and originators.

In this controversy between national and developed countries’ pharmaceutical companies, Colombia (and consequently the ACN) has agreed to amplify patent protection according to TRIPs. Certainly, Decision 486 (which encapsulates the current ACN legislation on patents) implements most of the TRIPs provisions on patent protection on pharmaceutical products, compulsory licensing and data exclusivity. Furthermore, the FTA between the US and Colombia has implemented further exclusivity beyond TRIPs standards in Colombia. For instance, Colombia, under pressure from the US, has provided up to five years of data exclusivity protection on pharmaceutical products, despite the fact that Decision 486 and TRIPs do not require any length of protection. This section analyses the implementation of TRIPs through Decision 486 in Colombia, the influence of TRIPs-Plus in that process of implementation, and the implications for the Colombian pharmaceutical industry.

* 1. **No Patents and No R&D: Decision 85 of 1974**

The ACN’s IPRs legislation used not to recognise patent protection on pharmaceutical products and was flexible on the use of compulsory licensing and working requirements.[[825]](#footnote-826) During the negotiation of the first IPRs’ common legal framework of the ACN, Members concluded that patents had given developed countries a competitive advantage in the pharmaceutical market in the Andean sub-region, thus affecting local industries and technological development as originators located in developed countries did not manufacture locally, but imported pharmaceutical products.[[826]](#footnote-827) The ACN Members’ common position on the technological disparity and competitive disadvantage with developed countries was recapitulated by the ATJ as follows:

*Lack of sufficient autonomous development of the chemical and pharmaceutical industry resources, since among other things [developing countries] should import raw materials that incorporate a high technological level, these [developing] countries cannot cope with an open world market, with competition likely to succeed. This situation that consolidates and increases this dependence, in general terms, to the detriment of the few available comparative advantages, such as cheap labour and unskilled production and, in general, other raw materials (mainly natural resources)*

*(…)*

*In such circumstances, these [developed] countries may not be interested in facilitating greater diffusion of technology and know-how (a reason often given in defence of technological monopolies) while in reality not in a position to assimilate and apply.* (Translation by the author) [[827]](#footnote-828)

This means that the ACN recognised the technological disparity between its Members and developed countries, and the difficulty to compete with originators, particularly if the ACN had granted patent exclusivity on pharmaceutical products and reduced patent flexibilities (e.g. compulsory licensing). This led ACN Member States to promulgate Decision 85 of 1974 in which pharmaceutical products were excluded from patentability,[[828]](#footnote-829) while compulsory licensing[[829]](#footnote-830) and working requirements[[830]](#footnote-831) were flexible. This led to a proliferation of local generic pharmaceutical companies in Colombia that were able to produce illegal generics from the 1970s without paying royalties to patents holders located in developed countries.[[831]](#footnote-832) However, Decision 85 did not lead local generic pharmaceutical companies to invest in R&D; this makes Patarroyo’s failed malaria vaccine the most significant breakthrough in drug development in Colombia under Decision 85.[[832]](#footnote-833) As concluded in Chapter 2, the ACN was more concerned at that time with securing the flow of technology to local companies which were able to imitate and adapt in order to supply local and regional demand for medicines, [[833]](#footnote-834) rather than the utilisation of genetic resources for drug development.

* 1. **Obtaining Patents and Exclusivity, but no R&D**

Whereas TRIPs negotiations were conducted in the Uruguay Round at the beginning of the 1990s, the ACN shifted its patent policy by gradually implementing (via three consecutive Decisions: 311 of 1991, 313 of 1992, and 344 of 1993) the TRIPs standards.[[834]](#footnote-835) Primarily, the ACN decided to remove the patent exclusion on pharmaceutical products, a provision that had been maintained in the Andean region for almost two decades.[[835]](#footnote-836) This legal amendment took place at first in Decision 311 of 1991, although Article 7 (d) permitted the exclusion of patentability medicines which were included in the list of essential medicines of the WHO.[[836]](#footnote-837) This disposition remained in Article 7 (d) Decision 313 of 1993 and Article 7 (e) of Decision 344 of 1993.

Decision 486 finally removed any patent exclusion of pharmaceutical products, even for public health reasons, in order to comply with Article 65 of TRIPs in which members of the WTO were obliged to implement TRIPs’ patents’ standards by the year 2005.[[837]](#footnote-838) However, patents on pharmaceutical products were not the only significant changes in the Andean community; the current legislation of Decision 486 also brought different mechanisms that have strengthened the ability of originators to obtain exclusivity protection ahead of Colombian industries. Those mechanisms are: limits to compulsory licensing and working requirements, and implementation of data exclusivity protection.

As explained in Chapter 3, the chemical and pharmaceutical industries have played a fundamental role in reducing the scope of compulsory licensing and working requirements.[[838]](#footnote-839) Those legal instruments used to be employed by governments in developed countries, such as Canada, the US, the UK and France, to reduce the monopoly of patent holders in order to force patent holders to manufacture locally (working requirements) or facilitate local producers to manufacture inventions regardless of patent holders’ rights – hence securing access to technology.[[839]](#footnote-840) Articles 28 and 31 of TRIPs reduced the scope of compulsory licensing and working requirements.[[840]](#footnote-841) Even though Article 31 of TRIPs allows Members of the WTO to issue compulsory licences, countries cannot discretionally employ compulsory licensing; for instance, if a WTO member wants to issue a compulsory licence, the patent authority has to prove that it has already made efforts to reach an agreement with the patent holder but has been unsuccessful. Article 28 establishes that working requirements can be met by importing.

Colombia, along with the other ACN State Members, has gone down a similar path. Decision 85 established a period of three years in which to exploit the invention locally, otherwise the local patent office could issue a compulsory licence.[[841]](#footnote-842) Compulsory licensing was not limited to working requirements, but also enabled the licensing to be implemented by local governments to protect public health or economic development.[[842]](#footnote-843)

With the implementation of TRIPs in the Andean Community, the scope of compulsory licensing and working requirements was reduced. For example, although Article 60 of Decision 486 establishes that patent holders should exploit the invention in the Andean Common Market, the working requirement can be met by importing.[[843]](#footnote-844) On issues related to compulsory licensing on the grounds of public interest, Articles 65-68 of Decision 486 also follow Article 31 of TRIPs; yet those articles allow Members of the ACN to determine what public interest is and how a compulsory licence should be issued. For instance, the Colombian Presidential Decree 4302 of 2008[[844]](#footnote-845) creates a procedure for the declaration of public interest, which requires the concept of what constitutes public interest in particular cases by a technical committee (integrated by agents of the government).[[845]](#footnote-846) However, ASINFAR, the national pharmaceutical industry’s lobby group, has complained that Decree 4302 does not comply with TRIPs (including the Doha Ministerial Declaration) and Decision 486, because the decree does not make it clear if public health, particularly the issue of access to medicines, constitutes grounds for a declaration of public interest.[[846]](#footnote-847)

ASINFAR has been concerned by the fact that the inclusion of the concept of ‘public health’ in Decree 4302 has not reduced the scope of compulsory licensing in favour of originators. Indeed, there has been only one case regarding compulsory licensing of pharmaceutical products in 2008. In this case, the government ruled out the granting of the compulsory licensing of the drug Kaletra (an antiretroviral drug to treat HIV/AIDS). The Colombian government found that the national health insurance system secured access to this medicine, despite the fact that local generic companies pointed out its high cost for insurance companies and the Colombian health system.[[847]](#footnote-848) Clearly, ASINFAR aimed to put pressure on the Colombian government to have a similar outcome to that of Indian pharmaceutical companies in 2012 when the Indian government issued a compulsory licence not only to protect public health, but also its national generic industry. [[848]](#footnote-849) However, the Kaletra case appeared at the time when Colombia was going through a negotiation process of an FTA with the US. As explained in Chapter 2, the US has influenced Colombian IPRs policy through trade.[[849]](#footnote-850) Therefore, it was no surprise that the Colombian government did not issue a compulsory licence for Kaletra. [[850]](#footnote-851)

Yet, this has not been the only time when Colombia has sided with US originators rather than their national industry. Data exclusivity protection has been a very contentious issue, not only in Colombia but also in the Andean sub-region. It has been particularly difficult since Article 39.3 of TRIPs set out guidelines, but has not been drafted in a mandatory form;[[851]](#footnote-852) compliance with minimum standards has created difficulties in the implementation in Colombia and the ACN.

Article 39.3 does not protect innovation itself, but the efforts to collect data for MA in pharmaceutical products from unfair commercial use.[[852]](#footnote-853) Article 266 of Decision 486, with a similar wording to Article 39.3 of TRIPs, establishes that any collected, undisclosed data or test, which are the result of an effort employed to obtain MA for a new biochemical compound, should be protected against any improper commercial use. Neither TRIPs nor Decision 486 establishes a period of time for undisclosed data or test protection or particular rules for their implementation.

However, Colombia, via Decree 2085 of 2002, makes mandatory the protection of undisclosed data and sets up a period of five years of protection after MA has been granted to new biochemical entities. [[853]](#footnote-854) Decree 2085 was the result of a legal battle between local and overseas pharmaceutical companies in Colombia. Originally, Decree 677 of 1995 allowed generic companies to use tests and data to obtain MA.[[854]](#footnote-855) As a result, AFIDRO, the Colombian lobby group of originators, and the US put pressure on Colombia to implement data exclusivity protection.[[855]](#footnote-856) AFIDRO took Colombia before the ATJ for not implementing Article 266 of Decision 486 into Colombian legislation and allowing generic companies to use undisclosed data for MA.[[856]](#footnote-857) AFIDRO’s claims were mainly based on the fact that this constituted an anti-competitive practice.[[857]](#footnote-858) Additionally, the US, the main Colombian trade partner,[[858]](#footnote-859) put pressure on Colombia to legislate on this issue via Decree 2085.[[859]](#footnote-860) As Colombia issued Decree 2085, AFIDRO dropped its claims before the ATJ.[[860]](#footnote-861)

However, in 2004 ASINFAR took Colombia before the ATJ for the opposite grounds given by AFIDRO in 2002, i.e. Decree 2085 gave exclusivity protection to pharmaceutical products beyond Decision 486 and TRIPs.[[861]](#footnote-862) ASINFAR claimed that Article 266 of Decision 486 is to protect data from unfair commercial exploitation (an anti-competitive practice) not a product itself.[[862]](#footnote-863) ASINFAR concluded that such a mechanism did not protect competition but restricted the entry of generics, thus affecting generic competitors and public health.[[863]](#footnote-864) The ATJ found that Colombia did not comply with the Andean regimen on IPRs as it had created a new term of exclusivity for a product, which Article 266 of Decision 486 did not establish; the ATJ ruled that Colombia should derogate Decree 2085.[[864]](#footnote-865)

Nevertheless, as the first drafts of the US-Colombia FTA had already established protection on data exclusivity,[[865]](#footnote-866) Colombia proposed an amendment to Decision 486 that would allow Colombia to implement data exclusivity protection without infringing the Andean IPRs regime.[[866]](#footnote-867) In 2006 the ACN enacted Decision 632 which basically overthrew the ATJ ruling and allowed Colombia to maintain Decree 2085.[[867]](#footnote-868)

However, Colombia has not always sided with originators and has resisted adopting other legal mechanisms that aim to extend patent protection on medicines, particularly second indication. Second indication provides patent protection over a second use or indication of a product that has already been granted patent protection.[[868]](#footnote-869) Article 21 of Decision 486 clearly states that patents over second indications or use of an already patented product or procedure are not allowed.

However, the implementation of this disposition at the national level has been problematic. Indeed, the case of Viagra by Pfizer illustrates how difficult it has been to implement Article 21 of Decision 486 in the ACN. Pfizer tried to obtain a patent on a second indication patent of *Pirazolipirimidinomas* which wascommercialised under the name of Viagra in all ACN countries.[[869]](#footnote-870) The first indication on this product was to treat cardiovascular infections and the second was to treat dysfunctional erections.[[870]](#footnote-871) Although Decision 486 indicates that there should not be patents on second uses, Ecuador, Venezuela[[871]](#footnote-872)and Peru granted patents on *Pirazolipirimidinomas* to treat dysfunctional erection. As a result, the Secretary of the ACN took all three countries before the ATJ. The tribunal ruled that the ACN legislation was clear in excluding second indication as it was established not only by the Andean legislation on patents but also in the preparatory works that led to its final wording.[[872]](#footnote-873) Regarding Colombia, its patent office followed the ATJ ruling and did not grant a patent on Pfizer’s second indication;[[873]](#footnote-874) such a decision was upheld by the Colombian Council of State in 2008.[[874]](#footnote-875)

The implementation of TRIPs and TRIPs-Plus provisions in Colombia by Decision 486 is a competitive battle between originators and Colombian pharmaceutical companies, rather than a discussion about how to increase capacity on R&D on Colombia’s genetic resources. National pharmaceutical companies have not invested in R&D for drug production, despite the fact that these companies could access technology without recognising patent protection as Decision 85 did not grant patent protection to pharmaceutical products.[[875]](#footnote-876) Furthermore, the number of granted patents for nationals on biotechnology and pharmaceutical products is 27 and 34 times respectively, less than for non-Colombians.[[876]](#footnote-877) However, originators, which have welcomed the adoption of TRIPs and TRIPs-Plus standards,[[877]](#footnote-878) have invested discreetly in R&D. AFIDRO has reported that its members have only invested around US$ 24 million in R&D between 2000 and 2006, particularly on clinical trials.[[878]](#footnote-879) Similarly, Espicom has found that no pharmaceutical companies (originators or generics) invest in R&D activity in Colombia for drug development.[[879]](#footnote-880) The Colombian pharmaceutical industry, as also explained in Chapter 2, has basically been transformed into a manufacturing sector in which patent legislation is employed as a mechanism of competitive advantage but not of capacity for drug production.

This indicates that Colombian authorities have been unable to deliver an effective policy that rewards R&D through patents, despite the fact that the Colombian government has mentioned that encouraging R&D on Colombian genetic resources for drug development is an important pillar for its pharmaceutical policy.[[880]](#footnote-881) What this analysis illustrates is that Colombia has traded off the policy of its pharmaceutical industry in order to comply with bilateral trade agreements, so this country could have access to international trade, particularly with the US. This means that Colombia’s IPRs has centred on granting and securing exclusivity for originators, but not encouraged R&D on genetic resources. Furthermore, local generic companies did not take advantage of Decision 85 (no patents on pharmaceutical products and flexible use of compulsory licensing) to increase capacity on R&D for drug development. Instead, local generic pharmaceutical companies still campaigned to maintain flexibilities or reduce the scope of patent protection and data exclusivity, but with no regard to R&D. Chapter 2 concluded that since Colombia has enacted legislation which aims to provide patent protection to pharmaceutical products and processes, it should facilitate further patent protection on genetic resources in order to encourage intellectual labour from users of genetic resources, including local ones. This is particularly relevant since the Colombian government, including the Colombian patent office or *Superintendencia de Industria y Comercio* (SIC), has created different initiatives to encourage publicly funded institutions such as universities and research centres to file for patents in key sectors including biotechnology. Indeed, since 2010 the SIC has been training universities, research centres, and small and medium sized companies on different aspects of the Colombian and international patent legislation, from introducing basic concepts in patents to how to fill and redact a patent application.[[881]](#footnote-882) Although patent applications for local residents remain comparatively low against patent applications for non-Colombians, there has been an increase on patent applications. Indeed, in 2000 there were only 75 patent applications for Colombians and 1694 for non-Colombians, but in 2013 there were 251 patents applications for Colombians, but 1781 for non-Colombians.[[882]](#footnote-883) This means that although patent application for non-Colombians increased by 5.13% between 2000 and 2013, Colombian patent applications increased by 235% during same period of time. This illustrates the interest of Colombia in encouraging R&D by facilitating patent protection for Colombians.

However, the regulation on access to genetic resources (Decision 391) and articles related to access to genetic resources of Decision 486 have created legal uncertainty among local labs, research centres and universities regarding obtaining patent protection on genetic resources in Colombia. The next section analyses those provisions from Decisions 391 and 486, and the impact on users of genetic resources, especially local ones.

1. **Focusing on Access: The Andean Regulation on Access to Genetic Resources in Colombia**

As mentioned above, the ACN has highlighted the technological and competitive disparity in the pharmaceutical markets between developed and developing countries.[[883]](#footnote-884) Section 1 analyses how the ACN tried to balance that disparity by excluding patents on pharmaceutical products and reducing the exclusivity rights of patent holders (e.g. compulsory licensing and working requirements). However, the interests of ACN countries (and particularly Colombia) to trade with developed countries have led these countries to have little manoeuvring room for implementing a policy in which they could improve the pharmaceutical industry’s capacity.

With 20% of the global biodiversity concentrated in countries of the regional organisation, the ACN has tried to create a policy to control access to their genetic resources in order to secure benefit sharing, and particularly access to technology.[[884]](#footnote-885) Different policy documents from the Colombian Minister of Environment and other governmental authorities, have stressed that genetic resources have a ‘strategic value’ that would enable the Andean region and Colombia to obtain benefits that arise from the exploitation of their genetic resources.[[885]](#footnote-886) As a result, the ACN enacted Decision 391 in 1996 with the aim of strictly controlling access to genetic resources.

Decision 391 implements the ABS regime and establishes the general guidelines for regulation on access to genetic resources and benefit sharing for each Member of the ACN. Gomez-Lee[[886]](#footnote-887) and Hernandez[[887]](#footnote-888) have praised Decision 391 as a coherent mechanism to counteract biopiracy and secure benefit sharing in the light of technologies that employ natural genetic resources for drug development in the ACN and Colombia. Furthermore, Decision 391 has even gone beyond the ABS regime as it has been able to create, for instance, a ‘legal bridge’ between legislation on access to genetic resources and patents by implementing disclosure of origin as a substantial requirement to obtain a patent.[[888]](#footnote-889) However, the implementation of Decision 391 in Colombia has led this country to create legislation which focuses almost exclusively on controlling access rather than benefit sharing. The Institute Alexander Von Humboldt,[[889]](#footnote-890) a research centre specialising in Colombian biodiversity, and Nemogá[[890]](#footnote-891) have criticised the implementation of Decision 391 as it has led Colombia to enact a regulatory framework that has deterred the country’s capacity from obtaining benefits from the utilisation of genetic resources rather than encouraged it. This section studies the ACN legislation on access to genetic resources, the implementation of this legal framework in Colombia and the impact that it has had on technologies that employ genetic resources.

* 1. **Decision 391, its Implementation in Colombia and Biological Resources**

Colombian legislation on access to genetic resources and benefit sharing is primarily based on Act 165 of 1994, which adopted the CBD, and Decision 391 which created a common regime on access to genetic resources for the Andean sub-region.[[891]](#footnote-892) Resolution 620 of 1997 implements the CBD and Decision 391 in Colombia. Additionally, this regulatory framework has been interpreted by two tribunals: the Constitutional Court and Council of State. The resolution regulates the procedure for access to genetic resources and benefit sharing in Colombia, whereas the Constitutional Court and the Council of State have tried to harmonise the CBD and Decision 391 within the Colombian legal system. Also, Decision 486 states that patent legislation should be applied in accordance with Decision 391.[[892]](#footnote-893)

Similarly to Articles 3 and 15 of the CBD,[[893]](#footnote-894) Article 5 of Decision 391 is based on the concept of sovereignty over genetic resources;[[894]](#footnote-895) hence, the access and exploitation of genetic resources is determined by the State. Article 6 of Decision 391 also mentions that genetic resources are property that belongs to the ACN members according to their own legislation; yet, they are inalienable. In other words, the regulation on access to genetic resources is under the sovereignty of States (Article 5) and, as a result, Article 6 establishes that genetic resources are subject to a property regime in which ACN members could ensure that those resources are not transferable.

The Colombian Council of State, one of the highest tribunals in the country, has interpreted these dispositions by decreeing that genetic resources are public property which cannot be subject to other property regimes, particularly the property regime on renewable natural resources, in which biological resources are included.[[895]](#footnote-896) The CBD highlights that biological resources and genetic resources involve two different legal obligations: biological resources entail an obligation of conservation and sustainable use; genetic resources are related to appropriate access to genetic materials.[[896]](#footnote-897) Decision 391 regulates access to genetic resources but not biological resources. The property and access regime for biological resources is established according to the rules of each member of ACN.[[897]](#footnote-898) In the case of Colombia, biological resources are regulated by the 1974 National Codex of Renewable Resources and Protection of Environment.[[898]](#footnote-899) Although, in principle, renewable resources are also public property, the Colombian legislation allows private property over those resources.[[899]](#footnote-900) However, for the Council of State, this is not the case for genetic resources which are public property, inalienable, and not subject to prescription or seizure.[[900]](#footnote-901) Furthermore, Decision 391 establishes the primacy of regulation on access to genetic resources over biological resources as the latter can be subject to Decision 391 if there is any activity that involves access to genetic resources, regardless of the property regime of the biological resources.[[901]](#footnote-902)

The difference in property regimes between genetic resources and biological resources is also relevant in terms of carrying out research on them. Even though biological resources contain genetic resources, research activities on biological resources are not subject to access to genetic resources and benefit sharing regulation (Article 2 of Decree 309 of 2000). In the case of Colombia, research activities into biological resources are regulated by Decree 309 of 2000. The objective of this regulation is to encourage the conservation and sustainability of biological resources, but not to control access to genetic resources and benefit sharing.[[902]](#footnote-903)

As Decree 309 regulates the activities of conservation and sustainability, it is more flexible than Decision 391; for instance, publicly funded research institutions can carry out research activities (e.g. collection and classification of biological species) without governmental authorisation.[[903]](#footnote-904) However, as discussed in subsection 2.3, the division between biological and genetic resources has raised concerns that both regulations do not draw a clear line when research involves only sustainability and conservation activities or access to genetic resources; such a situation has brought research centres and scientists in Colombia to the edge of legally breaching the dispositions of Decision 391. Furthermore, there are also other provisions that over-complicate R&D on genetic resources; these include extra requirements in patents (e.g. disclosure of origin), amplification of the scope of the nature of genetic resources and reducing the scope of patent protection on genetic resources. The next subsection analyses these elements.

* 1. **Building a ‘legal bridge’ between Access to Genetic Resources and Patents**

As genetic resources are considered to be public property and inalienable, Colombia has also set up three different legal mechanisms which means that the regulation on access to genetic resources prevails over patents on genetic resources. These mechanisms are: (1) extending the scope of Decision 391 over technologies that employ genetic resources, (2) creating a legal bridge between Decisions 391 and 486 by implementing disclosure of origin, and (3) strengthening patent requirements on genetic resources.

First, the scope of Decision 391 includes both genetic resources *in situ* and even derivatives, which do not include functional units of heredity. Therefore, For instance, Decision 391 includes by products and synthesised products.[[904]](#footnote-905) This means that Colombia aims to incorporate derivatives within the scope of regulation on access to genetic resources in order to include the technologies that employ genetic resources.[[905]](#footnote-906)

Second, disclosing origin plays a fundamental role in creating a legal bridge between patent legislation and access to genetic resources. Article 22 of Decision 391 makes it mandatory for users of genetic resources to disclose any information that involves genetic resources (including derivatives) in Mutually Agreed Terms (MATs) (the contract between the State and users which allows access to genetic resources).[[906]](#footnote-907) Decision 391 also includes administrative sanctions, fines, seizure, and civil and criminal sanctions for those users that do not disclose information related to genetic resources (Articles 46 and 47). Additionally, Article 26 (h) of Decision 486 requires any patent application that involves genetic resources to include MATs; otherwise the patent should not be granted (articles 38 to 49) or if granted, the patent office should decree the absolute invalidity of a patent at any time after the patent was granted (Article 75 (g) of Decision 486).

Such requirements make the legislation on disclosure of origin very strict as it does not only make it mandatory for users of genetic resources to disclose any information that involves genetic resources, as well as creating a legal bridge between Andean patent legislation and Andean legislation on access, but it also imposes different sanctions to users of genetic resources ranging from administrative sanctions to criminal and civil prosecution.

Third, as discussed in Chapter 3, Article 15 (b) of Decision 486 excludes from patent protection any products of nature, even if they are isolated, including ‘the genome or germ plasma’. Although developed countries have allowed patents on isolated genetic resources that have gone through some technical intervention or markedly different from naturally occurring one, the ATJ has interpreted this exclusion of natural products to include isolated genetic resources that are not completely different from the natural source on which they are based, regardless of any technical or substantial intervention.[[907]](#footnote-908) However, as discussed in Chapter 3, the exclusion of Article 15 (b) of Decision 486 is not distant from the US Supreme Court of Justice’s ruling on BRCA1 and BRCA2 which does not grant patents on isolated genes as they do not represent anything particularly different from the naturally occurring ones; yet, the Supreme Court of Justice upholds patents on complementary DNA (cDNA) as these were produced in a lab.[[908]](#footnote-909) However, the ATJ ruling does not only exclude isolated genes from patent protection according to Article 15 (b) of Decision 486, but also on ethical grounds because the isolated genes come from humans.[[909]](#footnote-910) Additionally to these three points, the Constitutional Court of Colombia has stated that in the case of technologies that employ genetic resources, the Andean legislation on access to genetic resources prevails over patents.[[910]](#footnote-911) However, this does not mean that the Andean legislation excludes all inventions related to genetic resources, but only those which are simply isolated, come from humans[[911]](#footnote-912) or do not comply with the ABS regime in the ACN. In other words, genetic resources that come from plants, animals and microorganisms in Colombia, which are not simply isolated but have been created in labs could be patent subject matter within the Andean legislation, as long as they comply with the ABS regulation.

On these aspects of patents and regulation on access to genetic resources, it is also important to mention that for Colombia it has been imperative to include legal mechanisms in the FTA with the US which ensure, in the case of a patent being granted over genetic resources, that this should take into account Decision 391. Indeed, although the US is not part of the CBD, it reached an agreement with Colombia (in a side letter to the main text of the FTA) that both parties should observe the regulation on access to genetic resources in the implementation of this trade agreement.[[912]](#footnote-913) Although scholars are still discussing whether the side letters of the US are binding,[[913]](#footnote-914) it proves that Colombia has managed to include at least some provisions into the FTA that could make Decision 391 prevail over patent legislation set up by TRIPs-Plus provisions. Furthermore, the FTA between the EU and Colombia and Peru has also established similar compromises to those established in the US-Colombia FTA, i.e. the parties should observe the ABS regime and the Andean regulation on access to genetic resources.[[914]](#footnote-915) On disclosure of origin in patents, the EU- Colombia and Peru FTA is not required to adopt this legal mechanism, but acknowledges its ‘usefulness’ in creating a more transparent mechanism of protection of countries’ genetic resources; yet there is nothing in the text of the treaty that suggests that the EU will create further patent requirements in the Union.[[915]](#footnote-916) Indeed, as discussed in Chapter 4, the EU Commission has recently implemented a Directive on the Regulation on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, in which is included a mechanism for the disclosure of origin; yet, the European Commission will define the nature and scope of disclosure of origin in the Union.[[916]](#footnote-917) Overall, the EU proposal aims to create users’ measures in accordance with the ABS regime (especially the NP) as the EU and its Members are parties to the ABS regime and have participated actively in the negotiations of these international instruments.[[917]](#footnote-918) This is why the EU- Colombia and Peru FTA included this within the main text rather than in a side letter, while the US is not part of the ABS regime.

However, these three legal mechanisms have not led to increase R&D, patents and MATs in Colombia, but just over-complicated the research on access to genetic resources. As analysed in section 2.4, the inclusion of regulation on access to genetic resources in the Andean patent legislation and the US-Colombia FTA is one of the elements in why Decision 391 does not provide an effective way to secure benefit sharing, but deters R&D on genetic resources.

* 1. **Decision 391: the Procedure**

Having analysed the substantive issues of Decision 391 in subsections 2.1 and 2.2, it is also important to analyse the practicality of the procedure of the Andean regime on access to genetic resources. In order to obtain access to genetic resources, Decision 391 has established a procedure that concludes with MATs between the user of genetic resources and a local authority, which is selected by each member of the ACN. In the case of Colombia, the local authority that is legally authorised to oversee this procedure and sign up to MATs on behalf of the State, is the Ministry of Environment.[[918]](#footnote-919)

Articles 16 and 17 of Decision 391 establish three steps in this procedure: (1) admission and formal review of the user’s application; in this part, the local authority should examine whether the applicant fulfils formal requirements such as a description of the access activities, a template of MATs, identification of the user, localisation of the area in which the access will take place, etc.;[[919]](#footnote-920) (2) publication and public registration of the user’s application; once the first step has been approved, the application should be registered in a public registration office (*Registro Público de Acceso a Recursos Geneticos y Productos Derivados*); the registration should also be published in a national newspaper;[[920]](#footnote-921) and, finally, (3) evaluation and negotiation of MATs;[[921]](#footnote-922) the final text of MATs should include the mechanisms of benefit sharing (although neither Decision 391 nor Resolution 620 mentions what these mechanisms are), the disclosure of origin and any relevant information, etc. [[922]](#footnote-923)

Although Decision 391 has set up deadlines for admission and formal review (15 days), the publication and public registration of the user’s application (which has an original deadline of 90 days) can be extended indefinitely by the local authority, and there is no deadline for the evaluation and negotiation of MATs.

* 1. **The (Un)expected Consequences?**

Although Decision 391 is the first regional regulation on access to genetic resources and benefit sharing, it has failed to enable the Andean sub-region, in particular Colombia, to develop not only an innovative pharmaceutical industry, but any innovative sector which employs genetic resources (e.g. chemical, agriculture, etc.). For instance, Colombia had approved and signed up only one MATs document in 2004, despite the fact that Decision 391 has been enforced since 1996; by 2011 the number of MATs was only 45 in total according to the Ministry of Environment.[[923]](#footnote-924)

Furthermore, although Decision 391 aims to encourage benefit sharing from the commercial exploitation of genetic resources, information collected through Colciencias’ database (the national agency for innovation and sciences) found that only 1% of the research on genetic resources might end up in a commercial product or process.[[924]](#footnote-925) Duarte and Velho point out that research on genetic resources is mainly carried out by governmental organisations and universities; and yet the participation of business (e.g. pharmaceutical and cosmetic companies) is almost insignificant.[[925]](#footnote-926) Duarte and Velho also illustrate that out of 193 scientific articles on research into Colombian genetic resources, only three had the participation of the private sector.[[926]](#footnote-927) This clearly undermines the country’s capacity to obtain benefits that arise from the utilisation of their own genetic resources.

In addition, the same study points out that there is only one case which could potentially be commercially exploited, i.e. the invention is a biopolymer extracted from a microorganism (*Lactococcus*) found in Colombia on which there was a patent application over the process to extract the biopolymer and the product for pharmaceutical use.[[927]](#footnote-928) The National University of Colombia (Spanish acronym UNC) (the largest publicly funded university in the country) and other public and private organisations have invested around US$ 1.6 million on research into this biopolymer and patent fees in Colombia, Europe, Japan and the US.[[928]](#footnote-929)

However, the Colombian Ministry of Environment is carrying out an investigation into the UNC for breaching Decision 391. The legal complexity and ineffectiveness of Colombian authorities in this particular case require further analysis. In 2001 the UNC filed an application for access to genetic resources before the Ministry of Environment on a biopolymer extracted from a microorganism.[[929]](#footnote-930) The application was filed as an academic project rather than a commercial one as the UNC was in the earliest stages of the research; hence there was no certainty about a possible commercial application.[[930]](#footnote-931) Although the UNC had not signed up to MATs at that time, it decided to carry on with the research due to its importance while the application was being studied by the Ministry of Environment.[[931]](#footnote-932) In 2002, the UNC found a potential commercial use for the biopolymer, decided to file for a patent and immediately communicated this to the Ministry.[[932]](#footnote-933)

Between 2002 and 2006, the UNC and governmental authorities exchanged approximately 18 communications and documents, and set up different working groups and committees to verify that the application met the requirements of Decision 391 and Resolution 620.[[933]](#footnote-934) In 2006 the Ministry decided to deny the application for the commercial use of the biopolymer as the original application did not specify commercial use (although the wording of Decision 391 and Resolution 620 does not indicate any legal difference); as a result, the Ministry required the UNC to file for a new application.[[934]](#footnote-935) The UNC responded that commercial arrangements were already on the way (e.g. the patent application was already filed) and recommended continuing with the original application, and indicated that other aspects such as benefit sharing could be discussed.[[935]](#footnote-936) Representatives of the UNC and the Ministry met and exchanged documents to establish a new methodology for the research, change the scope of the application and set up new benefit sharing arrangements.[[936]](#footnote-937) In 2007 a technical concept from the Economic Working-Group of the Ministry found that the project of benefit sharing was not clear enough.[[937]](#footnote-938) The same year a Technical Working-Group of the Ministry recommended prosecuting the UNC for illegally accessing genetic resources and asked the UNC to start a new application from the very beginning.[[938]](#footnote-939) By the end of 2007, the Ministry of Environment officially opened a criminal investigation into the UNC.[[939]](#footnote-940) In 2010, the Ministry imposed a fine on the UNC for illegally accessing genetic resources.[[940]](#footnote-941) The UNC appealed against the fine and is still waiting for a decision; it has also filed a new commercial application before the Ministry of Environment.[[941]](#footnote-942) However, the Colombian patent office denied the patent for not meeting the requirements of Decision 391.[[942]](#footnote-943) The patent office decision was based solely on the fact that there were no MATs enclosed in the patent application. In 2013, the Ministry of Environment granted MATs on the commercial application, but the criminal investigation is still pending and there has not been a new patent application.[[943]](#footnote-944) To sum up this point, it has taken about 12 years for a publicly funded university to unsuccessfully carry out a long, uncertain and complex legal procedure on a research that could have represented some commercial and academic significance in genetic resources for Colombia. Undoubtedly, the most alarming outcome of this case is that the research institution in charge of the project was a public university rather than an originator.

However, the Colombian government aims to solve the legal uncertainty and low numbers of granted MATs through different legal mechanisms. For instance, Decrees 1375 and 1376 of 2013 seek to facilitate access to genetic resources for non-commercial research by easing the requirements of PIC and MATs.[[944]](#footnote-945) Furthermore, in 2011, a government White Paper called upon the Ministry to ease access by increasing capacity in the process of granting MATs through measures such as reducing evaluation and negotiation periods.[[945]](#footnote-946) As a result, although the Ministry did not grant any MATs in 2012, it subscribed to 37 MATs in 2013 and 12 MATs by August 2014. This indicates that the number of MATs has increased dramatically when compared with the period 1996-2011 (i.e. 45 MATs). Furthermore, in 2014 the Ministry, in a performance and accountability report, has also highlighted that the average time to reach MATs with users of genetic resources is seven months.[[946]](#footnote-947)

Nevertheless, a closer look at the actual content of all MATs indicates that most of these are related to basic research (e.g. taxonomy activities). Only 10 MATs are linked to a particular industry, i.e. agroindustry (4),[[947]](#footnote-948) chemistry (3),[[948]](#footnote-949) and pharmaceutical (3). In the particular case of the pharmaceutical industry, the MATs include the case of the *Lactococcus* and the UNC (explained above), a research on a plant (*Asteraceae*) that aims to find an inhibitory substance for infection in-vitro for rotavirus and astrovirus (which cause diarrhoea), and a bioprospecting project for the discovery of new natural product for medicines and cosmetics. In the case of *Asteraceae*, the MATs were granted to a professor of the Javeriana University of Colombia in November 2013, but no commercial benefit or patents has been reported yet. On the bioprospecting project, this is a joint venture between the Santander Industrial University and the National Investigation Centre for the Agroindustrialisation of Aromatic Vegetates Tropical Medicines, CENIVAM (Spanish acronym). As the MATs for this bioprospecting were only granted in June 2014, there have been no research or commercial results yet.

Additionally, the SIC has tried to ease the requirement of disclosure of origin in patent applications. As mentioned in subsection 2.2, if a patent does not disclose information related to the origin of genetic resources, it should not be granted or, if granted, the SIC should decree its invalidity according to Articles 26 (h) and 75 (g) of Decision 486. In the case of the UNC and *Lactococcus*, the patent office did not grant a patent because the UNC was unable to enclose MATs in the patent application. In order to prevent users of genetic resources from breaching Andean legislation, the SIC is giving 60 days to users of genetic resources to enclose MATs in the patent application in case they have not done so at the moment they filed a patent application, as established by Article 45 of Decision 486. Article 45 states that the patent office could request the patent applicant to correct their application within 60 days if the patent office finds that the patent application is not patentable or does not fulfil any of the Decision 486 requirements.

As a result, the SIC has recently been requesting users of genetic resources to enclose MATs with correct patent applications within 60 days. For instance, the Technological University of Pereira filed for a patent application on the development of primers from the genome of the *Boroja Patinoi Cuarecasas* (Borojo) employed to identify the sex of plant species at an early stage of development, particularly in the Borojo plant.[[949]](#footnote-950) Although the plant specie is originally from the Choco/Darrien region (see Annex III), the university did not enclose MATs. In 2011, the SIC requested the university to enclose MATs within 60 days.[[950]](#footnote-951) The university responded to the SIC request by pointing out that it had been carrying out the process of obtaining MATs since 2008 from the Ministry of Environment but nothing had been decided.[[951]](#footnote-952) As a result, the SIC did not grant the patent.[[952]](#footnote-953) In February 2015, the SIC requested to enclose within 60 days MATs and clarify some aspects regarding claims of a patent applications which consist of molecular markets to identify fatty acid in plants, particularly in the palm specie *Elaesis Oleifera*.[[953]](#footnote-954) According to the SIC patent database, the applicant submitted a document on 22 of May 2015 witch clarify some specific claims but it did not enclose MATs within 60 days;[[954]](#footnote-955) hence, it is expected that the SIC will eventually not grant the patent, as occurred with the Borojo case. Although both cases illustrate the interest of the SIC to facilitate patents and users of genetic resource to obtain patents on genetic resources, the 60 days to correct the requirement of disclosure of origin in a patent does not match the seven months average time to reach MATs by the Ministry of Environment. In other words, SIC’s efforts to allow users of genetic resources to correct patent applications within 60 days when MATs are not enclosed seem to be ineffective as the average period to reach MATs is seven months. Therefore, Colombia could propose an amendment in Article 75 (g) of Decision 486 to implement a less strict disclosure of origin in which patent applications are not either rejected or invalid, but instead they are not processed until MATs are reached and enclosed.[[955]](#footnote-956)

Although Decrees 1375 and 1376 of 2013, the increase in the number of MATs in the last three years and the interests of users of genetic resources and the SIC to seek and grant, respectively, patents on genetic resources, illustrate some improvement, there are important elements that should be taken into account. For instance, as concluded in Chapter 4, developing countries rich in biodiversity need first to be capable of underlining the differences between non-commercial and commercial research, rather than creating new requirements or exceptions which over-complicate access to genetic resources; this with the aim that in the event that a non-commercial research turns into a commercial one, users of genetic resources should not be compelled to go through a new procedure to obtain different MATs. Otherwise, non-commercial researches could eventually be invalidated as they turn into a commercial one, as occurred in the UNC case analysed above.[[956]](#footnote-957)

Although originators have been accused by Gomez-Lee and Posada et al. for illegally accessing and patenting genetic resources for drug production, such as Yagé (Colombian plant to treat psychiatric disorders) and Paico (native plant to treat stomach related diseases), there is not a single criminal investigation or a patent revocation against overseas companies.[[957]](#footnote-958)

The ineffective implementation of Decision 391 via Regulation 620 and the Ministry of Environment’s decision are not the only problems of legal uncertainty for publicly funded or non-profit research institutions. There are also problems of interpretation of the current legal framework on access to genetic resources that are edging R&D activities towards illegality in Colombia. Indeed, Chaparro and Vanegas illustrate another particular problem of the implementation of Decision 391.[[958]](#footnote-959) As mentioned in subsection 2.1, Decree 309 of 2000 allows publicly funded research institutions to carry out research activities on biological resources without governmental authorisation. However, Chaparro and Vanegas find that three publicly funded research institutions have breached Decision 391 in at least 28 research projects that have involved access to genetic resources, since these institutions were carrying out research activities on what they assumed was under the scope of Decree 309 rather than Decision 391.[[959]](#footnote-960)

Additionally, Chaparro et al. carried out a study into the research activities of genetic resources of 957 research groups registered in Colciencias.[[960]](#footnote-961) They found that out of 565 potential research projects on access to genetic resources, the research groups have only signed up 21 MATs. Chaparro et al. concluded that the reason why research groups, even publicly funded ones, do not go through the procedure established by Decision 391 and Regulation 620, is that those groups ignored the possibility that their research might fall within the scope of the legislation on genetic resources.[[961]](#footnote-962)

The problems of the effectiveness and illegality of Colombian research activities in the light of Decision 391 and Resolution 620 clearly illustrate that Colombia has excessively focused on securing control over the access of genetic resources by creating a complex, uncertain, long and complicated legislation that has not even been complied with by publicly funded institutions. The Humboldt Institute claims that this legal framework and the Ministry of Environment have failed to give insights of clarity on aspects such as the difference between regulation on access to genetic resources and biological resources, the concept of genetic resources and derivatives (in which there is no a single decision on the scope of these concepts), and deadlines set up by Resolution 620.[[962]](#footnote-963)

Hoare & Tarasofsky argue that the breach of regulation on access to genetic resources is the result of the extensive and complicated process that a research project needs to go through in order to be granted MATs that allow it to obtain access to Colombian genetic resources.[[963]](#footnote-964) Decision 391 and Resolution 620 have only over-complicated the access to genetic resources and have deterred benefit sharing in Colombia. As analysed in Chapter 1, regulations on R&D in developed countries have succeeded as they aim to provide legal frameworks that encourage R&D through exclusivity rights. In the case of Colombia, policy makers have not only failed to encourage the national industry to carry out R&D activities on genetic resources, but have also led users of genetic resources towards illegality and biopiracy.[[964]](#footnote-965)

**Conclusions**

Decisions 391 and 486 have not encouraged pharmaceutical companies, research centres, universities and labs to carry out R&D on Colombia’s genetic resources. This is reflected primarily in the low numbers of patents filed by nationals and the low number of MATs subscribed to in research related to drug development in Colombia.

In the case of patents, Colombia went from no protection to broad protection on pharmaceutical products in order to obtain benefits from international trade. This means that its pharmaceutical dynamic in patents has centred on making patents a competitive mechanism through which developed countries’ originators aim to enter into the Colombian market ahead of local producers. In the meantime, the Colombian pharmaceutical industry seeks to maintain some provisions that restrict exclusivity on pharmaceutical products (e.g. second indication) to protect generic manufacturing, rather than making patents an instrument for benefit sharing. Both overseas and local pharmaceutical companies have not significantly become involved in R&D on Colombian genetic resources for drug development.

On the ABS regulation, Colombia (and the other Andean countries) aim to employ legislation on genetic resources (Decision 391) to obtain the benefits that arise from the exploitation of genetic resources and to strengthen their bargaining position on patents in two specific ways: (1) by making regulation on access to genetic resources prevail over other property regimes, such as regulation on biological resources and patents; and (2) by including a safeguard on biodiversity in TRIPs-Plus dispositions (particularly the FTAs with the US and the EU). Although Colombia might claim that the Andean regime on access to genetic resources provides an effective way to secure benefit sharing, in reality it has done the opposite, i.e. deterring R&D on genetic resources and benefit sharing.

The Andean legislation has not only made it difficult to obtain a patent for genetic resources, but it has also led research institutions, even public ones, towards illegality and biopiracy, as happened unwittingly with the UNC. Although Decision 391 is an important step to recognise the role that developing countries rich in biodiversity should have in the drug development process, it has been ineffective because it largely focuses on controlling the access to genetic resources rather than on benefit sharing. Colombia and originators should make a case for benefit sharing rather than simply access.

In order to make a case for benefit sharing, Colombia should explore different avenues within the wording of TRIPs (including TRIPs-Plus), the ABS regime and the Andean legislation. This is in line with the conclusions reached in Chapter 2. As Chapter 2 analysed Colombia’s capacity in its pharmaceutical industry, three important elements should be taken into account from that analysis: Colombia should consider providing further patent protection on genetic resources, facilitating access to genetic resources to both local and overseas users, and creating legal certainty in its ABS regulation.

First, as Chapters 2 and 5 have analysed, since Colombia provides a greater level of patent protection to pharmaceutical products and processes, there is room to evaluate further options within patents for local users of genetic resources. The increasing number of MATs illustrates the interest of local users of genetic resources in actually employing genetic resources as well as the interest of the SIC to improve patent protection on genetic resources. As a result, Chapter 5 particularly explores second indications and limits to the exclusion of Article 15 (b). On second indications, this type of patent seeks to protect second use or indication of a product that has already been granted patent protection. However, Article 21 of Decision 486 clearly establishes that patents over second indications or use of an already patented product or procedure are not allowed in the Andean Community. This has also been ratified by the Colombian patent office, the Council of State and the ATJ in the Viagra case. Additionally, second indications do not necessarily lead to increased capacity in R&D on genetic resources since second indications target existing biochemical entities, rather than potentially new ones that could come from Colombia’s genetic resources. Regarding Article 15 (b) of Decision 486, this provision states that genetic resources, even if they have been isolated, cannot be patentable subject matter. Although the exclusion of Article 15 (b) of Decision 486 can be constructed in a way that excludes all inventions related to genetic resources, this Article does not necessarily oppose what developed countries have established regarding patents on genetic resources. Indeed, the US Supreme Court of Justice’s decision on BRCA1 and BRCA2 did not grant patents on isolated genes since those gene sequences were found to be no different from the naturally occurring ones; but the Supreme Court did not overthrow patents on complementary DNA (cDNA) because the inventor could prove that the cDNA was actually produced in a lab. However, the ATJ ruling does not only exclude isolated genes from patent protection according to Article 15 (b) of Decision 486, but also on ethical grounds since the invention was from an isolated gene from a human. As a result, genetic resources that come from plants, animals and microorganisms and are not simply isolated but have been created could be patent subject matter within the Andean legislation as long as they comply with the ABS regulation, particularly disclosure of origin. Therefore, Colombia could facilitate further patent protection on genetic resources without being in breach of Article 15 (b) of Decision 486.

Second, in the case of ABS, there is a need to increase capacity in national authorities on how to regulate and oversee access to genetic resources, and reach MATs (which contain specific benefit sharing agreements). By facilitating and simplifying requirements on access to genetic resources, users of those resources (especially the locals) could easily gain access to them.

Third, in order to facilitate access to genetic resources, it is important that Colombia creates legal certainty in users of those resources. This approach includes five important elements:

1. Adopting a single PIC procedure for both biological and genetic resources. As analysed in section 2.4, according to Decree 309 of 2000, which regulates access to biological resources, publicly funded research institutions can access biological resources without PIC. Nevertheless, there are publicly funded research institutions that are in breach of Decision 391 because they assumed that the research that they carried out was under the scope of Decree 309 rather than Decision 391. A single procedure to obtain PIC for both biological and genetic resources could ease access and avoid confusion among users of genetic resources on which PIC procedure they should carry out;
2. Simplifying the nature of genetic resources (hence, technologies that employ genetic resources are negotiated in MATs). Subsection 2.4 concludes that the Ministry of Environment has not clarified the concept of genetic resources and derivatives. In fact, there is no a single decision on the scope of these concepts in Colombia, which could create difficulties to reach MATs since each case of access could vary depending on the actual use that users of genetic resources give to those resources;
3. Centralising MATs through organisations that have the capacity to negotiate the scope of these agreements. Subsection 2.4, also points out that the Ministry of Environment led the UNC to be in breach of the regulation on access to genetic resources because it over-complicated the negotiation process. An alternative to this is to legally entitle an organisation that actually has the capacity to define the nature of genetic resources and to negotiate with users of genetic resources to provide support to the Ministry in granting PIC and reaching MATs
4. Considering the removal or easing of disclosure of origin in patents. It is clear that the Andean legislation has created a very strict legislation on disclosure of origin that not only demands users to disclose any information related to genetic resources, but also creates a legal bridge between patents and the regulation on access, as well as criminal, civil and administrative sanctions for those who failed to disclose the origin of the genetic resources. The problem with the strict legislation on disclosure that is in place in Colombia is that it has already affected two publicly research funded universities (UNC and University of Pereira) as they did not obtain a patent due to the difficult process of obtaining MATs. However, there are positive signs from the Colombia patent office which seeks to ease this legal requirement by allowing users of genetic resources that did not reach MATs in the original application to enclose MATs within 60 days; yet, the seven months average to obtain MATs from the Ministry of Environment makes it difficult for users of genetic resources to correct the patent application. A disclosure of origin requirement that does not invalidate or deny a patent, but it does not allow the processing of a patent until MATs are reached and enclosed, could also be an alternative in Colombia; and
5. Not creating new requirements that over-complicate access to genetic resources (e.g. different procedures for non-commercial and commercial activities). Subsection 2.4 highlights that recently the Colombian government has enacted two decrees (Decrees 1375 and 1376) which facilitate access to genetic resources for non-commercial research. However, such provisions could create further legal uncertainty since it is difficult to draw a line where it can be decided when research is non-commercial and when it is commercial.

These legal mechanisms might require amendments to Decisions 391 and 486 in the Andean community, and Colombian legislation (i.e. Decrees 1375 and 1376 and Resolution 620) as well as a different interpretation by the ATJ on the Andean legislation. These different elements are assessed and discussed in depth in the next chapter.

Discussion and Conclusions: Obtaining Benefit Sharing by Facilitating Access to Technology and Access to Genetic Resources

1. **Discussion**

This thesis focuses on the ABS regime and TRIPs and the impact of both regulations on technologies that employ genetic resources for drug development in developing countries rich in biodiversity, especially in Colombia. As a result, this thesis carries out a normative analysis of the ABS regime and TRIPs through focusing on three important elements (i.e. capacity, global markets and genetic resources) and a theoretical framework constructed upon social contract theorists Locke and Rawls, and upon Nussbaum’s Capability Approach.

First, regarding capacity, this thesis analyses the capacity of the pharmaceutical industry in developing countries rich in biodiversity. As explained in the Introduction of this thesis, the term ‘capacity’ has been employed in economic and social development, particularly related to skills and abilities for development. However, the term capacity has also been employed in other areas. For instance, Chapter 4 highlights that Article 22.4 of the NP provides a non-exhaustive list of areas in which capacity plays an important role, i.e. capacity to implement and to comply with the obligations of the NP; capacity to negotiate MATs; capacity to develop, implement and enforce domestic legislative and administrative measures on access and benefit sharing; and capacity to develop a country’s own endogenous research. Additionally, as analysed in the introduction of the thesis, the trilateral work of WHO, WTO and WIPO on *Promoting Access to Medical Technologies and Innovation to Medicines* is a response to an increasing demand from developing countries to increase capacity for ‘policy-making in areas of intersection between health, trade and IPRs, focusing on access to and innovation of medicines and other medical technologies’.[[965]](#footnote-966) As a result, the report aims to create synergies between the three international organisations and countries to create ‘more effective and tailored capacity-building activities’ based upon factual information on countries’ capacity.[[966]](#footnote-967)

However, this thesis does not solely understand capacity in terms of mechanisms or programmes that seek to increase capacity (i.e. capacity building), but it should be understood in terms of entitling countries. In other words, although it is important not only to increase specific capacities (skills and abilities), countries need to be entitled to enhance their local resources, initiatives and ownership, otherwise capacity could become more of a burden to them, making them more dependent. The Capability Approach seeks to entitle countries because it focuses on functioning (doing and being) and involves an assessment of countries’ capacities in order to compare and address those capacities to achieve different goals. This means that better capability means better capacities.[[967]](#footnote-968)

As this thesis carries out an analysis of access to technology and to genetic resources for drug development, it centres that analysis on the capacity of developing countries rich in biodiversity to develop a pharmaceutical industry capable of employing genetic resources for drug development. As a result, capacity is placed as an indicator by which countries are assessed in order to determine whether they have the intellectual labour that actually adds value to genetic resources. That is why Chapters 1 and 2 carry out an analysis of the pharmaceutical industries of China, India and Colombia to find out whether these countries employ their own genetic resources to increase capacity in their pharmaceutical industry, particularly for drug development. The analysis of India and China has been undertaken because these are countries with which Colombia can be contextualised regarding industry capacity, policies and legislation.

Chapters 3 and 4 analyse how TRIPs (including TRIPs-Plus provisions) and the ABS regime, and their implementation locally, affect or increase developing countries rich in biodiversity’s capacity to employ genetic resources for drug development. Indeed, capacity, as the intellectual labour that adds value to genetic resources, comes from the interpretative analysis that this thesis carries out on Locke’s labour theory. Locke’s labour is interpreted as the intellectual labour that entitles inventors to appropriate from what is in nature or the commons.[[968]](#footnote-969) Additionally, Locke’s theory is also employed to justify limits to IPRs, particularly when it creates barriers to others to have access to the commons (i.e. sufficiency proviso) and when the value lost by hoarding an intangible affects third parties or the distribution of tangibles (e.g. unmet demand for medicines), i.e. spoiled proviso.[[969]](#footnote-970)

Second, capacity also allows the contextualising of developing countries rich in biodiversity in the global context. As an analysis of the capacity of China, India and Colombia is carried out in Chapters 1 and 2, this thesis highlights that the pharmaceutical global market is characterised according to the medicines market identities (i.e. originators, generic medicines and illegal generics) and global centres of production and distribution. Chapter 1 points out that originators are located in developed countries since a greater degree of protection is granted to originators in these countries.

Chapter 1 also mentions that since India focuses on increasing capacity by protecting its generic pharmaceutical industry, its pharmaceutical industry centres on manufacturing and distributing generic medicines and active pharmaceutical ingredients locally and globally. Yet India does not rely on its own genetic resources to innovate. In the meantime, although China also has interests in protecting its generic industry, recently this Asian country has increased its capacity through biotechnology in genetic resources and, in particular, Chinese traditional medicine (e.g. artemisinin). LDCs are filling the gap left by China and India as this category of countries can manufacture and distribute illegal generics according to TRIPs flexibilities. Finally, there are developing countries rich in biodiversity, such as Colombia, which have accepted granting greater protection to originators via TRIPs-Plus. This has led them to develop a local pharmaceutical industry able to manufacture and distribute generics and originators under licensing agreement, but they cannot compete with developed countries or China and India in terms of market share.[[970]](#footnote-971) However, developing countries rich in biodiversity, such as Colombia, still have some room for manoeuvre to increase their capacity if they were to implement TRIPs and the ABS regime according to their own capacity.[[971]](#footnote-972)

Genetic resources is the third element that is taken into account in order to carry out the normative analysis of this thesis. Its importance dwells in the fact that genetic resources (including traditional knowledge associated with genetic resources) are an important source for drug development.[[972]](#footnote-973) The availability of and access to those resources in developing count­ries rich in biodiversity gives them the opportunity to trade off those resources for access to technology that employs genetic resources as established by the ABS regime, i.e. users of genetic resources are obligated to share the benefits from the utilisation of genetic resources with countries where those genetic resources are located, as established by the third objective of the CBD.

Regarding the global market and genetic resources, this thesis argues that although Locke’s theory provides an understanding of why there are IPRs on genetic resources and limits to the exclusivity of those rights, the dynamics between international trade and IPRs (which led to the promulgation of TRIPS in the WTO), and the distributive nature of ABS (the trade-off for access to genetic resources for access to technology) cannot only be interpreted by using Locke’s theory. As a result, Locke’s theory is studied along with Rawls’ social contract theory and the “Capability Approach”. Through Rawls’ social contract theory, flexibilities and limits to IPRs are justified because developing countries, including those rich in biodiversity, could address the inequalities that have risen from the TRIPs and TRIPs-Plus provisions, particularly access to technology.

As explained in Chapter 3, developing countries rich in biodiversity have accepted the implementation of TRIPs minimum standards in exchange for benefits from international trade (FDI, exports, etc.); hence TRIPs does not necessarily aim to increase countries’ capacity in technologies that employ genetic resources but their access to international trade. However, developing countries, including those rich in biodiversity, have addressed those inequalities that emerged from TRIPs in the Doha Ministerial and the Doha Declaration on the TRIPs Agreement and Public Health Declaration, which have entitled countries to employ flexibilities (e.g. compulsory licensing) in order to reduce the negative effects of TRIPs. Yet, the Doha Declarations have not served developing countries, including those rich in biodiversity, to increase capacity, but rather as a bargaining point in international trade. In fact, Chapter 3 points out how developing countries rich in biodiversity, such as Colombia, have bargained for further access to technology countries for greater benefits from international trade through TRIPs-Plus provisions. This is because TRIPs-Plus created a set of new mechanisms that increased exclusivity protection not only via patents, but also data exclusivity and patent linkage. As occurred with TRIPs of the WTO, TRIPs-Plus does not aim to increase capacity in technologies that employ genetic resources, but their access to international trade.

In addition, Chapter 4 highlights that the ABS regime has entitled developing countries rich in biodiversity to claim sovereignty rights on genetic resources with the aim that these countries could trade off those resources for technologies that employ genetic resources. However, the ABS regime has created a set of legal and administrative requirements that create a burden for users of genetic resources, including publicly funded institutions and research centres. This has not led to increased capacity but created barriers and legal uncertainty for users of genetic resources.

However, Chapters 3 and 4 suggest that the distributive measures that emerged from TRIPs and, especially, from the ABS regime should be addressed through an assessment of countries’ capacity. Such an assessment is inspired by the Capability Approach which suggests that distributive measures cannot be implemented in general terms or categories, but rather should be implemented according to an assessment of indicators (i.e. capacity) that allows defining what countries are capable of in technologies that employ genetic resources for drug development. This means that despite the fact that the Capability Approach and capacity are not equal terms, this thesis articulates both in order to provide a framework in which countries’ capacity could be assessed in order to create policies that entitle them to obtain the benefits that arise from the utilisation of genetic resources.[[973]](#footnote-974) This is reflected, for instance, in Article 22.3 of the NP, which requires parties to undertake a ‘self-assessment’ to define ‘national capacity needs and priorities’.

Finally, this normative analysis is reflected in the specific case of Colombia. The implementation of both TRIPs and ABS in Colombia has deterred local pharmaceutical companies, publicly funded institutions and universities from carrying out R&D activities on Colombia’s genetic resources rather than increasing Colombia’s capacity in technologies that employ genetic resources.[[974]](#footnote-975) Although the Colombian Government has expressed an interest in developing a pharmaceutical industry based on the utilisation of genetic resources in its national biodiversity strategy and other policy documents,[[975]](#footnote-976) Colombia’s pharmaceutical industry is not fully engaged in the utilisation of genetic resources for R&D activities in the drug development process; only a few publicly funded institutions have actually had access to genetic resources on technologies that employ genetic resources for drug development.

To sum up, according to this thesis’ interpretation of Locke’s labour theory, it is important to grant IPRs on genetic resources in order to increase the capacity for drug development in developing countries rich in biodiversity, especially Colombia, as it is fundamental to reward those who through the intellectual productive activity transform what is in nature or the commons. It is also fundamental to note that the interpretation given to Locke’s theory also encapsulates limits to IPRs via Locke’s provisos (i.e. sufficient and spoiled provisos). However, the linkage between international trade and IPRs has necessarily created inequalities between developed countries and developing countries, including those rich in biodiversity, as the former has trade-off access to international trade for access to technology.

This is reflected in both TRIPs of the WTO and TRIPs-Plus provisions, which require developing countries to create minimum standards of exclusivity protection (e.g. patents, data exclusivity, patent linkage, etc.) in order to secure local markets for originators, hence local companies cannot freely access technology to increase capacity by replicating the originators’ technology. As a result, Rawls provides a procedural mechanism to balance the inequalities that emerge from situations in which technologies are not equally distributive. This is reflected in the Doha Ministerial and the Doha Declaration on the TRIPs Agreement and Public Health Declaration which aims to secure that developing countries could address inequalities by employing flexibilities such as compulsory licensing.[[976]](#footnote-977) The ABS also aims to counterbalance inequalities, especially the lack of technology of developing countries rich in biodiversity, by granting ownership control on genetic resources to developing countries rich in biodiversity, so they are able to trade them off for access to technology.[[977]](#footnote-978) However, the ABS regime and TRIPs’ flexibilities cannot be evenly implemented to all developing countries rich in biodiversity, but it would require carrying out an assessment of these countries’ capacity to determine both what they want to do and what they are capable of (i.e. the Capability Approach).[[978]](#footnote-979)

This provides a framework in which developing countries rich in biodiversity could effectively trade off access to genetic resources for access to technology. As a result, distributive measures that the ABS regime and TRIPs’ flexibilities have created (i.e. the Doha Declarations) could actually entitle countries to implement the ABS and TRIPs, and carry out their own research priorities according their capacity for drug development.

Therefore, this thesis seeks to assess the capacity of developing countries rich in biodiversity in technologies that employ genetic resources, particularly Colombia, in the implementation of TRIPs and the ABS regime as these are relative to the pharmaceutical industry and the capacity of developing countries rich in biodiversity, also particularly Colombia. This analysis leads to recommendations on how to argue for these instruments to be changed in a manner that enables these countries to increase capacity to access technology in order to develop a pharmaceutical industry able to obtain benefits from the utilisation of genetic resources in technologies that employ genetic resources for drug development.

This thesis has paid particular attention to Colombia’s pharmaceutical industry. To that end, one research question is elaborated on in the Introduction of this thesis. This discussion chapter aims to assess the research question according to the arguments and conclusions presented in the different chapters of the thesis.

The research question is formed in the Introduction as follows: To what extent do TRIPs and the ABS regime, and their implementation in developing countries rich in biodiversity, especially Colombia, impact on countries’ capacity to develop a pharmaceutical industry that could obtain benefits from the utilisation of genetic resources in the light of technologies employ genetic resources for drug development?

In order to assess the research question, this thesis has analysed different elements which are reviewed and discussed in this chapter: (1) the capacity of the pharmaceutical industries of developing countries rich in biodiversity’ in technologies that employ genetic resources, i.e. China, India and, especially, Colombia (Chapters 1 and 2); (2) the wording of TRIPs and the ABS regime, and the policy behind both legal frameworks in technologies that employ genetic resources for the pharmaceutical industry (Chapters 3 and 4); and (3) the implementation of the legal framework in Colombia and its impact on this country’s pharmaceutical industries (Chapters 2 and 5). This analysis underlines the most important arguments that will lead this chapter to conclude with a series of recommendations to Colombia that will include policies and legal mechanisms that could entitle this country that is rich in biodiversity to effectively obtain the benefits that arise from the utilisation of genetic resources by trading off these resources for access to technology.

This chapter is divided up as follows: the first part analyses the different arguments and conclusions that have been explained in this thesis on the capacity of the pharmaceutical industries of developing countries rich in biodiversity to adopt TRIPs and the ABS regime with the particular aim of acquiring access to technology. The second part assesses TRIPs and suggests a series of legal measures in patents to encourage or improve Colombia pharmaceutical industry’s capacity to ensure that benefits that arise from the utilisation of genetic resources are equitably shared. The third part provides an analysis of the different elements of the ABS regime which Colombia should take into account as they implement ABS; especially the NP which has not been implemented in Colombia yet. The final part sums up the previous sections and concludes by answering the thesis research question.

* 1. **The Policy Context in Developing countries rich in biodiversity: Access to Technology, Capacity and Global Markets**

Capacity, as the intellectual labour that adds value to what is available in nature, is a fundamental element in the analysis of this thesis to evaluate how countries should implement international legislation, the ABS regime and TRIPs, locally. Therefore, this thesis has pointed out that in order to develop a pharmaceutical industry capable of carrying out R&D on technologies that employ genetic resources, countries have to develop a policy in which they can assess their capacity in technologies that are relevant for the drug development process.

Chapter 1 points out that, traditionally, developed countries have developed a policy which focuses on the demand for, and protection of, pharmaceutical products and processes. Despite the fact that the demand is an element to incentivise R&D, developed countries also employ patent protection to biotechnological and pharmaceutical inventions to encourage further R&D. Indeed, patent protection is an important element for developed countries to encourage R&D on medicines that treat orphan diseases.[[979]](#footnote-980)

Additionally, this thesis identifies that the developed countries have required developing countries, including those rich in biodiversity, to implement similar policies at national and regional levels in exchange for access to developed countries’ markets through TRIPs and trade bilateral agreements or FTAs (i.e. TRIPs-Plus).[[980]](#footnote-981) In the ABS regime, developed countries recognise the sovereignty rights of developing countries rich in biodiversity over their own genetic resources, yet these countries seek to protect originators from obligations that will compel them to transfer technology.[[981]](#footnote-982) Indeed, developed countries have campaigned within the Conference of Parties of the CBD that any transfer of technology should be mutually agreed between developing countries rich in biodiversity and the holders of technology via MATs.[[982]](#footnote-983) This is relevant for developed countries as it is through patents that holders of technology secure access to developing countries rich in biodiversity markets ahead of local producers; hence holders of technology can opt for whether or not to transfer it to developing countries rich in biodiversity in exchange for access to genetic resources.[[983]](#footnote-984) This means that developed countries encourage originators to provide benefit sharing by negotiating, in a case-by-case approach, with developing countries rich in biodiversity.

However, the capacity of developing countries rich in biodiversity is different from that of developed countries; hence, the former have responded differently to the implementation of TRIPs and the ABS regime. Nevertheless, this thesis assesses that developing countries rich in biodiversity also differ from each other as they have different capacities that have led them to implement TRIPs and the ABS in diverse ways. As a result, this thesis centres its normative analysis on China, India and Colombia since they are countries with high and medium high biodiversity (see Annexes II and III). The analysis of India and China has been undertaken because these are countries with which Colombia can be contextualised regarding industry capacity, policies and legislation.

As a result, Chapter 1 analyses China and India, and Chapter 2 Colombia. Regarding the former, Chapter 1 finds that in the past China and India did not grant patent protection to pharmaceutical products and processes, and restricted patents on biotechnological inventions as the policy of these developing countries rich in biodiversity was to access technologies (regardless of whether patent protection was granted in developed countries) in order to gain capacity to transform their illegal industry into a competitive generic industry.[[984]](#footnote-985) However, China is currently delivering a policy which is less restrictive in granting patents to pharmaceutical and biotechnological inventions on traditional Chinese medicine (i.e. traditional knowledge associated with genetic resources), yet, it restricts access to genetic resources in order to benefit sharing. For instance, China in 2009 in its patent legislation, has implemented disclosure of origin.[[985]](#footnote-986)

In the meantime, India has developed a competitive generic industry, and has participated in different stages of the drug development process (e.g. clinical trials). However, India seeks to protect its generic industry rather to encourage R&D in drug development, as recent judicial decisions indicate this particular trend. Indeed, in *Novartis,* the Supreme Court of Justice of India denied a patent on a follow-on product (Glivec) as it did not provide an enhanced therapeutic efficiency of a known substance; while in *Natco Pharma*, the Intellectual Property Appellate Board granted that a compulsory licensing of a drug (a treatment for kidney cancer) owned by Bayer was not affordable, and the invention was not manufactured locally or licensed to local companies.[[986]](#footnote-987) Regarding genetic resources and traditional knowledge associated with them, India has adopted a defensive to prevent misappropriation of those resources through TDKL, which is a database that documents information on genetic resources and traditional knowledge associated with them to different patent offices such as USPTO, EPO, JPO in order to prevent misappropriation (biopiracy). India has also implemented disclosure of origin in patents.

In this landscape, it is important to note that China and India are complying with TRIPs minimum standards, but they have implemented them according to their own capacity. Such a situation has left a gap for illegal generics, since China and India moved towards generic production and distribution.[[987]](#footnote-988) As a result, LDCs are taking over the supply of illegal generics, since they can delay the implementation of TRIPs minimum standards, including patent protection, to pharmaceutical products. In fact, the WTO, WHO and WIPO have called upon LDCs to take advantage of the TRIPs transitional period of time to enhance capacity on manufacturing and distribution of pharmaceutical products since they are not to comply with patent protection on originators.[[988]](#footnote-989) This has also facilitated that China and India now pays particular attention to LDCs to increase these countries’ capacity in manufacturing and distributing illegal generics by building facilities and transferring technology to them.

In the case of Colombia, the analysis of the capacity of this developing country rich in biodiversity is different; Colombia has developed a pharmaceutical industry able to distribute and manufacture generics and originators under licensing agreements, but has not engaged actively in R&D activities on its own biodiversity. Before TRIPs and TRIPs-Plus provisions were implemented in Colombia, the country had managed to create a significant generic pharmaceutical industry able to manufacture and distribute generic medicines in the Andean region; yet this country’s generic pharmaceutical industry has still not engaged in any relevant R&D activity.[[989]](#footnote-990) With the implementation of TRIPs and TRIPs-Plus, the Colombian pharmaceutical industry has not taken any significant steps towards R&D on technologies that employ genetic resources. Instead, it has focused on manufacturing generic medicines and originator drugs under licensing agreements with developed countries’ pharmaceutical companies, as well as distributing generic medicines to other Latin-American countries, particularly ACN countries. Moreover, although Colombia is granting patents on pharmaceutical products and processes to overseas companies, it has created additional requirements through the regulation of access to genetic resources (as the ABS regime has been implemented in the country).[[990]](#footnote-991) This has created difficulties in granting patents on Colombian’s genetic resources, particularly for local and publicly funded institutions (e.g. universities).[[991]](#footnote-992)

As a result, Colombia’s policy on its pharmaceutical industry does not take advantage of the country’s biodiversity, but rather it is international trade which has set up Colombia’s policy, particularly for local generic companies. It should be highlighted that in order to understand Colombia’s context, it is important to point out that Colombia’s main trade partner is the US, a developed country that has not ratified any of the international instruments of the ABS regime, i.e. the CBD, Bonn Guidelines and NP.[[992]](#footnote-993) Since the US is Colombia’s main trade partner, Colombia complies with the trade agreements that have emerged from the WTO, as well as the US-Colombia FTA (especially its IPR provisions).[[993]](#footnote-994)

In addition to the assessment of countries’ capacity for technologies that employ genetic resources, capacity creates indicators to compare countries within the global market, but also to understand the global market shift. According to Warren-Jones, the global shift involves originators being based primarily in developed countries since these countries create legislation that grants a greater degree of exclusivity through patent protection and other exclusivity mechanism.[[994]](#footnote-995) In the meantime, China and India are moving towards production and manufacturing of generic medicines, and distribution to other developing and developed countries. LDCs are filling the gap left by China and India on illegal generics since they are entitled to delay the implementation of TRIPs. Finally, there are other countries, such as Colombia, that have a different dynamic and challenges in the global market because although they have developed a pharmaceutical industry able to manufacture and distribute generics and originators under licence agreements, they cannot compete with China and India in terms of volume and market share; neither can they compete with LDCs since Colombia has largely committed to implement TRIPs patent requirements in its national legislation, and has also accepted further protection of pharmaceutical products and processes via TRIPs-Plus provisions.

To sum up this section, capacity cannot be assessed collectively in all countries as they have different socio-economic conditions and policies towards their pharmaceutical industries. While China and India benefited from not implementing patent protection before TRIPs was enacted, it has resulted in a pharmaceutical industry that has grown in terms of market size and capacity to manufacture and distribute generic medicines. They have even been able to create links with other countries to which they transfer technology, especially to LDCs, in order to benefit from those countries’ flexibilities in TRIPs. Although China is aiming to create a more innovative pharmaceutical industry based on its genetic resources and traditional knowledge associated with them, India has delivered a more protectionist policy for its generic industry.[[995]](#footnote-996) Meanwhile, LDCs are finding different avenues to increase their capacity (e.g. international cooperation and transfer of technology from China and India). In the case of Colombia, there is no coherent or harmonious policy that implements TRIPs, TRIPs-Plus, Doha and the ABS regime with Colombia’s capacity. Despite the fact that authorities in Colombia stress the importance of genetic resources for increasing capacity in the country’s pharmaceutical industry, Colombia’s implementation of TRIPs, TRIPs-Plus and the ABS aim to obtain benefits from international trade, rather than obtaining the benefits from the utilisation of its genetic resources.

This assessment of the capacity and the global market illustrates that Colombia should implement a policy that is in line with its own capacity. Therefore, the different elements studied in the thesis of both ABS and TRIPs are reviewed in order to identify a policy to implement them; this should be constructed in such a way that Colombia could transform its pharmaceutical industry from generic manufacturers to an industry able to take a more active role in the different stages of the drug development process. The core of the analysis is to secure a trade-off of genetic resources for access to technology for users of genetic resources, particularly those users who are at the beginning of the drug development process. This is because it is during the first stage of the drug development process (i.e. discovery stage) in which the Colombia pharmaceutical industry (e.g. universities, publicly funded initiatives and botanical gardens) is well placed to obtain the benefits that arise from the utilisation of genetic resources.

* 1. **Changing Colombia’s Perspective on its Pharmaceutical Industry through Patents on Genetic Resources**

Chapter 3 analysed the Paris Convention, which sought to protect originators’ intellectual labour, yet it left countries with the possibility of implementing patent protection according to their own capacity through mechanisms that limit patent protection. Chapter 3 points out that the Paris Convention was in line with Locke’s theory since it sought to protect the intellectual labour that adds value from originators in different countries, but it also permits those countries, particularly developing ones, to employ mechanisms such as compulsory licensing, and limit or restrict patents in particular technologies, especially the pharmaceutical industry (i.e. Locke’s proviso).[[996]](#footnote-997)

However, as IPRs have been linked to international trade, developing countries, including those rich in biodiversity, accepted the implementation of the TRIPs standards of the WTO into their national legislation. This has led developing countries rich in biodiversity to campaign with the WTO and the Council for TRIPs to bargain for reducing the scope of patent protection. This means in spite of Locke’s labour theory allowing us to understand why there should be IPRs that protect the intellectual labour that adds value, there are circumstances in which such protection is not granted to protect innovation but is rather the result of bargaining for international trade for access to technology. That is why developing countries, including those rich in biodiversity, have campaigned within the WTO and the Council for TRIPs; efforts that led to the Doha Ministerial Declaration, and the Doha Declaration on the TRIPs Agreement and Public Health. This fits within Rawls’ work on the principles of justice and his ‘veil of ignorance’ as he acknowledges the existence of inequalities among participants of the social contract, but those inequalities could also be addressed by participants in order to compensate for inequalities that emerge from the social contract. James, in his academic scholar of fairness and social contract theory in international trade, also points out that it is perfectively justifiable to allow countries to “eviscerate TRIPs” to level the playing field with developed countries regarding IPRs in order to ‘advance in [developing countries] development goals’, even if those countries have decided to participate within the rules of TRIPs.[[997]](#footnote-998)

However, Rawls’ egalitarianism, particularly the ‘veil of ignorance’ which assumes that participants of social contract that arrive in the original situation are equal, is difficult to apply in the relationships among States. Indeed, James precisely highlights this aspect which has made Rawls’ veil of ignorance difficult to employ in a global context and suggests ‘a parochial egalitarianism’.[[998]](#footnote-999) Instead, Nussbaum highlights that there is no rough equality among States, as they are economically and politically stronger (i.e. developed countries); as a consequence, strong countries’ own interests prevail over those of weaker countries in the international context.[[999]](#footnote-1000) Therefore, Nussbaum considers that there should be an assessment of countries’ capabilities as they operate, as an indicator of what countries want and are actually capable of in the initial position or veil of ignorance.

The importance of capacity in TRIPs, therefore, dwells in assessing countries as they implement TRIPs nationally. In fact, Chapter 3 points out that despite the fact that TRIPs create minimum standards for patents, it also left some loopholes which include the possibility of limiting patent protection on technologies that employ genetic resources or the use of compulsory licensing. Chapter 3 highlights that developed countries seek to address those loopholes via TRIPs-Plus dispositions (e.g. limits to compulsory licensing, data exclusivity and patent linkage), and that developing countries rich in biodiversity pursue their own interests, by campaigning in the WTO for amendments. However, as analysed in the previous section, TRIPs does not reflect an assessment of countries’ capacity, but rather it is a mechanism in which developing countries, including those rich in biodiversity bargain for access to international trade for higher IPRs standards.

Additionally, developing countries rich in biodiversity such as Colombia have continued to bargain for access to technology for access to international trade, as they have implemented higher standards of patent protection via TRIPs-Plus which limits the use of compulsory licensing and creates new mechanisms of exclusivity protection.[[1000]](#footnote-1001)

However, developing countries rich in biodiversity can still manoeuvre to exclude inventions that might affect their interests by implementing Articles 27.2 and 27.3 according to their own capacity. These two Articles are the substantive elements in TRIPs that define the scope of patent protection on genetic resources. In the case of Colombia, Article 27 of TRIPs has been implemented through Articles 14 to 21 of Decision 486. Chapter 5 concludes that despite Colombia’s obligation having been acquired through TRIPs-Plus provisions (i.e. data exclusivity, patent linkage, limits to compulsory licensing), Colombia still has some room to implement Article 27 of TRIPs in a way that could benefit its pharmaceutical industry, especially patents on second indications and exclusion of patents over genetic resources.

First, the second and subsequent indications of a biochemical compound come as a result of further R&D on existing medicines; the R&D on a second indication might take place after patent protection has expired or during the patent term.[[1001]](#footnote-1002) This might result in new therapeutic uses or a change of formulation of an existing biochemical entity. Chapter 5 concludes that the ATJ denied a patent on a second indication on *Pirazalipirimidinomas* (Viagra) on the basis that the patent did not meet the requirement of novelty according to Article 21 of Decision 486.[[1002]](#footnote-1003) However, Colombia (as a member of the ACN) could modify the ACN legislation. Colombia has already amended an ACN regulation in order to allow data exclusivity on pharmaceutical products in the Andean region, as this was part of the commercial compromises acquired with the US.[[1003]](#footnote-1004) Therefore, it is important to assess whether or not Colombia could improve its capacity in technologies that employ genetic resources by developing second indications.

One of the advantages of this possibility is that, since R&D is being undertaking on an already existing biochemical compound, a second indication will require pharmaceutical companies to find a new therapeutic use rather than going through different biochemical compounds in order to find one that already has some therapeutic use. Nevertheless, a second indication does require further R&D, such as clinical trials, in order to find a new indication.[[1004]](#footnote-1005)

Chapter 2 points out that Colombia’s pharmaceutical industry has little investment in clinical trials and little experience in this particular part of the drug development process.[[1005]](#footnote-1006) Additionally, developed countries’ pharmaceutical companies are likely to have carried out parallel development in the developed countries on second indication products. Indeed, Correa argues that since developed countries have been very flexible in granting patents on drugs that do not involve ‘a genuine therapeutic innovation’, this has only led to the proliferation of patents on pharmaceutical products with inexistent innovation.[[1006]](#footnote-1007) This means that as the patent term comes to an end, the patent holder will be ready to obtain a new patent on the second indication and get it onto the market. Therefore, Colombia’s pharmaceutical industry, which has only reported some participation in the early stages of the drug development process (i.e. discovery), will not benefit from second indications. Even in the unlikely scenario that the developed countries’ pharmaceutical companies will carry out R&D on second indications in Colombia, this might not encourage capacity on R&D on genetic resources (e.g. bioprospecting) because second indications would target existing biochemical entities, rather than Colombia’s genetic resources.

Second, Chapter 3 concludes that developing countries rich in biodiversity have employed exclusion of patents over genetic resources in order to maintain control over access to those resources and secure transfer of technology.[[1007]](#footnote-1008) In the case of Colombia, the ATJ has interpreted Article 15 (b) of Decision 486 in such a way that excludes isolated genes (DNA) even if there is a technical intervention that makes them different from the natural version. Yet, the ATJ’s decision does not rule out the option to provide patents on, for instance, complementary DNA (cDNA) or microorganisms. Furthermore, the ATJ’s decision is not far from the scope of the US Supreme Court of Justice decision on BRCA1 and BRCA2 in which patents on isolated genes (DNA) were invalidated, but patents on cDNA are maintained as they are produced in a lab rather than just being an isolated DNA.[[1008]](#footnote-1009) Furthermore, the ATJ’s decision is not distant from Biotech Directive (Article 5.2) either, since this regulation grants patent protection to isolated DNA as long as it has been produced by means of a technical process. As a result, an approach that allows patents on genetic resources and recognises the importance of technical intervention to grant patents will benefit the Colombian pharmaceutical industry.

Indeed, Chapter 5 points out that there are different publicly funded institutions carrying out R&D on Colombia’s biodiversity and genetic resources but only a few private companies have engaged in these activities.[[1009]](#footnote-1010) By restricting patents on genetic resources, R&D activities on those resources, such as bioprospecting, are discouraged. Facilitating patents on genetic resources could encourage publicly funded institutions or small companies in Colombia to apply for patents. Chapter 5 also highlights that the SIC, the Colombian patent office, has been involved in different programmes (e.g. training to small entrepreneurs, research centres and universities) to increase patent applications among Colombians. This has resulted in the fact that Colombian patent applications have increased from 75 in 2000 to 251 in 2013.[[1010]](#footnote-1011)

Therefore, Colombia does not need to amend Articles 15 and 21 of Decision 486. First, Colombia should not modify Article 21 of Decision 486; hence, the prohibition on second indications should be maintained by the ATJ as they do not bring benefits to the Colombian pharmaceutical industry. Although Colombia should also uphold Article 15 of Decision 486, a more flexible approach should be considered. As a result, Colombia and the ATJ should provide and facilitate patent protection on genetic resources, particularly if those resources have gone through technical interventions that make them different from the natural genetic resource. Such an interpretation that allows patents on genetic resources, that are different from genetic resources as such, can be assessed in the light of decisions such as those of the US Supreme Court of Justice’s ruling on BRCA 1 and BRCA2 and the EU Biotech Directive, as this is in line with ATJ’s interpretation of Article 15 of Decision 486.[[1011]](#footnote-1012)

However, patents on genetic resources would only be possible if the objectives of Article 1 of the CBD were met, particularly benefit sharing. Therefore, it is now important to discuss how Colombia should implement the ABS regime in order to increase capacity, so they could benefit from the exploitation of genetic resources.

* 1. **Benefit Sharing and Capacity in Colombia**

Chapter 4 highlights that developing countries rich in biodiversity seek to counterbalance the linkage of international trade and IPRs, for a different trade-off that includes restricting the scope of patents on genetic resources and securing ownership control on those resources in order to bargain with them for access to technology.[[1012]](#footnote-1013) This can be observed in the third objective of the CBD: users of genetic resources are obligated to share the benefits from the utilisation of genetic resources with countries where those genetic resources are located (i.e. developing countries rich in biodiversity).

The third objective of the CBD, in which countries are allowed to counterbalance TRIPs provisions that might affect them, is particularly reflected in Rawls’ work. For instance, as explained in the Introduction of this Thesis and Chapter 4, in the light of Rawls’ social contract theory, developing countries rich in biodiversity are entitled to claim ownership control of genetic resources as a result of a bargain between developed and developing countries rich in biodiversity – despite the fact that developing countries rich in biodiversity do not carry out any intellectual labour that adds value.[[1013]](#footnote-1014) However, such a trade-off between access to genetic resources and access to technology does not depend exclusively on having control over genetic resources, but also on users of genetic resources that hold technology which employs genetic resources for drug development. Therefore, it is important that users of genetic resources can actually have access to those resources in order to trade-off technology for access to genetic resources, otherwise such a trade-off would not occur. For instance, Chapter 5 highlights that local users of genetic resources in Colombia (e.g. universities and publicly funded initiatives) have been affected by the Colombian implementation of the ABS regime’s implementation since it creates legal uncertainty, and legal and administrative burdens.[[1014]](#footnote-1015) In this regard, Nozick’s criticism of the distributive nature of Rawls’ theory is reflected in the ABS regime. In fact, Nozick considers that distributive theories, especially Rawls’ theory, could affect individual’s liberties as they impose unnecessary burdens on people’s activities.[[1015]](#footnote-1016) Therefore, the ABS regime can create a burden on users of genetic resources as it creates ‘redistributive activities’ that deter the capacity from innovating.[[1016]](#footnote-1017) In other words, the ABS could indeed impose administrative and legislative burdens on users of genetic resources, leading them to reduce their capacity on technologies that employ genetic resources.

Therefore, distributive mechanisms such as benefit sharing of the ABS regime should not create unnecessary burdens on users of genetic resources and developing countries rich in biodiversity. Instead, the implementation of the ABS regime in developing countries rich in biodiversity should centre on entitling countries to assess their own capacity and create legal mechanisms accordingly. As analysed in the previous section on the implementation of TRIPs and TRIPs-Plus in Colombia, the Capability Approach allows the definition of what developing countries rich in biodiversity are capable of and how they can actually increase capacity in technologies that employ genetic resources for drug development.

Through the legal analysis of the ABS regime, the Capability Approach is significantly reflected in Article 22 of the NP; this Article not only mentions capacity and capacity-building as important elements that countries should take into account as they implement the ABS regime locally, but it requires that countries carry out ‘self-assessment’ of their capacity. Specifically, the NP calls parties, as they implement this protocol, to address, *inter alia*, their capacity to implement and comply with the obligations of the NP; capacity to negotiate MATs; capacity to develop, implement and enforce domestic legislative and administrative measures on access and benefit sharing; and capacity to develop their own endogenous research. Following Article 22 of NP, this thesis considers that capacity on technologies which employ genetic resources, as referred to in Article 22, is related to the three elements analysed in Chapter 4: the nature of genetic resources, PIC and MATs. For instance, capacity to implement and to comply with the obligation of the NP as well as capacity to enforce access and benefit sharing, are analysed in the legal and administrative mechanisms that they create to regulate PIC or the way that these countries define the nature of genetic resources.

* + 1. **Nature of Genetic Resources**

Chapter 4 analyses the importance of the definition of the nature of genetic resources in Article 2 of the CBD as it defines whether or not technologies that employ genetic resources are included within the scope of this Article.[[1017]](#footnote-1018) This discussion seems to be settled by Article 2 of the NP which includes derivatives and utilisation of genetic resources within the meaning of genetic resources; hence technologies that employ genetic resources could be included within the scope of Article 2 of the CBD.[[1018]](#footnote-1019) This could mean that users of genetic resources should transfer technology not as part of MATs and benefit sharing agreements, but in order to comply with the obligation on access. However, as discussed in Chapter 4, the NP did not completely clarify this aspect, instead the nature of genetic resources remains open to be interpreted by the different Parties. [[1019]](#footnote-1020)

For instance, developing countries rich in biodiversity (including Colombia) have interpreted the scope of Article 2 of the CBD to include derivatives. For example, Articles 1, 16 and 17 of Decision 391 of the ACN include not only naturally occurring genetic resources with functional units of heredity, but also by products and synthesises products which might not contain functional units of heredity.[[1020]](#footnote-1021) Furthermore, other developing countries rich in biodiversity, such as India, have also employed a utility standard to include technologies that employ genetic resources within the scope of the nature of genetic resources; indeed, the 2002 Indian Biological Diversity Act includes any uses of genetic resources for drugs (pharmaceutical products) within the scope of the obligation to access.[[1021]](#footnote-1022) This means that for developing countries rich in biodiversity the technology that employs genetic resources should be included within the nature of genetic resources according to Article 2 of the CBD.

Nevertheless, this provision misleads users of genetic resources as it does not take into account the complexity of defining the nature of genetic resources in research activities. For instance, Chapter 5 concludes that there are different Colombian research institutions (most of them publicly funded) that are, for instance, carrying out taxonomic activities on Colombia’s biological resources and, as a result of their research, these institutions might have had access to genetic resources; yet most of these research initiatives have not complied with Decision 391.[[1022]](#footnote-1023) Furthermore, the Colombian Ministry of Environment (the designated national authority) which should be ensuring that these research activities comply with Decision 391, has not taken any action or created guidelines on how to define genetic resources according to Articles 1, 16 and 17 of Decision 391. This indicates that Colombia has not developed enough capacity to clearly outline the scope of the nature of genetic resources according to Article 2 of the CBD and Articles 1, 16 and 17 of Decision 391. This has led to legal uncertainty, particularly for local publicly funded research activities. As a result, the local pharmaceutical industry is the one being targeted by Decision 391 rather than originators.

One way to solve this problem is by not extending the nature of genetic resources beyond Article 2 of the CBD. This means that concepts such as derivatives and ‘utilisation of genetic resources’ should be defined within MATs rather than within particular legislation.[[1023]](#footnote-1024) A simplified definition of genetic resources will facilitate access to genetic resources for developing countries rich in biodiversity users and will increase the capacity to explore and understand those countries’ genetic resources.

In the case of technologies that are protected by patents, these should be discussed within MATs too. This also fits within what has been proposed in Section 2 of this chapter. Patent exclusions need to be interpreted in a more flexible way to grant further patent protection on technologies that employ genetic resources to users of those resources, especially the local users. Finally, in the particular case of research activities that are carried out on biological resources, and which eventually turn into R&D on genetic resources, a simplified definition of genetic resources could also be of benefit (particularly for activities to comply with Decision 391). However, there are countries (regional organisations such as the ACN) and border countries (e.g. the Central American countries) that have different properties and access regimes for genetic resources and biological resources, regardless of whether they have regional treaties on access to genetic resources or not. This means that a narrow definition of the nature of genetic resources should also be complemented with a simplified procedure to gain access to genetic resources. The next subsection discusses this point in more depth.

* + 1. **Prior Informed Consent**

Chapter 4 analyses Articles 3 and 15 of the CBD entitled developing countries rich in biodiversity (under the sovereign right that they have over their genetic resources) to regulate access to genetic resources.[[1024]](#footnote-1025) Article 15 of the CBD enables developing countries rich in biodiversity to establish legal and administrative mechanisms to ensure that users of genetic resources require PIC before they have access to genetic resources.

In the case of Colombia, it has implemented both Articles 3 and 15 of the CBD into its national legislation through Articles 16 and 17 of Decision 391 and Resolution 620 of 1997.[[1025]](#footnote-1026) Although this procedure involves three steps,[[1026]](#footnote-1027) Colombia’s users faced different problems at that time in going through with this procedure.[[1027]](#footnote-1028) This is particularly reflected in the case of the UNC, a publicly funded university that spent approximately 12 years in different administrative procedures to obtain PIC and reach MATs.[[1028]](#footnote-1029) However, the UNC did not obtain PIC and has even been criminally prosecuted for infringing Decision 391 and Resolution 620.[[1029]](#footnote-1030) This is even more worrying since there are around 600 publicly funded research projects on Colombia’s genetic resources, of which only 21 have obtained PIC.[[1030]](#footnote-1031)

Another problem is the multiplicity of property regimes, which means that there are also different rules and procedures to obtain PIC. This includes different procedures for biological resources, genetic resources and patents on genetic resources. For instance, in the case of Colombia and the Andean regulation on access to genetic resources, Article 6 of Decision 391 mentions that both biological and genetic resources are the public property of each member of the ACN and are subject to their national regulation. For Colombia, biological resources access is regulated by a property regime different from those for genetic resources (i.e. Decree 309 of 2000). The most relevant aspect of this legislation is that, because biological resources are related to conservation and sustainability, publicly funded research institutes can access biological resources without PIC in order to carry out activities such as collection and classification of biological species. However, if the research activity is transformed into an R&D on genetic resources, the user of those resources has to commence a different procedure to obtain PIC as the regulation on access to genetic resources prevails over biological resources (Article 6 of Decision 391).

Furthermore, Article 8 (a) of the NP requires parties to encourage non-commercial research on genetic resources by facilitaiting rules on access, including PIC. This means that countries could distinguish between the types of research (i.e. commercial and non-commercial) to make access to legislation more flexible for non-commercial research. In the case of Colombia, due to the UNC’s case, the government issued Decrees 1375 and 1376 in which publicly funded institutions such as public universities are excluded from PIC if they are carrying out non-commercial activities on genetic resources. [[1031]](#footnote-1032) However, if a non-commercial research activity turns into a commercial one, users of genetic resources have to obtain PIC. Moreover, if users of genetic resources in Colombia opt to obtain patent protection on genetic resources, they will have to go through a patent process, as established in the Andean patent regime of Decision 486. This means that research activities in Colombia, including taxonomy and bioprospecting activities, have to go through three different property regimes and procedures.

This is even more problematic if there is a trans-boundary situation. As explained in Chapter 4, a trans-boundary scenario occurs when genetic resources are located in different countries; hence, it is difficult to obtain PIC.[[1032]](#footnote-1033) For instance, the case of Hodia (analysed in Chapter 4) exemplifies this problem as this plant is located in three African border countries (i.e. Namibia, South Africa and Botswana); the lab that carried out the bioprospecting initiative required access to South Africa and Namibia, but not to Botswana as there is no regulation on access to genetic resources and benefit sharing.[[1033]](#footnote-1034) A similar situation arises in the ACN. Although Colombia belongs to the ACN of which other developing countries rich in biodiversity (Bolivia, Ecuador and Peru) are a part, the ACN allows each of the members to set up their own property rules regarding genetic and biological resources as well as having diverse procedures to obtain PIC. This means that if there is a trans-boundary situation, users of genetic resources will need to go through different property regimes and procedures to obtain PIC and, hence, access to genetic resources.

The long time required to decide about granting PIC, different property regimes and rules, division between commercial and non-commercial, and trans-boundary situations, indicate that developing countries rich in biodiversity should simplify PIC in order to provide legal certainty not only to developed countries’ users but to their own users in particular. In the case of Colombia, it should establish a single legal procedure to obtain PIC in both genetic and biological resources, and derogate provisions that distinguish commercial and non-commercial research in Decrees 1375 and 1376. Finally, the trans-boundary situation remains an uncertain field as the NP only encourages countries to consider a global multilateral mechanism, but parties of the NP have not agreed on the scope of the concept of trans-boundary situations and how to solve them through a global multilateral mechanism. As a result, Colombia should not yet consider creating extra requirements or mechanisms that could over-complicate PIC procedures.[[1034]](#footnote-1035)

By simplifying and unifying the procedures to obtain PIC for developing countries rich in biodiversity, users of genetic resources (especially publicly funded research initiatives) could easily access both biological and genetic resources, irrespective of whether a particular research is commercial or non-commercial, or is carried out by publicly funded actors or private stakeholders. For the particular case of Colombia, this will also facilitate the work of the designated national authority (i.e. Ministry of Environment), which not only observes access to genetic resources but also access to biological resources. This will not require further legal amendment at the regional level as Articles 5 and 6 of Decision 391 entitle members of the ACN to implement property rules on biological and genetic resources according to national legislation.

* + 1. **Disclosure of Origin**

There are also two important issues regarding PIC that should be considered in this discussion: disclosure of origin and the IRCC. Disclosure of origin demands users of genetic resources to disclose all the information related to the origin of genetic resources when a patent application is filed. Although this issue has been largely discussed in different international forums, such as the Conference of Parties of the CBD, the Council for TRIPs and the WIPO’s IGC, it has been an instrument that has had more relevance for developing countries rich in biodiversity than developed countries. [[1035]](#footnote-1036)

For example, Article 22 of Decision 391 adds an extra requirement for patent applications as it demands that whoever uses genetic resources should disclose all information related to the origin of those resources and demonstrate that there are PIC and MATs.[[1036]](#footnote-1037) If users of genetic resources fail to disclose such information in the patent application, Article 75 (g) of Decision 486 establishes that the Colombian patent office should nullify the patent.[[1037]](#footnote-1038) Equally, Decision 391 has established criminal and administrative sanctions for those who do not meet this requirement. However, Chapter 5 concludes that this requirement has only affected the local users. Indeed, the UNC case illustrates that due to the lack of capacity of the Ministry of Environment in granting PIC and negotiating MATs, the patent application was invalidated on the grounds that there was no disclosure of origin.[[1038]](#footnote-1039) Additionally, criminal and administrative sanctions have been imposed against the UNC.[[1039]](#footnote-1040) Although the Ministry of Environment has improved the average period of time in which MATs are granted (seven months), Chapter 5 points out that the SIC could only grant up to 60 days to patent applicants for them to enclose MATs according to Article 45 of Decision 486. This problem is reflected in the SIC not granting a patent on a genetic resource to the University of Pereira, because it could not enclose MATs with its patent application, despite the fact that the University was actually carrying out a process of obtaining MATs with the Ministry of Environment at the time of the patent application.

This situation indicates that disclosure of origin does not target originators in developed countries but rather users of genetic resources that are at the beginning of the drug development process, particularly in the stage of discovery.[[1040]](#footnote-1041) These stakeholders rely on patent protection in order to make R&D activities sustainable. Indeed, it is during the first stage of the drug development when there is no certainty regarding whether or not a selected biochemical entity derived from genetic resources could have any commercial success. For instance, Costa Rica’s INBio (which has experience in R&D on genetic resources and patents over them) has not yet delivered any commercial products or processes based on genetic resources.[[1041]](#footnote-1042) Finally, it is also important to mention that users of genetic resources who are right at the beginning of the drug development process do not always pursue patents.[[1042]](#footnote-1043) For instance, although there is low research activity in Colombia, the few initiatives of Colombia’s pharmaceutical industry on genetic resources also have a low patent activity. Indeed, Colombia has more than 957 research groups on genetic resources, but only few users of genetic resources have filed a patent application.[[1043]](#footnote-1044) Chapter 5 suggests that Colombia could propose an amendment to Article 75 (g) of Decision 486 in which patent applications on genetic resources that do not enclose MATs, are not processed until MATs are reached and enclosed. Belgium has already implemented a similar approach, in theory, but in practice its patent office does not check that applicants have met this requirement.[[1044]](#footnote-1045) However, the SIC in Colombia checks and requests patent applicants to meet this requirement as occurred with the cases of the UNC, the University of Pereira and, most recently, the *Elaesis Oleifera* case. This approach could prevent users of genetic resources from not obtaining patents on genetic resources when it has not been possible to reach MATs with the Ministry of Environment.

Therefore, it is necessary to amend 75 (g) of Decision 486 to eliminate the invalidity of a patent application if users of genetic resources do not disclose the origin of those resources. Instead, Article 75 (g) of the Decision should not process a patent application on genetic resources until their origin has been disclosed.

Finally, IRCC is also a problematic issue in disclosure of origin. Chapter 4 explains that the IRCC is a mechanism to track and monitor the flow of generic resources, i.e. to establish the origin of those resources.[[1045]](#footnote-1046) This requires creating checkpoints in different countries and a system of notification to CHM of the CBD; the issuance of IRCC takes place at the time PIC is obtained and MATs is reached. As Chapter 4 points out, IRCC was proposed by developing countries rich in biodiversity with the original purpose of including it within the disclosure of origin in patent applications.[[1046]](#footnote-1047) However, the EU Regulation on access to genetic resources included the IRCC as a mechanism to certify the existence of PIC and MATs with developing countries rich in biodiversity.[[1047]](#footnote-1048) This indicates there is also another possibility, i.e. that both developing countries rich in biodiversity and developed countries find common ground in the importance of IRCC. However, the IRCC system is still in the early stages of development and has not been implemented in any developing countries rich in biodiversity. Developing countries rich in biodiversity should not require IRCC until this mechanism is further developed, otherwise the implementation of IRCC will only create more legal uncertainty.

As a result, Colombia should amend Article 75 (g) of Decision 486, which invalidates patents on genetic resources that have not disclosed information regarding access to genetic resources. Instead, Article 75 (g) should not process a patent application on genetic resources until the origin of the genetic resources has been disclosed.

* + 1. **MATs**

Finally, it is important to consider MATs, whose importance dwells in the fact that it is the legal instrument that establishes benefit sharing and defines what technologies that employ genetic resources will be in the MATs (according to the interpretation given in this chapter to Article 2 of the CBD). This requires that developing countries rich in biodiversity comprehend (in a case-by-case approach) both the nature of genetic resources and its value in drug development. As concluded in Chapter 4 most developing countries rich in biodiversity are far from developing such a capacity to design an institutional framework that could enable them to negotiate MATs. For instance, Eli Lilly’s bioprospecting initiative in Cameroon was withdrawn due to legal uncertainty on how to negotiate a MATs; equally Laird and Wynberg point out similar cases in different developing countries rich in biodiversity.[[1048]](#footnote-1049)

In the case of Colombia, this country is also far from developing the required capacity as the institutional design involved in negotiating and reaching MATs does not take into account Colombia’s capacity. Although the Ministry of Environment has increased the number of MATs to 49 between 2012 and 2014, in the case of genetic resources for drug development there are only three that have potential commercial value for drug development. Indeed, publicly funded institutions (with little or no participation from the private sector) are the users who mainly carry out R&D activities on genetic resources. Indeed, only 1% of Colombia’s R&D in genetic resources has some commercial importance.

Furthermore, Colombia has over-complicated the process of negotiation to reach MATs. Again, the case of the UNC illustrates the difficulties to reach an agreement that would have not only benefited a publicly funded institution, but also have important commercial value. As analysed in Chapter 5, there were more than 18 communications and documents, different working groups and meetings that took place over almost 12 years.[[1049]](#footnote-1050) This indicates that Colombia does not recognise what the potential value of their genetic resources is in order to design a policy that could improve Colombia’s capacity.

However, there are two elements that Colombia should take into account regarding MATs. Firstly, Colombia should increase and centralise negotiations of MATs through organisations that have some level of expertise in biodiversity and genetic resources. For instance, Costa Rica’s INBio has proved to be an effective organisation that has played a key role in increasing Costa Rica’s technical and legal capacity in technologies that employ genetic resources; although Chapter 4 discusses how INBio has gone through financial problems, this situation was the result of different circumstances that were not related to the utilisation of genetic resources.[[1050]](#footnote-1051). In the case of Colombia, there is the Institute Alexander Von Humboldt which has been carrying out research activities on Colombia’s biodiversity and has also taken part in policy discussions regarding biodiversity and utilisation of genetic resources.[[1051]](#footnote-1052) This sort of organisation could participate in the negotiations of MATs; however, their legal nature and the way that they can participate will depend on each country’s legislation. In Colombia, if the Institute Alexander Von Humboldt negotiates MATs, the Ministry of Environment (as the designated national authority) has to grant PIC and ratify MATs. These will require further changes in Colombia’s legislation on access to genetic resources, particularly Resolution 620 of 1997, to allow the Institute Alexander von Humboldt to take an active role in negotiations of MATs. Secondly, as organisations such as INBio in Costa Rica and the Institute Alexander Von Humboldt in Colombia are well placed to negotiate benefit sharing disposition in MATs, these organisations could better assess the scope of genetic resources as such and what patents holders on technologies that employ genetic resources could actually offer to developing countries rich in biodiversity in exchange for access to genetic resources (i.e. licensing agreements, milestone payments, upfront payments and joint patent ownership). Indeed, an organisation such as INBio, along with users of genetic resources, could define what the capacity is to carry out endogenous research on their own genetic resources, according to Article 22 of the NP

To summarise, this chapter discusses three different elements that aim to increase R&D in the first stages of the drug development process (particularly discovery): evaluation of capacity, patents on genetic resources and ABS measures that facilitate access to genetic resources. This is because the discovery stage is the part in which developing countries rich in biodiversity are well placed to create mechanisms that encourage their own pharmaceutical industry to take a more active role in pharmaceutical research based on their own genetic resources.

1. **Conclusions**

This thesis proposes that developing countries rich in biodiversity, especially Colombia, should observe their local pharmaceutical industries’ capacity as they implement TRIPs and the ABS regime in order to meet the three objectives of Article 1 of the CBD, particularly the share of benefits that arise from the utilisation of genetic resources. With the purpose of doing so, developing countries rich in biodiversity should adopt the following policies and legal mechanisms:

1. They should focus on facilitating both access to genetic resources and access to technology to users of genetic resources, particularly users at the beginning of the drug development process.
2. This thesis has centred primarily in Colombia, although it has analysed other developing countries rich in biodiversity in order to create comparator regions within which Colombia can be contextualised. As a result, this thesis proposes the following point on the implementation of TRIPS and the ABS regime which depends on Colombia’s capacity:
   1. As Colombia’s pharmaceutical industry policy is oriented towards obtaining access to international trade and complying with TRIPs and TRIPs-Plus provisions, Colombia should make an effort to grant further patent protection on genetic resources to its local pharmaceutical industry and facilitate access to genetic resources.
3. The legal mechanisms that Colombia should observe in order to increase its capacity in the utilisation of genetic resources for drug development are:
   1. On patent protection, Colombia should grant further patent protection on genetic resources, especially if there is a technical intervention that makes invention based upon genetic resources different from natural occurring genetic resources. For Colombia, this legal mechanism will not require further modification to Article 15 of Decision 486, but a more detailed interpretation by ATJ.
   2. In the case of second indications, Colombia should not amend Article 21 of Decision 486 which rules out second indications from patent protection, as there is no evidence that Colombia will benefit from patents’ second indications, particularly in the utilisation of genetic resources. Indeed, second indications do not aim to carry out R&D on new biochemical entities but rather on existing ones.
   3. Colombia should not extend the nature of genetic resources beyond Article 2 of the CBD. This means that concepts such as derivatives and ‘utilisation of genetic resources’ should be defined within MATs rather than within a particular legislation.
   4. Colombia should adopt a single legal procedure to obtain PIC in both genetic and biological resources, and remove any distinction between commercial and non-commercial research. This means that a procedure should be created that involves both genetic and biological resources and derogates the dispositions of Decrees 1375 and 1376 that distinguish between non-commercial and commercial research.
   5. Dispositions on trans-boundary situations and IRCC remain uncertain; hence Colombia should not adopt any extra requirements or mechanisms that deal with these two issues yet.
   6. Colombia should not invalidate patent application on the grounds of lack of disclosure of origin but rather not to process patent application until users reach MATs. For Colombia and the other members of the ACN, this will require amending Article 75 (g) of Decision 486, which invalidates patents that do not disclose the origin of the genetic resources.
   7. On MATs, developing countries rich in biodiversity should increase and centralise negotiations of MATs through organisations such as Costa Rica’s INBio. This requires that, in the case of Colombia, Resolution 620 of 1997 should be modified to allow, for instance, the Institute Alexander Von Humboldt to negotiate MATs; yet the designated national authority (i.e. Ministry of Environment) should grant PIC and validate MATs.

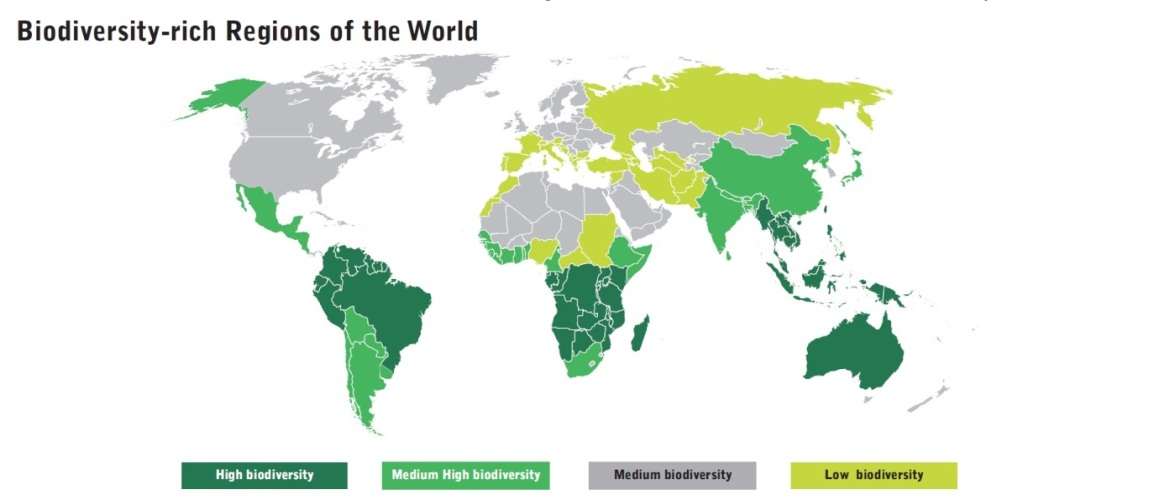
**Annexes**

**Annex I**

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Source: GAO Report to Congressional Requesters, <http://www.gao.gov/new.items/d0749.pdf>

**Annex II**

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Source: K. Kurien & A. Das, ‘Nagoya Protocol and its Implications on Pharmaceutical Industry’ (2011, BEROE) < <http://www.beroeinc.com/insights/whitepapers/nagoya-protocol-and-its-implication-pharmaceutical-industry>> accessed 28.07.2013

**Annex III**

Colombian biodiversity hotspots: Tropical Andes (left) and the Choco/Darien coast (right). Source: *Conservation International* <http://www.conservation.org/where/priority_areas/hotspots/south_america/Pages/south_america.aspx>



Amazon Rain Forests. Source: *Inter Press Service*. <http://ipsnews.net/new_focus/amazon/>

**Appendix I**

**Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organisation, signed in Marrakech,   
Morocco 15 April, 1994**

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[[1052]](#footnote-1053) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3.Members may also exclude from patentability:

* (a)  diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
* (b)  plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28   
Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
   * (a)  where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing[[1053]](#footnote-1054) for these purposes that product;
   * (b)  where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[[1054]](#footnote-1055) of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

* (a)  authorization of such use shall be considered on its individual merits;
* (b)  such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non- commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
* (c)  the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non- commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
* (d)  such use shall be non-exclusive;
* (e)  such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
* (f)  any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
* (g)  authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
* (h)  the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
* (i)  the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
* (j)  any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
* (k)  Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
* (l)  where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
  + (i)  the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
  + (ii)  the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
  + (iii)  the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.  Article 32 Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.8

(…)

SECTION 7:

PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[[1055]](#footnote-1056) so long as such information:

* (a)  is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
* (b)  has commercial value because it is secret; and
* (c)  has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

(…)

PART VI TRANSITIONAL ARRANGEMENTS

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67

Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

(…)

## Article 71 Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2.Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

(…)

**Appendix II**

**Convention on Biological Diversity**

**United Nations 1992**

*Preamble* •

*The Contracting Parties,*

*Conscious of the* intrinsic value of biological diversity and the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components.

*Conscious also* of the importance of biological diversity for evolution and for maintaining life-sustaining systems of the biosphere,

*Affirming* that the conservation of biological diversity is a common concern of humankind,

*Reaffirming* that States have sovereign rights over their own biological resources.

*Reaffirming also* that States are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner,

*Concerned that* biological diversity is being significantly reduced by certain human activities.

*Aware* of the general lack of information and knowledge regarding biological diversity

and of the urgent need to develop scientific, technical and institutional capacities to provide the basic understanding upon which to plan and implement appropriate measures,

*Noting* that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,

*Noting also that where there is a threat* of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as are as on for postponing measures to avoid or minimize such a threat.

*Noting further* that the fundamental requirement for the conservation of biological diversity is the *in-situ* conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings,

*Noting further that ex-situ measures, preferably* in the country of origin, also have an important role to play,

*Recognizing* the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components,

*Recognizing also* the vital role that women play in the conservation and sustainable use of biological diversity and affirming the need for the full participation of women at all levels of policy-making and implementation for biological diversity conservation,

*Stressing* the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and the sustainable use of its components,

*Acknowledging* that the provision of new and additional financial resources and appropriate access to relevant technologies can be expected to make a substantial difference in the world's ability to address the loss of biological diversity,

*Acknowledging further* that special provision is required to meet the needs of developing countries, including the provision of new and additional financial resources and appropriate access to relevant technologies,

*Noting* in this regard the special conditions of the least developed countries and small island States,

*Acknowledging* that substantial investments are required to conserve biological diversity and that there is the expectation of a broad range of environmental, economic and social benefits from those investments,

*Recognizing* that economic and social development and poverty eradication are the first and overriding priorities of developing countries,

*Aware* that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential,

*Noting* that, ultimately, the conservation and sustainable use of biological diversity will strengthen friendly relations among States and contribute to peace for humankind,

*Desiring* to enhance and complement existing international arrangements for the conservation of biological diversity and sustainable use of its components, and

*Determined* to conserve and sustainably use biological diversity for the benefit of present and future generations.

Have agreed as follows:

Article 1

Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity. The sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 2

Use of Terms

For the purposes of this Convention:

"Biological diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species and of ecosystems.

"Biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

"Country providing genetic resources' means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

"Domesticated or cultivated species' means species in which the evolutionary process has been influenced by humans to meet their needs.

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

"Genetic resources" means genetic material of actual or potential value.

'Habitat" means the place or type of site where an organism or population naturally occurs.

In-situ conditions' means conditions where genetic resources exist within ecosystems and natural habitats, and. in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"In-situ conservation' means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

"Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives.

Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

"Sustainable use" means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

"Technology" includes biotechnology

Article 3

Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 4

Jurisdictional Scope

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:

(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and

(b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

Article 5

Cooperation

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or. Where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

Article 6

General Measures for Conservation and Sustainable Use

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and

(b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectorial or cross-sectorial plans, programmes and policies.

Article 7

Identification and Monitoring

Each Contracting Party shall, as far as possible and as appropriate, in particular for the purposes of Articles 8 to 10:

(a) Identify components of biological diversity important for its conservation and sustainable use having regard to the indicative list of categories set down in Annex I:

(b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to subparagraph (a) above, paying particular attention to those requiring urgent conservation measures and those which offer the greatest potential for sustainable use;

(c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and

(d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

Article 8

In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity:

(b) Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity:

(c) Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;

(d) Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings:

(e) Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas:

(f) Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies:

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health:

(h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species:

(i) Endeavour to provide the conditions needed for compatibility between present uses and the conservation of biological diversity and the sustainable use of its components:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices:

(k) Develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations:

(1) Where a significant adverse effect on biological diversity has been determined pursuant to Article 7, regulate or manage the relevant processes and categories of activities: and

(m) Cooperate in providing financial and other support for in-situ conservation outlined in subparagraphs (a) to (1) above, particularly to developing countries.

Article 9

Ex-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures:

(a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components:

(b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources:

(c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

(d) Regulate and manage collection of biological resources from natural habitats for ex-situ conservation purposes so as not to threaten ecosystems and in-situ populations of species, except where special temporary ex-situ measures are required under subparagraph (c) above: and

(e) Cooperate in providing financial support for ex-situ conservation outlined in subparagraphs (a) to (d) above and in the establishment and maintenance of ex-situ conservation facilities in developing countries.

Article 10

Sustainable Use of Components of Biological Diversity

Each Contracting Party shall, as far as possible and as appropriate:

(a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;

(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

(c) Protect аnd encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;

(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and

(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.

Article 11

Incentive Measures

Each Contracting Party shall, as far as possible and as appropriate, adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Article 12

Research and Training

The Contracting Parties, taking into account the special needs of developing countries, shall:

(a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries:

(b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, inter alia, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice: and

(c) In keeping with the provisions of Articles 16. 13 and 20. promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Article 13

Public Education and Awareness

The Contracting Parties shall:

(a) Promote and encourage understanding of the importance of. and the measures required for, the conservation of biological diversity, as well as its propagation through media, and the inclusion of these topics in educational programmes; and

(b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Article 14

Impact Assessment and Minimizing Adverse Impacts

1. Each Contracting Party, as far as possible and as appropriate, shai1:

(a) Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate. allow for public participation in such procedures;

(b) Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account:

(c) Promote, on the basis of reciprocity, notification, exchange information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;

(d) In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and

(e) Promote national arrangements for emergency responses to activities or events, whether caused naturally or otherwise, which present a grave and imminent danger to biological diversity and encourage international cooperation to supplement such national efforts and, where appropriate and agreed by the States or regional economic Integration organizations concerned, to establish joint contingency plans.

2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Article 15

Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create renditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in. such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16

Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1. 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17

Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Article18

Technical and Scientific Cooperation

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building.

3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.

4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this

Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Article 19

Handling of Biotechnology' and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate to provide for the Affective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Article 20

Financial Resources

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.

2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties. Other Parties, including countries undergoing the process of transition to a market economy, may voluntarily assume the obligations of the developed country Parties. For the purpose of this Article, the Conference of the Parties, shall at its first meeting establish a list of developed country Parties and other Parties which voluntarily assume the obligations of the developed country Parties. The Conference of the Parties shall periodically review and if necessary amend the list. Contributions from other countries and sources on a voluntary basis would also be encouraged. The implementation of these commitments shall take into account the need for adequacy, predictability and timely flow of funds and the importance of burden-sharing among the contributing Parties included in the list.

3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.

4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

6. The Contracting Parties shall also take into consideration the special conditions resulting from the dependence on, distribution and location of biological diversity within developing country Parties, in particular small island States.

7. Consideration shall also be given to the special situation of developing countries, including those that are most environmentally vulnerable, such as those with arid and semi-arid zones, coastal and mountainous areas.

Article 21

Financial Mechanism

1. There shall be a mechanism for the provision of financial resources to developing country Parties for purposes of this Convention on a grant or concessional basis the essential elements of which are described in this Article. The mechanism shall function under the authority and guidance of, and be accountable to. the Conference of the Parties for purposes of this Convention. The operations of the mechanism shall be carried out by such institutional structure as may be decided upon by the Conference of the Parties at its first meeting. For purposes of this Convention, the Conference of the Parties shall determine the policy, strategy, programme priorities and eligibility criteria relating to the access to and utilization of such resources. The contributions shall be such as to take into account the need for predictability, adequacy and timely flow of funds referred to in Article 20 in accordance with the amount of resources needed to be decided periodically by the Conference of the Parties and the importance of burden-sharing among the contributing Parties included in the list referred to in Article 20, paragraph 2. Voluntary contributions may also be made by the developed country Parties and by other countries and sources. The mechanism shall operate within a democratic and transparent system of governance.

2. Pursuant to the objectives of this Convention, the Conference of the Parties shall at its first meeting determine the policy, strategy and programme priorities, as well as detailed criteria and guidelines for eligibility for access to and utilization of the financial resources including monitoring and evaluation on a regular basis of such utilization. The Conference of the Parties shall decide on the arrangements to give effect to paragraph 1 above after consultation with the institutional structure entrusted with the operation of the financial mechanism.

3. The Conference of the Parties shall review the effectiveness of the mechanism established under this Article, including the criteria and guidelines referred to in paragraph 2 above, not less than two years after the entry into force of this Convention and thereafter on a regular basis. Based on such review, it shall take appropriate action to improve the effectiveness of the mechanism if necessary.

4. The Contracting Parties shall consider strengthening existing financial institutions to provide financial resources for the conservation and sustainable use of biological diversity.

Article 22

Relationship with Other International Conventions

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.

2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights" and obligations of States under the law of the sea.

(…)

Appendix III

Nagoya Protocol on Access to Genetic Resources and the Fair And Equitable Sharing Of Benefits Arising from their Utilization to the Convention on Biological Diversity

## The Parties to this Protocol,

*Being* Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

*Recalling* that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and *recognizing* that this Protocol pursues the implementation of this objective within the Convention,

*Reaffirming* the sovereign rights of States over their natural resources and according to the provisions of the Convention,

*Recalling further* Article 15 of the Convention,

*Recognizing* the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

*Recognizing* that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

*Acknowledging* the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

*Acknowledging* the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

*Recognizing* the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

*Further recognizing* the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

*Recognizing* *also* the vital role that women play in access and benefit-sharing and *affirming* the need for the full participation of women at all levels of policymaking and implementation for biodiversity conservation,

*Determined* to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

*Recognizing* that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

*Recognizing* the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

*Recognizing* the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

*Recognizing* the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

*Mindful* of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

*Acknowledging* ongoing work in other international forums relating to access and benefit-sharing,

*Recalling* the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

*Recognizing* that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

*Recalling* the relevance ofArticle 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

*Noting* the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

*Recognizing* the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

*Mindful* that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

*Further recognizing* the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

*Noting* the United Nations Declaration on the Rights of Indigenous Peoples, and

*Affirming* that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

Article 1

Objective

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article 2

Use Of Terms

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

1. “Conference of the Parties” means the Conference of the Parties to the Convention;
2. “Convention” means the Convention on Biological Diversity;

(c) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

(e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article 3

Scope

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article 4

Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article 5

Fair and Equitable Benefit-Sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non‑monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 6

Access to Genetic Resources

1.In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit‑sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Article 7

Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article 8

Special Considerations

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;

(b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;

(c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article 9

Contribution to Conservation and Sustainable use

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Article 10

Global Multilateral Benefit-Sharing Mechanism

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article 11

Transboundary Cooperation

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.

2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article 12

Traditional Knowledge Associated with Genetic Resources

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities’ customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.

2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.

3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:

(a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;

(b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and

(c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article 13

National Focal Points and Competent National Authorities

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:

(a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;

(b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and

(c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit‑sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.

3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Article 14

The Access and Benefit-Sharing Clearing-House and Information‑Sharing

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing‑house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.

2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:

(a) Legislative, administrative and policy measures on access and benefit-sharing;

(b) Information on the national focal point and competent national authority or authorities; and

(c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

3. Additional information, if available and as appropriate, may include:

(a) Relevant competent authorities of indigenous and local communities, and information as so decided;

(b) Model contractual clauses;

(c) Methods and tools developed to monitor genetic resources; and

(d) Codes of conduct and best practices.

4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 15

Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non‑compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 16

Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing for Traditional Knowledge Associated with Genetic Resources

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit‑sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article 17

Monitoring the Utilization of Genetic Resources

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:

(a) The designation of one or more checkpoints, as follows:

1. Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;
2. Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;
3. Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;

(iv) Check points must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.

(b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and

(c) Encouraging the use of cost-effective communication tools and systems.

2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

1. Issuing authority;
2. Date of issuance;
3. The provider;
4. Unique identifier of the certificate;
5. The person or entity to whom prior informed consent was granted;
6. Subject-matter or genetic resources covered by the certificate;
7. Confirmation that mutually agreed terms were established;

(h) Confirmation that prior informed consent was obtained; and

(i) Commercial and/or non-commercial use.

Article 18

Compliance with Mutually Agreed Terms

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law; and/or

(c) Options for alternative dispute resolution, such as mediation or arbitration.

2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:

(a) Access to justice; and

(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article 19

Model Contractual Clauses

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 20

Codes of Conduct, Guidelines and Best Practices and/or Standards

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article 21

Awareness-Raising

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit‑sharing issues. Such measures may include, *inter alia*:

(a) Promotion of this Protocol, including its objective;

(b) Organization of meetings of indigenous and local communities and relevant stakeholders;

(c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;

(d) Information dissemination through a national clearing-house;

(e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;

(f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;

(g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;

(h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and

(i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article 22

Capacity

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.

2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity‑building and development to implement this Protocol.

3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:

(a) Capacity to implement, and to comply with the obligations of, this Protocol;

(b) Capacity to negotiate mutually agreed terms;

(c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and

(d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:

(a) Legal and institutional development;

(b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;

(c) The monitoring and enforcement of compliance;

(d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;

(e) Development and use of valuation methods;

(f) Bioprospecting, associated research and taxonomic studies;

(g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;

(h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;

(i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and

(j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.

6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

Article 23

Technology Transfer, Collaboration and Cooperation

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article 24

Non-parties

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Article 25

Financial Mechanism and Resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.

3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

(…)

Article 33

Entry Into Force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

(…)

### Annex

# Monetary and Non-Monetary Benefits

1. Monetary benefits may include, but not be limited to:

1. Access fees/fee per sample collected or otherwise acquired;
2. Up-front payments;
3. Milestone payments;
4. Payment of royalties;
5. Licence fees in case of commercialization;
6. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
7. Salaries and preferential terms where mutually agreed;
8. Research funding;
9. Joint ventures;
10. Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

1. Sharing of research and development results;
2. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
3. Participation in product development;
4. Collaboration, cooperation and contribution in education and training;
5. Admittance to *ex situ* facilities of genetic resources and to databases;
6. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
7. Strengthening capacities for technology transfer;
8. Institutional capacity-building;
9. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
10. Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
11. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
12. Contributions to the local economy;
13. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
14. Institutional and professional relationships that can arise from an access and benefit‑sharing agreement and subsequent collaborative activities;
15. Food and livelihood security benefits;
16. Social recognition;
17. Joint ownership of relevant intellectual property rights.

Annex II

# Work Plan for The Intergovernmental Committee for the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing Of Benefits Arising out Of Their Utilization to the Convention on Biological Diversity

## A. Issues for consideration by the Intergovernmental Committee at its first meeting

1. The modalities of operation of the Access and Benefit-sharing Clearing-House, including reports on its activities (Article 14, paragraph 4).

2. Measures to assist in the capacity-building, capacity development and strengthening of human resources and institutional capacities in developing countries, in particular the least developed countries and small island developing States amongst them, and Parties with economies in transition, taking into account the needs identified by the Parties concerned for the implementation of the Protocol (Article 22).

3. Measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues (Article 21).

4. Cooperative procedures and institutional mechanisms to promote compliance with the Protocol and to address cases of non-compliance, including procedures and mechanisms to offer advice or assistance, where appropriate (Article 30).

## B. Issues for consideration by the Intergovernmental Committee at its second meeting

5. Development of a programme budget for the biennium following the entry into force of the Protocol.

6. Elaboration of guidance for the financial mechanism (Article 25).

7. Elaboration of guidance for resource mobilization for the implementation of the Protocol.

8. Consideration of rules of procedure for the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 5).

9. Elaboration of a draft provisional agenda for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (Article 26, paragraph 6).

10. The need for and modalities of a global multilateral benefit-sharing mechanism (Article 10).

11. Continued consideration of items taken up at the first meeting of the Intergovernmental Committee, as needed.

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**Appendix IV**

**Decision 391  
Common Regime on Access to Genetic Resources**

**(Non-official translation)**

TITLE I

ON THE DEFINITIONS

Article 1.- The following definitions shall apply for purposes of this Decision:

ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.

ACCESS CONTRACT: agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.

ACCESS RESOLUTION: an administrative order issued by the Competent National Authority that executes the access to genetic resources or their by-products, after having fulfilled all requirements or conditions stipulated in the access procedure.

BIOLOGICAL DIVERSITY: the variability of living organisms of any source whatsoever, including, among others, land and ocean ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they are a part. Covers the diversity that exists within each species and between species and within ecosystems as a result of natural and cultural processes.

BIOLOGICAL RESOURCES: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products.

BIOTECHNOLOGY: any technological application that utilizes biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses.

BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.

COMPETENT NATIONAL AUTHORITY: State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in this common regime and to ensure their performance.

COUNTRY OF ORIGIN OF THE GENETIC RESOURCE: country that possesses genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions.

ECOSYSTEM: a dynamic complex of communities of human beings, plants, animals and micro-organisms and their non-living medium that interact as a functional unit.

EX SITU CONDITIONS: those in which the genetic resources are not found in in situ conditions.

EX SITU CONSERVATION CENTER: a person or institution recognized by the Competent National Authority that conserves and collects genetic resources or their by-products outside their in situ conditions.

GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.

GENETIC EROSION: the loss of or decrease in genetic diversity.

GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.

IN SITU CONDITIONS: those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties.

INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes.

NATIONAL SUPPORT INSTITUTION: national institution devoted to biological research of a scientific or technical nature, that accompanies the applicant and participates jointly with it in the access activities.

NATIVE, AFRO-AMERICAN OR LOCAL COMMUNITY: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them.

PROGRAM FOR THE LIBERALIZATION OF GOODS AND SERVICES: a program whose purpose is to eliminate levies and restrictions of all kinds on the importation of goods originating in the territory of any Member Country, pursuant to the provisions of the pertinent chapter of the Cartagena Agreement and all other applicable rules and regulations of its body of law.

SUPPLIER OF THE BIOLOGICAL RESOURCE: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products.

SUPPLIER OF THE INTANGIBLE COMPONENT: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products.

SUSTAINABLE USE: use of the components of biological diversity in a way and at a rate that does not cause their reduction in the long term and that enables them to maintain their possibilities for satisfying the needs and the aspirations of existing and future generations.

SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).

TITLE II

ON THE PURPOSE AND AIMS

Article 2.- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to:

a) Establish the conditions for just and equitable participation in the benefits of the access;

b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;

c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;

d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels; and

e) Strengthen the negotiating capacity of the Member Countries.

TITLE III

ON THE SCOPE

Article 3.- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.

Article 4.- The following are excluded from the scope of this Decision:

a) Human genetic resources and their by-products; and

b) The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices.

TITLE IV

ON THE PRINCIPLES

CHAPTER I

ON THE SOVEREIGNY OVER GENETIC RESOURCES AND

THEIR BY-PRODUCTS

Article 5.- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.

The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.

Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.

(…)

TITLE V

ON THE ACCESS PROCEDURE

CHAPTER I

ON THE GENERAL ASPECTS

Article 16.- All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Article 17.- The applications for access and access contracts and, if appropriate, accessory contracts shall include conditions like the following:

a) The participation of Subregional nationals in the research on genetic resources and their by-products and on the associated intangible component;

b) Support for research within the jurisdiction of the Member Country of origin of the genetic resource or in any other Subregional Member Country that contributes to the conservation and sustainable use of the biological diversity;

c) The strengthening of mechanisms for the transfer of know-how and technology, including biotechnology, that is culturally, socially and environmentally healthy and safe;

d) The supply of information about the background and status of the science and about other matters that would contribute to a better knowledge of the situation regarding the genetic resource that originated in the Member Country, its by-product or synthesized product and its associated intangible component;

e) The strengthening and development of the institutional capacity of the country or the Subregion in regard to genetic resources and their by-products;

f) The strengthening and development of the capacities of the native, Afro-American and local communities with relation to the associated intangible components, the genetic resources and their by-products;

g) The compulsory deposit of duplicates of all material collected, at institutions designated by the Competent National Authority;

h) The obligation to inform the Competent National Authority about the results of the research carried out; and

i) The terms for the transfer of the material to which third parties are given access.

Article 18.- The documents connected with the access procedure shall appear in a public file that the Competent National Authority shall keep.

That file shall consist of the following, at least: the application; the identification of the applicant, the resource supplier, and the national support person or institution; the site or area to which the access applies; the access methodology; the project proposal; the parts of the access contract that are not subject to confidentiality; the opinion about and registry of visits; and, if applicable, the evaluation studies of the economic, social and environmental impact or of the environmental permits.

Also included in the file are the Resolution executing the access, the reports supplied by the national support person or institution, and the follow-up and supervisory reports provided by the Competent National Authority or the entity delegated to perform that task. That file is open to consultation by any person.

Article 19.- The Competent National Authority may give confidential treatment to data and information supplied to it in the course of the access procedure or the contract performance, and not previously disclosed, which could be put to unfair commercial use by third parties, unless the knowledge of this data and information by the public is necessary to protect the social interest or the environment.

Accordingly, the applicant should state the grounds for its petition, accompanied by a non-confidential summary that will become a part of the public file.

The information or documents referred to in the second paragraph of Article 18 of this Decision cannot be made confidential.

The confidential aspects shall be covered in a separate file, in the custody of the Competent National Authority, and may not be disclosed to third parties, unless that is judicially ordered.

Article 20.- If the petition for confidential treatment fails to comply with the requirements established in the previous article, the Competent National Authority shall deny it as a matter of right.

Article 21.- The Competent National Authority shall keep a public registry where the following information shall be entered, among other data: the Resolution that may possibly deny the petition, the access contract signing, amendment, suspension and termination dates, the date and number of the Resolution executing or canceling it, the date and number of the Resolution, award or sentence determining the nullity or imposing penalties, with an indication of their kind and the parties, and accessory contract signing, amendment, suspension, termination and nullification dates.

That registry shall be of a declaratory nature.

Article 22.- As stipulated in Article 15, the execution of the access is dependent upon the provision of full and reliable information by the applicant, as called for by law.

In this connection, the applicant should present the Competent National Authority with all of the information about the genetic resource and its by-products that it knows or is in a position to know at the moment the application is presented. That information shall include the present and potential uses of the resource, by-product or intangible component, their sustainability and the risks that could result from the access.

The statements made by the applicant in the application and in the contract, including their respective annexes, shall be in the nature of a sworn statement.

Article 23.- The permits, authorizations and other documents that support the investigation, obtaining, provision, transfer, etc., of biological resources, shall not determine, qualify or presume the authorization of the access.

Article 24.- It is forbidden to use genetic resources and their by-products in biological weapons or for practices that are harmful to the environment or to human health.

Article 25.- The transfer of technology shall be carried out in accordance with the provisions contained in the body of law of the Cartagena Agreement, complementary national provisions and such rules and regulations on biosecurity and the environment as the Member Countries may approve.

Article 26.- The access to and transfer of technology subject to patents or other intellectual property rights, shall be accomplished in keeping with the Subregional and complementary national provisions regulating that area.

CHAPTER II

ON THE APPLICATION FOR ACCESS

Article 26.- The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:

a) Identification of the applicant and, if pertinent, documents that accredit its legal capacity to make a contract;

b) Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component;

c) Identification of the national support person or institution;

d) Identification and curriculum vitae of the person responsible for the project and of his working group;

e) The access activity applied for; and

f) The location or area where the access is to be carried out, with an indication of its geographical coordinates.

The application shall be accompanied by the project proposal, considering the referential model the Board approves through a Resolution.

Article 27.- If the application with its accompanying project proposal is complete, the Competent National Authority shall accept it, assign it a presentation or filing date, record it in the report and enter it with a declarative intent in the public registry it shall keep for that purpose and open the corresponding file.

Were the application to be incomplete, the Competent National Authority would return it without delay, indicating the information that is missing, so that it might be completed.

Article 28.- Within five working days following the date of entry of the application in the public registry referred to in the previous article, an extract of that application shall be published in a newspaper with broad national circulation and in another medium of the place where the access is to be effected, so that those that wish to might supply information to the Competent National Authority.

Article 29.- Within thirty working days after its registration, the Competent National Authority shall evaluate the application, make the visits it deems necessary and issue a technical and legal opinion about its propriety or invalidity. That period may be extended to up to sixty working days if the Competent National Authority considers it desirable.

Article 30.- When the time limit stipulated in the previous article expires, or before that, if appropriate, the Competent National Authority shall accept or deny the application, based on the results of the opinion, the records of visits, the information supplied by third parties, and the fulfillment of the conditions established in this Decision.

The applicant shall be advised about the acceptance of the application and project proposal within five working days after this occurs. The access contract shall then be immediately drawn up and negotiated.

In the event that the application and project proposal are denied, this shall be communicated through a justified Resolution and the matter shall be considered finished. This does not, however, preclude the filing of such objections as are in order, according to the procedures established in the national legislation of Member Countries.

Article 31.- If required by the national law of the Member Country or if the Competent National Authority deems it necessary, the applicant shall comply with environmental provisions in effect.

The procedures that should be followed in that event shall be independent from those stipulated in this Decision and may be started beforehand. Nonetheless, they must be concluded before the expiration of the time limit stipulated in Article 29 and must be considered by the Competent National Authority in making its evaluation.

Were the Competent National Authority to require such studies, it could grant the applicant a supplementary period set exclusively in accordance with the time needed to complete and submit them for its consideration.

CHAPTER III

ON THE ACCESS CONTRACT

Article 32.- The parties to the access contract are:

a) The State, represented by the Competent National Authority; and

b) The applicant requesting the access.

The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.

Article 33.- The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.

Article 34.- The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.

Article 35.- When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.

The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision.

Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

Article 36.- The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.

Article 37.- The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision.

That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.

CHAPTER IV

ON THE EXECUTION OF THE ACCESS

Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.

Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.

Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.

TITLE VI

ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT

Article 41.- Ancillary contracts are those that are signed in order to carry out activities connected with the genetic resource or its by-products, between the applicant and:

a) The owner, possessor or manager of the land where the biological resource containing the genetic resource is located;

b) The ex situ conservation center;

c) The owner, possessor or manager of the biological resource containing the genetic resource; or

d) The national support institution, with regard to activities that it should perform and that are not a part of the access contract.

Making an ancillary contract does not authorize access to the genetic resource or its by-product, and its contents are subject to the stipulations of the access contract as provided for in this Decision.

The national support institution must be accepted by the Competent National Authority.

Article 42.- Such ancillary contracts as are signed shall include a condition that subjects their execution to that of the access contract.

As of that moment, they shall become effective and binding and shall be governed by the mutually agreed terms, the provisions of this Decision and applicable Subregional and national legislation. The responsibility for their execution and compliance lies only with the parties to the contract.

Article 43.- Without detriment to what has been agreed upon in the accessory contract and independently of it, the national support institution shall be obliged to collaborate with the Competent National Authority in the follow-up and supervision of the genetic resources, by-products or synthesized products and associated intangible components, and to submit reports about the activities for which it is responsible, in the way or with the frequency that the Authority stipulates, according to the access activity.

Article 44.- The nullity of the access contract produces the nullity of the ancillary contract.

The Competent National Authority may also terminate the access contract when the nullity of the ancillary contract is declared, if the latter is essential for the access.

Its amendment, suspension, rescission or resolution may likewise produce the amendment, suspension, rescission or resolution of the access contract by the Competent National Authority if it substantially affects the conditions of the latter contract.

TITLE VII

ON THE LIMITATIONS TO ACCESS

Article 45.- Member Countries may establish, through an express legal rule, partial or total limitations on access to genetic resources or their by-products in the following cases:

a) Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;

b) Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access activities;

c) Adverse effects of access activities on human health or on elements essential to the cultural identity of nations;

d) Undesirable or not easily controlled environmental effects of access activities on the ecosystems;

e) Danger of genetic erosion caused by access activities;

f) Regulations on biosecurity; or

g) Genetic resources or geographic areas rated as strategic.

TITLE VIII

ON VIOLATIONS AND SANCTIONS

Article 46.- Any person performing access activities without the respective authorization shall be liable for punishment.

Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of this Decision.

Article 47.- The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime.

Those sanctions shall be applied without detriment to the suspension, cancellation of nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.

TITLE IX

ON THE NOTIFICATIONS BETWEEN MEMBER COUNTRIES

Article 48.- The Member Countries shall notify each other immediately through the Board, of all applications for access and access resolutions and authorizations, as well as of the suspension and termination of such contracts as are signed.

They shall also advise each other about the signing of any bilateral or multilateral agreement on the subject, which must be in keeping with the provisions of this Decision.

Article 49.- Without prejudice to the stipulations of the previous article, the Member Countries shall immediately inform each other through the Board of all provisions, decisions, regulations, judgments, resolutions and other rules and acts adopted nationally that have to do with the provisions of this Decision.

TITLE X

ON THE COMPETENT NATIONAL AUTHORITY

Article 50.- The Competent National Authority shall perform all of the functions conferred on it in this Decision and in Member Country national legislation. In this connection, it shall be empowered to:

a) Issue the necessary internal administrative provisions to comply with this Decision and, until the appropriate Community rules and regulations are enacted, stipulate how the genetic resources and their by-products shall be identified and packed;

b) Receive, evaluate, accept or deny applications for access;

c) Negotiate, sign and authorize access contracts and issue the corresponding access resolutions;

d) Ensure the rights of suppliers of biological resources that contain genetic resources and of the intangible component;

e) Keep the technical files and the Public Registry of Access to Genetic Resources and their by-products;

f) Keep a directory of persons or institutions pre-qualified to perform scientific or cultural support tasks;

g) Amend, suspend, nullify or terminate access contracts and arrange their cancellation, as the case may be, in keeping with the terms of those contracts, this Decision and Member Country legislation;

h) Oppose the suitability of the national support institution proposed by the applicant and demand its replacement by another, suitable one;

i) Supervise and control compliance with the contractual conditions and the provisions of this Decision and accordingly establish such monitoring and evaluation mechanisms as it deems advisable;

j) Review, in keeping with this Decision, contracts involving access already signed with other institutions or persons and carry out the corresponding actions for repossession;

k) Delegate supervisory activities to other institutions, while keeping the responsibility and direction over that supervision, in conformity with national legislation;

l) Supervise the state of conservation of the biological resources containing the genetic resources;

m) Coordinate continuously with its respective liaison institutions all matters having to do with fulfillment of the provisions of this Decision;

n) Keep the national inventory of genetic resources and their by-products;

o) Keep in continuous contact with the competent national offices for industrial property and set up appropriate information systems with them; and

p) All such other functions as the domestic legislation of the Member Country itself may assign it.

(…)

COMPLEMENTARY PROVISIONS

FIRST.- The Member Countries shall, in keeping with their national legislation, set up or reinforce funds or other types of financial mechanisms financed by the profits from the access and resources from other sources to promote compliance with the aims of this Decision, under the direction of the Competent National Authority.

Through the Andean Committee on Genetic Resources, the Member Countries shall design and implement joint programs for the conservation of genetic resources and shall study the viability and desirability of creating an Andean Fund for their conservation.

SECOND.- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

THIRD.- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

FOURTH.- Such health certificates supporting the export of biological resources as are issued in accordance with Commission Decision 328, its amendments or addenda, shall incorporate the following statement at the end of the format: "Use of this product as a genetic resource is not authorized."

FIFTH.- The Competent National Authority may enter into, with the institutions referred to in Article 36, contracts for the deposit of genetic resources or their by-products or of the biological resources containing them, exclusively for purposes of their care, keeping those resources under its jurisdiction and control.

Likewise, it may make contracts that do not involve access, such as intermediation or administration contracts, in relation to genetic resources or their by-products or synthesized products, in keeping with the provisions of this Regime.

SIXTH.- When requesting access to genetic resources from protected areas or their by-products, the applicant must fulfill, in addition to the stipulations of this Decision, also the special national legislation on the subject.

(…)

**Appendix V**

**DECISION 486**

**Common Intellectual Property Regime  
(Non-official translation)**

**(…)**

**TITLE II  
ON PATENTS**

**CHAPTER I**

On Patentability Requirements

Article 14.- The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable.

Article 15.- The following shall not be considered inventions:

a) discoveries, scientific theories, and mathematical methods;

b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;

c) literary and artistic works or any other aesthetic creation protected by copyright;

d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;

e) computer programs and software, as such; and,

f) methods for presenting information.

Article 16.- An invention may be deemed new when not included in the state of the art.

The state of the art comprises everything that has been made available to the public by written or oral description, use, marketing, or any other means prior to the filing date of the patent or, where appropriate, of the priority claimed.

Solely for the purpose of determining novelty, the contents of a patent application pending before the competent national office and having a filing date or priority application date earlier than the date of the patent or patent priority application under examination, shall likewise be considered part of the state of the art, provided that the said contents are included in the earlier application when published or that the period stipulated in Article 40 has concluded.

Article 17.- For the purposes of determining patentability, no account shall be taken of any disclosure of the contents of the patent during the year prior to the filing date of the application in the Member Country or during the year before the date of priority, if claimed, providing that the disclosure was attributable to:

a) the inventor or the inventor’s assignee;

b) a competent national office that publishes the contents of a patent application filed by the inventor or the inventor’s assignee in contravention of the applicable provision; or,

c) a third party who obtained the information directly or indirectly from the inventor or the inventor’s assignee.

Article 18.- An invention shall be regarded as involving an inventive step if, for a person in the trade with average skills in the technical field concerned, the said invention is neither obvious nor obviously derived from the state of the art.

Article 19.- An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as that involving any productive activity, including services.

Article 20.- The following shall not be patentable:

a) inventions, the prevention of the commercial exploitation within the territory of the respective Member Country of the commercial exploitation is necessary to protect public order or morality, provided that such exclusion is not merely because the exploitation is prohibited or regulated by a legal or administrative provision;

b) inventions, when the prevention of the commercial exploitation within the respective Member Country of the commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment, provided that such exclusion is not made merely because the exploitation is prohibited or regulated by a legal or administrative provision;

c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;

d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

Article 21.- Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

CHAPTER II  
On the Patent Owners

Article 22.- The right to a patent belongs to the inventor and may be assigned or transferred by succession.

Patent owners may be natural or judicial persons.

If several persons make an invention jointly, they shall share the right to patent it.

If several persons make the same invention, each independently of the others, the patent shall be granted to the person or assignee with the first filing date or, where priority is claimed, date of application.

Article 23.- Without prejudice to the provisions of national law in each Member Country, in the case of inventions made in the course of an employment relationship, the employer, whatever its form and nature, may transfer part of the economic benefits deriving from the innovations to the employee inventors in order to promote research activity.

Entities receiving state funding for their research shall reinvest part of the royalties received from the marketing of those inventions to generate a continuing supply of research funds and encourage researchers by giving them a share of the proceeds from the innovations, in accordance with the legislation in each Member Country.

Article 24.- The inventor shall have the right to be cited as such in the patent or to oppose being so mentioned.

(..)

CHAPTER VI  
On the Obligations of the Patent Owner

Article 59.- Owners of patents shall be under the obligation to exploit their patented inventions in any Member Country, either directly or through a person they authorize to do so.

Article 60.- For the purposes of this Chapter, exploitation shall be understood to mean the industrial manufacture of the patented product or the full use of the patented process, including the distribution and marketing of the results thereof on a scale sufficient to satisfy the demands of the market. Exploitation shall also be understood to mean the importation of the patented product, including its distribution and marketing, where this is done on a scale sufficient to satisfy the demands of the market. Where the patent refers to a process that does not result in a product, the requirements for marketing and distribution shall not be enforced.

CHAPTER VII  
On the Regime of Compulsory Licensing

Article 61.- At the expiry of a period of three years following a patent grant or of four years following the application for a patent, whichever is longer, the competent national office may grant a compulsory license mainly for the industrial manufacture of the product covered by the patent, or for full use of the patented process, at the request of any interested party, but only if, at the time of the request, the patent had not been exploited in the manner specified in articles 59 and 60, in the Member Country in which the license is sought, or if the exploitation of the invention had been suspended for more than one year.

Compulsory licenses shall not be granted if patent owners are able to give valid reasons for their failure to act, which may be reasons of force majeure or an act of God, in accordance with the domestic provisions in effect in each Member Country.

A compulsory license shall be granted only if, prior to applying for it, the proposed user has made efforts to obtain a contractual license from the patent holder on reasonable commercial terms and conditions and that such efforts were not successful within a reasonable period of time.

Article 62.- Decisions to grant a compulsory license, as stipulated in the previous article, shall be taken after the patent owners have been notified to present their arguments as they see fit within the following sixty days.

The competent national office shall specify the scope or coverage of the license, and in particular shall specify the period for which it is granted, the subject matter of the license, the amount of the remuneration, and the conditions for the payment thereof. The remuneration shall be set at an adequate level in accordance with the individual circumstances of each case and, in particular, the economic value of the authorization.

Opposition to a compulsory license shall not prevent its exploitation or have any effect on any periods that may be running. The filing of an objection shall not prevent the patent owner, in the meantime, from collecting the remuneration specified by the competent national office on the part unaffected by the objection.

Article 63.- At the request of the owner of the patent or the licensee, the conditions governing the compulsory license may be changed by the competent national office where new circumstances so dictate and, in particular, when the patent holder grants another license on terms that are more favorable than the existing ones.

Article 64.- The licensee shall exploit the licensed invention within a period of two years following the date the license was granted, unless that licensee is able to give valid reasons for inaction consisting of force majeure or an act of God. Otherwise, at the patent owner’s request, the competent national office shall revoke the compulsory license.

Article 65.- Following the declaration by a Member Country of the existence of public interest, an emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time. In that case, the competent national office shall grant the licenses that are applied for. The owner of the patent so licensed shall be notified as soon as is reasonably possible.

The competent national office shall specify the scope or extent of the compulsory license and, in particular, the term for which it is granted, the subject matter of the license, and the amount of remuneration and the conditions for its payment.

The grant of a compulsory license for reasons of public interest shall not reduce the right of the patent owner to continue exploiting it.

Article 66.- The competent national office may, either ex officio or at the request of a party, and after having obtained the consent of the national antitrust authority, grant compulsory licenses where practices are noted that are detrimental to the exercise of free competition, especially where they constitute an abuse by the patent owner of a dominant position in the market.

The need to correct anti-competitive practices shall be taken into account in determining the amount of remuneration to be paid in such cases.

The competent national office shall refuse termination of a compulsory license if and when the conditions which led to the granting of the license are likely to recur.

Article 67.- The competent national office shall grant a license, upon request by the owner of a patent whose exploitation necessarily requires the use of another patent, and that right holder has been unable to secure a contractual license to the other patent on reasonable commercial terms. That license shall, without prejudice to the provisions of article 68, be subject to the following conditions:

a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

b) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and,

c) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 68.- In addition to the conditions provided for in the preceding articles, compulsory licenses shall be subject to the following:

a) they shall be non-exclusive and may not be sublicensed;

b) they shall be non-assignable, except with the part of the business or goodwill which permits its industrial use. This shall be evidenced in writing and registered with the competent national office. Otherwise, those assignments or transfers shall not be legally binding;

c) they shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to them cease to exist and are unlikely to recur;

d) their scope and duration shall be limited to the purposes for which they were authorized;

e) in the case of patents protecting semi-conductor technology, a compulsory license shall be authorized only for public non-commercial use or to remedy a practice declared by the competent national authority to be anti-competitive in accordance with articles 65 and 66;

f) they provide for payment of adequate remuneration according to the circumstances of each case, taking into account the economic value of the license, without prejudice to the stipulations of article 66; and,

g) they shall be used predominantly for the supply of the domestic market.

Article 69.- Compulsory licenses that fail to comply with the provisions of this Chapter shall be devoid of any legal effect whatsoever.

CHAPTER VIII  
On Acts Subsequent to the Grant

Article 70.- A patent owner may request the competent national office to modify the patent in order to enter any change in the name, address, residence or other information about the rights holder or the inventor or to amend or limit the scope of one or more of the claims. The owner of the patent may, likewise, request that any material error in the patent be rectified.

The provisions in respect of the modification or correction of an application shall be applicable as pertinent.

Article 71.- The owner of a patent may, through a declaration addressed to the competent national office, withdraw one or more patent claims or a claim to the patent as a whole. That withdrawal shall become effective as of the date the respective declaration is received.

Article 72.- The owner of a patent may divide it into two or more fractional patents. The provisions regarding the division of an application shall be applicable to that of patents, in all pertinent matters.

Article 73.- A patent owner may also combine two or more patents. The provisions regarding the combination of applications shall be applicable to these patents, in all pertinent matters.

Article 74.- The competent national office may establish the fees on acts carried out after the patent grant.

CHAPTER IX  
On the Invalidation of the Patent

Article 75.- The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:

a) the subject matter of the patent is not an invention according to the requirements stipulated in article 15;

b) the invention fails to comply with the requirements for patentability set out in article 14;

c) the patent was granted for an invention covered by article 20;

d) the patent fails to disclose the invention, as required by article 28 and, if pertinent, article 29;

e) the claims included in the patent are not fully substantiated by the description provided;

f) use of the patent granted has been broader than was indicated in the original application and requires having to extend its scope of protection;

g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their byproducts originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;

h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries; or,

i) there are grounds for absolute invalidation according to domestic legislation covering administrative acts.

Where the grounds specified above are applicable only to some of the claims or some parts of a claim, invalidation shall be pronounced only in respect of those claims or those parts of the said claim, as the case may be.

The patent, claim, or part of a claim that has been invalidated shall be deemed null and void as from the filing date of the patent application.

Article 76.- Where defects in administrative acts fail to produce absolute invalidation as specified in the preceding article, those acts shall be relatively invalidated. In such cases, the competent national authority shall, in conformity with domestic legislation, declare them null and void within a period of five years counted from the patent grant date.

Article 77.- The competent national authority may, where a patent has been granted to a person who has no right to it, annul that patent. Invalidation proceedings may be initiated only by the person who has a right to obtain that patent. That right of action shall lapse five years after the patent grant date or two years following the date on which the person to whom that right belongs learned about the use of the invention, whichever period expires first.

Article 78.- In invalidation proceedings, the competent national authority shall request the patent owners to present arguments and submit the proof they deem advisable.

Where that authority under the domestic law of a Member Country is the competent national office, the patent owner shall present the arguments and submit the proof referred to in the previous article within a period of two months after being notified thereof.

Before the expiry of the period stipulated in the previous article, the interested party may request an extension of two additional months.

Once the periods stipulated in this article have expired, the competent national office shall rule on the patent’s invalidation and inform the parties of its decision.

Article 79.- The competent national authority may, where necessary to rule on the invalidation of a patent, request the patent owner to submit one or more of the documents referred to in article 46 with regard to the patent that is the subject matter of the proceeding.

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26. GAO, *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts* (GAO Report to Congressional Requesters, November 2006, GAO-07-49) <<http://www.gao.gov/new.items/d0749.pdf>> accessed 25.03.2012 [↑](#footnote-ref-27)
27. ‘New’ here means that an invention does not form part of the art; in other words the invention is unknown at the time that a patent application is filed; see for instance Article 54 of the European Patent Convention (EPC) 1973, as amended in 2007 [↑](#footnote-ref-28)
28. This element requires that the applicant for a patent demonstrates that a person skilled in the art finds that the invention is non-obvious when compared with the current state-of-the-art; see Article 56 of EPC [↑](#footnote-ref-29)
29. Industrial application or usefulness refers to an invention that can be made or used in any kind of industry, including the pharmaceutical industry; see Article 57 of EPC [↑](#footnote-ref-30)
30. T. Bartfai & G. Lees, *Drug Discovery: From Bedside to Wall Street* (Elsevier, London, 2006) [↑](#footnote-ref-31)
31. On the protection of Trade Secrets, see the US Uniform Trade Secrets Act (model law, as amended in 1985 The National Conference of Commissioners on Uniform State Laws 1985); on trade secrets and patents see E. Kitch ‘The Nature and Function of the Patent System’ [1977] 20 *Journal of Law and Economics* 265-290; for further information on the US Trade Secrets Act see S. Sandeen, ‘The Evolution of Trade Secret Law and Why Courts Commit Error when They do not Follow the Uniform Trade Secrets Act’ [2010] 33 *Hamline Law Review* 493-543; J. Pooley & C. Graves, *Trade Secrets* (LSLF, 1997); see also protection of undisclosed information in Article 39 of TRIPs [↑](#footnote-ref-32)
32. For further discussion on disclosure and its role in innovation and patent law see A. Devlin ‘The Misunderstood Function of Disclosure in Patent Law’ [2010] 23 *Harvard Journal of Law & Technology* 401-446; see also J. Fromer ‘Patent Disclosure’ [2009] 94 *Iowa Law Review* 540-606; B. Roin ‘The Disclosure Function of the Patent System (Or Lack Thereof)’ [2005] 118 *Harvard Law Review* 2007-2028 [↑](#footnote-ref-33)
33. In the USA the FDA has established that generic medicines are identical or bioequivalent to originators in active ingredients, dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. FDA, ‘Generic Drugs: Questions and Answers’ (FDA website, 2011) <<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>> accessed 04.02.2012; in the case of EU, see: Article 10(2)(b) Directive 2001/83/EC; Committee for Medicinal Products for Human Use-EMA, ‘Guideline on the Investigation of Bioequivalence’ (EMA Doc. Ref: CMP/EWP/QWP/1401/98 Rev. 1, London, 2010) <<http://www.emea.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/01/WC500070039.pdf>> accessed 04.02.2012 [↑](#footnote-ref-34)
34. A Warren-Jones, ‘Regulation Beyond Selfish Interests: Trading Interests for Growth in the context of European Medicines Regulation’ (forthcoming) [↑](#footnote-ref-35)
35. see A. Warren-Jones, "Mapping Science and New Health Technologies: In search of a definition" in M. L. Flear, A-M. Farrell, T. K. Hervey and T. Murphy (Eds), *European Law and New Health Technologies* (Oxford: OUP, 2013), pp 79-80; n 34 subsection 1.2; [↑](#footnote-ref-36)
36. See Article 31 of TRIPs [↑](#footnote-ref-37)
37. n 34, subsection 1.2 [↑](#footnote-ref-38)
38. Ibid. [↑](#footnote-ref-39)
39. n 34, subsection 1.2 [↑](#footnote-ref-40)
40. UN Convention on Biological Diversity, Rio de Janeiro, as adopted in June 1992 [↑](#footnote-ref-41)
41. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, adopted by the Conference of the Parties of the CBD at its sixth meeting, in The Hague in April 2002 [↑](#footnote-ref-42)
42. Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Utilisation, adopted by the Conference of Parties of the CBD at its tenth meeting, in Nagoya, Japan in October 2010 [↑](#footnote-ref-43)
43. D. Kingston, ‘Modern Natural Products Drug Discovery and Its Relevance to Biodiversity Conservation’ [2011] 74 *Journal of Natural Products* 496-511; see also K. ten Kate & S. Laird *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (2000, Kew (UK) Earthscan Publications Ltd) [↑](#footnote-ref-44)
44. n 4, p 34; Conference of Parties of the CBD, *Access to Genetic Resources* (COP 2 Decision II/11, 1995) [↑](#footnote-ref-45)
45. G. Soto Laveaga, *Jungle Laboratories: Mexican Peasants, National Projects, and the Making of the Pill* (2009, Duke University Press) [↑](#footnote-ref-46)
46. G. Cragg et al., ‘The Impact of the UN Convention on Biological Diversity on Natural Products Research’ [2012] 29 *Natural Products Reports* 1407-1423; see also G. Cragg & D. Newman et al., ‘Products as Sources of New Drugs over the 30 Years from 1981 to 2010’ [2012] 75 *Journal of Natural Products* 311-335 [↑](#footnote-ref-47)
47. G. Cragg et al., n 46, p 1408 [↑](#footnote-ref-48)
48. Pharmacophore refers to a part of a molecular structure that is responsible for a particular biological or pharmacological interaction that it undergoes [↑](#footnote-ref-49)
49. G. Cragg et al., n 46, p 1408 [↑](#footnote-ref-50)
50. FDA, ‘FDA Approves Vibativ for Hospitalized Patients with Bacterial Pneumonia’ (FDA website, 2013) <<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358209.htm>> accessed 23.11.2014 [↑](#footnote-ref-51)
51. D. Levine, ‘Vancomycin: A History’ [2006] 42 *Clinical Infectious Diseases* Supplement 1-12 [↑](#footnote-ref-52)
52. P. Oldham et al., ‘Biological Diversity in the Patent System’ [2013] 8 PLUS ONE 1-16 [↑](#footnote-ref-53)
53. A. Kursar et al., ‘Securing Economic Benefits and Promoting Conservation through Bioprospecting’ [2006] 56 *BioScience* 1005-1012 [↑](#footnote-ref-54)
54. V. De Luca et al., ‘Mining the Biodiversity of Plants: A Revolution in the Making’ [2012] 336 *Science* [↑](#footnote-ref-55)
55. Ibid., p 1661 [↑](#footnote-ref-56)
56. n 52, p 5 [↑](#footnote-ref-57)
57. n 53, p 1008 [↑](#footnote-ref-58)
58. n 52, p 5 [↑](#footnote-ref-59)
59. Ibid. [↑](#footnote-ref-60)
60. E. Yong, ‘Evolutionary Trees of Traditional Medicine Plants Provide Hints for Drug-Makers’ (Discover, Blog, September 2012)<<http://blogs.discovermagazine.com/notrocketscience/2012/09/11/evolutionary-trees-of-traditional-medicine-plants-provide-hints-for-drug-makers/#.VFGIH_TF9eF>>accessed 01.10.2014 [↑](#footnote-ref-61)
61. *Association for Molecular Pathology et al. v. Myriad Genetics Inc, et al.* [2012] 569 US 12-398 [↑](#footnote-ref-62)
62. Ministerial Declaration, Fourth Season of the Ministerial Conference adopted in Doha on 14 November 2001 [↑](#footnote-ref-63)
63. Patent Cooperation Treaty, 1970, Washington, as in force from April 1, 2000 [↑](#footnote-ref-64)
64. Patent Law Treaty adopted in Geneva on June 1, 2000 [↑](#footnote-ref-65)
65. The EBL is an umbrella of different approaches based on a process of enquiry which includes Problem-Based Learning (PBL); EBL and PBL were originally developed in medical careers and have been included in other areas of higher education; for further information on EBL and PBL see P. Kahn & K. O’Rourke, ‘Understanding Enquiry-Based Learning’ in T. Barrett et al., *Handbook of Enquiry & Problem Based Learning* (CELT, Galway, 2005) <<http://www.nuigalway.ie/celt/pblbook/>> accessed 20.12.2013; and J. Ashby et al., ‘The Enquiry-Based Learning Experience: an Evaluation Project’ [2005] 6 *Nurse Education in Practice* 22-30 [↑](#footnote-ref-66)
66. See for instance, Section 107 of US Copyright Law (17 US Code) [↑](#footnote-ref-67)
67. A. Cudd, ‘Contractarianism’, The Stanford Encyclopedia of Philosophy (Winter 2013 Edition), Edward N. Zalta (ed.), URL = <http://plato.stanford.edu/archives/win2013/entries/contractarianism/> accessed 04.07.2014 [↑](#footnote-ref-68)
68. J. Locke, *Second Treatise of Government* (1690, Edited in 1980 by C.B. McPherson, Hackett Publishing Company, Indianapolis and Cambridge) [↑](#footnote-ref-69)
69. J. Rawls, *A Theory of Justice* (1990, Harvard University Press) [↑](#footnote-ref-70)
70. T. Hobbes, *Leviathan* (1651, Printed for Andrew Crooke, ebook) [↑](#footnote-ref-71)
71. D. Gauthier, *Morals by Agreement* (2003, Oxford Scholarship Online) [↑](#footnote-ref-72)
72. Locke’s property theory has an enormous influence on the discussion of whether there is a justification for IPRs, for instance see J. Hughes, ‘The Philosophy of Intellectual Property’ [1988-1989] 77 *The Georgetown Law Journal* 287-366); T. Palmer, ‘Are Patents and Copyrights Morally Justified?’ [1990] 13 *Harvard Journal of Law and Public Policy* 817-865 see also: L. Sharp Paine, ‘Trade Secrets and the Justification of Intellectual Property: A Comment On Hettinger’ [1991] 3 *Philosophy and Public Affairs* 247-263; A. Moore, ‘A Lockean Theory of Intellectual Property’ [1997] 21 *Hamline Law Review* 65-107; W. Fisher, ‘Theories of Intellectual Property’ in S. Munzer (ed.), *New Essays in the Legal and Political Theory of Property* (2001, Cambridge University Press); H. Tavani, ‘Locke, Intellectual Property Rights, and the Information Commons’ [2005] 7 *Ethics and Information Technology* 87-97 [↑](#footnote-ref-73)
73. G. Hull, ‘Clearing the Rubbish: Locke, the Waste Proviso and the Moral Justification of Intellectual Property’ [2009] 23 *Public Affairs Quarterly* 67-93 [↑](#footnote-ref-74)
74. W. Gordon, *A Property Right in Self-Expression: Equality and Individualism in the Natural Law of Intellectual Property* [1993] 102 *Yale Law Journal* 1540-1578 [↑](#footnote-ref-75)
75. R. Merges, *Justifying Intellectual Property* (Harvard University Press, 2013) [↑](#footnote-ref-76)
76. A. Mossoff, ‘Saving Locke from Marx: the Labour Theory of Value in Intellectual Property Theory’ [2012] 29 *Social Philosophy and Policy* 283-317 [↑](#footnote-ref-77)
77. R. Nozick, *Anarchy, State and Utopia* (1974, Blackwell, USA) [↑](#footnote-ref-78)
78. n 68, S 28 [↑](#footnote-ref-79)
79. E. Hettinger, ‘Justifying Intellectual Property’ [1989]18 *Philosophy & Public Affairs* 31-52 [↑](#footnote-ref-80)
80. n 77, p 171 [↑](#footnote-ref-81)
81. n 68, S 40 [↑](#footnote-ref-82)
82. Locke’s *First Treaty* and *An Essay Concerning Human Understanding*, n 76, p 297 [↑](#footnote-ref-83)
83. n 76, p 297 [↑](#footnote-ref-84)
84. n 68, S 36 [↑](#footnote-ref-85)
85. n 68, S 37 [↑](#footnote-ref-86)
86. n 79, pp 36-40 [↑](#footnote-ref-87)
87. see n 76, p 292; n 68, S 45 [↑](#footnote-ref-88)
88. n 68, S 34 [↑](#footnote-ref-89)
89. n 76, p 303 [↑](#footnote-ref-90)
90. J. Hughes, ‘Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson’ [2006] 79 *Southern California Law Review* 993-1084 [↑](#footnote-ref-91)
91. [1911] 189 F. 95 [↑](#footnote-ref-92)
92. Ibid., p 103 [↑](#footnote-ref-93)
93. Ibid. [↑](#footnote-ref-94)
94. n 74, pp 1545-1546; n 75, p 37 [↑](#footnote-ref-95)
95. B. G. Damstedt, ‘Limiting Locke: A Natural Law Justification for the Fair Use Doctrine’ [2003] 112 *Yale Law Journal* 1179-1221 [↑](#footnote-ref-96)
96. n 68, S 37 [↑](#footnote-ref-97)
97. n 90, p 995 [↑](#footnote-ref-98)
98. n 68, S 27 [↑](#footnote-ref-99)
99. n 68, S 31 [↑](#footnote-ref-100)
100. n 68, S 27 [↑](#footnote-ref-101)
101. [2012] US\_ 566 [↑](#footnote-ref-102)
102. Ibid., p 23 [↑](#footnote-ref-103)
103. n 61, p 13 [↑](#footnote-ref-104)
104. n 73, p 80 [↑](#footnote-ref-105)
105. [2012] The Controller of Patents, Mumbai India (Compulsory License Application No 1 of 2011) <<http://patentdocs.typepad.com/files/compulsory-license-application.pdf>> accessed 16.03.2012 [↑](#footnote-ref-106)
106. n 75, p 57 [↑](#footnote-ref-107)
107. n 75, p 57 [↑](#footnote-ref-108)
108. n 75, p 65 [↑](#footnote-ref-109)
109. n 75, p 66 [↑](#footnote-ref-110)
110. P. Drahos, *A Philosophy or Intellectual Property Rights* (Ashgate, Dartmouth, USA, 1996) [↑](#footnote-ref-111)
111. Rawls’ theory of social contract centres on principles of justice rather than establishing a form of government, as previous social contract supporters claimed (e.g. Hobbes, Locke, Rousseau and Kant); n 69, p 10 [↑](#footnote-ref-112)
112. Ibid., p 11 [↑](#footnote-ref-113)
113. Ibid., p 54 [↑](#footnote-ref-114)
114. D. Murphy, ‘Are Intellectual Property Rights Compatible with Rawlsian Principles of Justice?’ [2012] 14 *Ethics Inf Technology* 109-121 [↑](#footnote-ref-115)
115. n 110, p 178 [↑](#footnote-ref-116)
116. A. James, *Fairness in Practice* (Oxford University Press, 2012) [↑](#footnote-ref-117)
117. The other two problems that Nussbaum points out are impairment and disability, and species membership, see M. Nussbaum, *Frontier of Justice: Disability, Nationality and Species Membership* (Harvard University Press, 2007) [↑](#footnote-ref-118)
118. Ibid., p 19 [↑](#footnote-ref-119)
119. Ibid., p 70 [↑](#footnote-ref-120)
120. Apsan Frediani, ‘Planning for Freedoms: the Contribution of Sen’s Capability Approach to Development Practice’ (2008, UCL Web site) <discovery.ucl.ac.uk/1317962/> accessed 03.09.2015; see also: D. Eade, ‘Capacity Building: Who Builds Whose Capacity?’ [2007] 17 *Development Practice* 630-639 [↑](#footnote-ref-121)
121. A. Sen, ‘Capability and Well-Being’ in D. Hausman, *The Philosophy of Economics: and Anthology* (2007, Cambridge University Press) [↑](#footnote-ref-122)
122. n 117, p 71 [↑](#footnote-ref-123)
123. n 4, p 7 [↑](#footnote-ref-124)
124. See Commission on IPRs, Innovation and Public Health of WHO, ‘Capacity Building’ (Commission on IPRs website 2015) <http://www.who.int/intellectualproperty/topics/capacity/en/> [↑](#footnote-ref-125)
125. n 77, p 168 [↑](#footnote-ref-126)
126. n 77, p 172 [↑](#footnote-ref-127)
127. Ibid. [↑](#footnote-ref-128)
128. EU Regulation 511 of 2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing Benefits Arising from their Utilisation [↑](#footnote-ref-129)
129. A. Chander & M. Sunder, ‘Is Nozick Kicking Rawls´ Ass? Intellectual Property and Justice [2007] 40 *U.C. Davis Law Review* 563-579 [↑](#footnote-ref-130)
130. For further information on the regulation on clinical trials see n 18; see also EMA, ‘Guideline for Good Clinical Practice’ (CPMP/ICH/135/95) <<http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf>> accessed 25.12.2013; EMA, ‘Reflection Paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries’ (2010) <http://www.ema.europa.eu/docs/en\_GB/document\_library/Regulatory\_and\_procedural\_guideline/2010/06/WC500091530.pd> accessed 25.12.2013 [↑](#footnote-ref-131)
131. For a notional analysis of the impact of the ABS regulation on different sectors including the agriculture industry see K. ten Kate & S. Laird, n 43 [↑](#footnote-ref-132)
132. The International Union for the Protection of New Varieties of Plants (UPOV, French acronym) as signed in Geneva in 1961, and amended in 1972, 1978 and 1991; for further information on UPOV history see A. Heitz, *The History of Plant Variety Protection* (1987, UPOV); for further discussion on the relationship between biodiversity, food security, international trade and the UPOV see G. Dutfield, *Food, Biological Diversity and Intellectual Property: the Role of the International Union for the Protection of New Varieties of Plants (UPOV)* (Global Economic Issue Publications, Intellectual Property Issue Paper N 9, 2011); on food security, biodiversity, the agro industry and the UN Millennium Development Goals see T. Tscharntke et al. ‘Global Food Security, biodiversity Conservation and the Future of Agricultural Intensification’ [2012] 151 *Biological Conservation* 53-59 [↑](#footnote-ref-133)
133. For further information see M. Llewellyn & M. Adcock, *European Plant Intellectual Property* (Hart Publishing, Oxford, 2006,); M. Llewellyn, ‘Which Rules In World Trade Law: Patents or Plant Variety Rights in Intellectual Property Rights’ in T. Cottier & P. Mavroidis (eds) *Intellectual Property: Trade, Competition and Sustainable Development* (The World Trade Forum Vol 3, University of Michigan, 2003); for further information on the conflict between plant breeders protection and patents in Europe see A. Hubel, ‘The Limits of Patentability: Plan Bioscience’ in A. Hubel et al. (eds.) *Limits of Patentability: Plant Sciences, Stem Cells and Nucleic Acids* (Springer, 2013) [↑](#footnote-ref-134)
134. The International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference through [Resolution 3/2001](ftp://ftp.fao.org/ag/cgrfa/res/c3-01e.pdf) [↑](#footnote-ref-135)
135. Conference of Parties of the CBD, n 44 [↑](#footnote-ref-136)
136. For further information on human genetic resources and the ABS regime see D. Schroeder & C. Lasén-Díaz, ‘Sharing the Benefits of Genetic Resources: From Biodiversity to Human Genetics’ [2006] 6 *Developing World Bioethics* 135-143; and D. Schroeder et al. ‘Sharing the Benefits of Genetic Research’ [2005] 331 *British Journal of Medicine* 1331 [↑](#footnote-ref-137)
137. For further information on traditional knowledge and genetic resources see: G. Dutfield, ‘Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What’s left to Discuss’ in M. David & D. Halbert (eds.) *The Sage Handbook of Intellectual Property* (2014, Sage) S. Lewinski (ed), *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (2008, Kluwer Law International, Second Edition, Netherlands); see also: G. Van Overwalle, ‘Protecting and Sharing Biodiversity and Traditional Knowledge: Holder and User Tools’ [2005] 53 *Ecological Economics* 585-607; for further information on traditional knowledge associated with genetic resources after the NP see: Kamau et al. ‘The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Science Community’ [2010] 6 *Law, Environment and Development* 246-262; and G. Nijar, *Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (2011, South Centre); C. Timmermann, ‘Life Sciences, Intellectual Property Regimes and Global Justice’ (PhD Thesis, Wageningen University, Netherlands, 2013) [↑](#footnote-ref-138)
138. n, Introduction of Thesis pp 4-10 [↑](#footnote-ref-139)
139. n Introduction of the Thesis, pp 38-39 [↑](#footnote-ref-140)
140. n 76, p 303 [↑](#footnote-ref-141)
141. n 68, S 27 [↑](#footnote-ref-142)
142. n 68, S 31 [↑](#footnote-ref-143)
143. n, 69, pp 11 and 54 [↑](#footnote-ref-144)
144. n Introduction of the Thesis, p 42 [↑](#footnote-ref-145)
145. C. Grace, ‘The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China’ (DFID Health Systems Resource Centre, London, 2004) <<http://www.who.int/hiv/amds/Grace2China.pdf>> accessed 09.01.2012 [↑](#footnote-ref-146)
146. Similar analysis is carried out by Hoffman article’s on the current shift in bioscience innovation in which the author finds that the strength of China is biotechnology in medicine and India’s is its generic industry; see W. Hoffman, ‘The Shifting Currents of Bioscience’ [2014] 5 *Global Policy* 76-84 [↑](#footnote-ref-147)
147. As explained in the introduction of this thesis, the analysis of the shift in the global markets is taken from the academic scholarship of Amanda Warren-Jones: see n 34, subsection 1.2 [↑](#footnote-ref-148)
148. Ibid. [↑](#footnote-ref-149)
149. n 145, p 46; fur further information of the drug development process see n Introduction of the Thesis, pp 4-10 [↑](#footnote-ref-150)
150. n 8, pp 15-24 [↑](#footnote-ref-151)
151. IMS Institute for Healthcare Informatics *The Global Use of Medicines : Outlook Through 2016* (IMS Institute for Healthcare Informatics, 2012) < <http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/Global%20Use%20of%20Meds%202011/Medicines_Outlook_Through_2016_Report.pdf>> accessed 09.09.2013; and IFPMA *The Pharmaceutical Industry and Global Health: Facts and Figures* (Issue 2011, IFPMA)< <http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA__Facts_And_Figures_2012_LowResSinglePage.pdf> > accessed 09.09.2013 [↑](#footnote-ref-152)
152. World population in July 2013 is calculated to be 7.2 billion people, of which 1.25 billion lived in developed countries. Further statistics on world’s population, see: UN Department of Economic and Social Affairs, Population Division, [*World Population Prospects: The 2013 Revision, Highlights and Advance Tables*](http://esa.un.org/unpd/wpp/Documentation/pdf/WPP2010_Highlights.pdf)(UN Documents, ESA/P/WP.228, 2013) <<http://esa.un.org/wpp/Documentation/pdf/WPP2012_HIGHLIGHTS.pdf> > accessed 09.09.2013 [↑](#footnote-ref-153)
153. P. Trouiller et al., ‘Drug Development for Neglected Diseases: A Deficient Market and Public Health Policy Failure’ [2002] 359 *Lancet* 2188-2194 [↑](#footnote-ref-154)
154. Ibid., p 2189; neglected diseases are communicable diseases that although they affect around 1 billion people in poor countries, there is little investment for the development of drugs for these diseases. Further information on neglected diseases see: WHO, *Working to Overcome the Global Impact of Neglected Tropical Diseases: Second WHO Report on Neglected Tropical Diseases* (WHO, 2012) <<http://www.who.int/neglected_diseases/2012report/en/index.html>> accessed 09.10.2013. For further information regarding the way that R&D is funded for neglected diseases see: see also G-FINDER, *Neglected Disease Research and Development: Five Year Review* (Global Funding of Innovation for Neglected Diseases, 2012) <<http://policycures.org/downloads/GF2012_Report.pdf>> accessed 20.11.2012 [↑](#footnote-ref-155)
155. See WHO website on neglected diseases: <http://www.who.int/neglected_diseases/en/>; and the Global Fund to Fight AIDS, Tuberculosis and Malaria website: <http://www.theglobalfund.org/en/> [↑](#footnote-ref-156)
156. J. Cohen et al., ‘Development of and Access to Products for Neglected Diseases’ [2010] 5 *Plus One* 1-10 [↑](#footnote-ref-157)
157. Ibid., p 3 [↑](#footnote-ref-158)
158. A. Mann, ‘Demand for Malaria Drug Soars’ [2010] 465 *Nature* 672-673 [↑](#footnote-ref-159)
159. n 156, p 3; for further information on originators role in neglected diseases see: the 2012 London Declaration on Neglected Tropical Diseases at <<http://www.who.int/neglected_diseases/London_meeting_follow_up/en/>> accessed 09.10.2013 [↑](#footnote-ref-160)
160. Communication from the Commission, *Fostering Structural Change: an industrial policy for an enlarged Europe* COM (2004) 274 final, p 19 <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0274:FIN:en:PDF>> accessed 12.03.2012; see < http://www.ema.europa.eu> accessed 05.01.2012; for further commentary on this issue see A. Van Troostenburg & G. Tabusso, ‘Medicines Regulation in the European Union’ in L. Edwards et al. (eds.), *Principle and Practice of Pharmaceutical Medicine* (third edition, Wiley-Blackwell, 2011); T. Hervey & J. McHale, *Health Law and the European Union* (Law in Context, Cambridge University Press, 2004); L. Hancher, ‘The Pharmaceutical Market: Competition and Free Movement Actively Seeking Compromises’ in M. McKee et al. (eds.), *The Impact of EU Law on Health Care Systems* (Peter Lang, Switzerland, 2003); on medical product liability see M. Brazier & E. Cave, *Medicine, Patients and the Law* (5th edition, Penguin Books, 2011); in the case of the FDA in the US see current legislation: Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) (September 27, 2007). For further information see also: P. Barton et al., *Food and Drug Law: Cases and Materials* (third edition, Foundation Press, 2007); K. Pina & W. Pines (eds.), *A Practical Guide to Food and Drug Law and Regulation* (Food and Drug Law Institute, 1998) <<http://www.fdli.org/pdf/pubs/FDLI-Practical-Guide.pdf>> accessed 05.01.2012; H. Grabowski & J. Vernon, *The Regulation of Pharmaceuticals: Balancing the Benefits and Risks* (AEI Press, 1987) [↑](#footnote-ref-161)
161. n 17 [↑](#footnote-ref-162)
162. The ratio in the EU is 5 in 10,000 people within the EU, see Article 3 of Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on Orphan Medicinal Products; the US Rare Diseases Act of 2002 (Public Law 107-280) defines rare diseases as those which affect a population of 200,000 in the US; see also A. Lavandeira, ‘Orphan Drugs: Legal Aspects, Current Situation’ [2002] 8 *Haemophilia* 194-198 [↑](#footnote-ref-163)
163. See section 527 of the Orphan Drug Act 1983 (Public Law 97-414); Article 8 of the Regulation [141/2000](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000R0141:EN:NOT" \t "_blank" \o "141/2000) of 16 December 1999on Orphan Medicinal Products; for further information on the Orphan Drug Act see: M. Haffner, ‘Adopting Orphan Drugs — Two Dozen Years of Treating Rare Diseases’ [2006] 354(5) *New England Medicine Journal* 445-447; M. Griggs et al., ‘Clinical Research for Rare Disease: Opportunities, Challenges, and Solutions’ [2009] 96 *Molecular Genetics and Metabolism* 20-26; Communication From the Commission, *Rare Diseases: Europe’s Challenges* (COM, 679 Final, 2008) <<http://ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf>> accessed 08.01.2014 [↑](#footnote-ref-164)
164. Section 4(a) and 5 (a) Subpart A of Part IV of Subchapter A of Chapter 1 of the Internal Revenue Code of 1954 (relating to credits allowable) as amended by the Orphan Act of 1983; Article 9 of the EU Regulation on Orphan Medicinal Products [↑](#footnote-ref-165)
165. Section 528 of the Orphan Act; Article 7 of EU Regulation on Orphan Medicinal Products [↑](#footnote-ref-166)
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250. Ibid., pp 253-254 [↑](#footnote-ref-251)
251. *Novartis v. Union of India* [2013] Indian Supreme Court of Justice (Civil Appeal Nos. 2706-2716 of 2013); for further information, see F. Abbot, ‘Inside Views: The Judgment in Novartis v. India: What the Supreme Court of India Said’ (IP-Watch Blog, 2013) <<http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/>> accessed 08.10.2013; S. Barazza, ‘Incremental Pharmaceutical Innovation in India: the Supreme Court’s Judgment in the Novartis’ [2013] 8 *Journal of Intellectual Property Law & Practice* 776-790; for background information on this case see: *Novartis v. Union of India* [2007] W.P. Nos. 24759 and 24760 of 2006 <<http://www.scribd.com/doc/456550/High-Court-order-Novartis-Union-of-India>> accessed 09.01.12; see also Mueller, n 208, pp 550-556; for further background see: S. Fyan, ‘Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the US’ [2010] 15 *Virginia Journal of Law and Technology* 198-226 [↑](#footnote-ref-252)
252. The Court also denied the patent on the first form of Imatinib Mesylate as it was an already known substance; this is because the substance was already disclosed to the public in a journal and a pre-TRIPs patent; *Novartis v. Union of India*, n 251, p 82 [↑](#footnote-ref-253)
253. Ibid., p 67 [↑](#footnote-ref-254)
254. Ibid., p 91 [↑](#footnote-ref-255)
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270. Ibid., p 468; Mueller, n 208, p 562 [↑](#footnote-ref-271)
271. Mueller, n 208, p 560 [↑](#footnote-ref-272)
272. A. Jauhart & S. Narnaulia, ‘Patenting Life the American, European and Indian Way” [2010] 15 *Journal of Intellectual Property Rights* 55-65 [↑](#footnote-ref-273)
273. For further discussion on the report see: Report of the Expert Committee, n 230 [↑](#footnote-ref-274)
274. H. Malhotra, ‘Biosimilar and non-Innovator Biotherapeutics in India: An Overview of the Current Situation’ [2011] 39 *Biologicals* 321-324 [↑](#footnote-ref-275)
275. Ibid., pp 322-323 [↑](#footnote-ref-276)
276. Mueller, n 208, p 560; for further information on biopiracy see G. Stenton, ‘Biopiracy within the Pharmaceutical Industry: a Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process can be Towards Countries in the South’ [2004] 26 *European Intellectual Property Review* 17-26; J. Koopman, ‘Amidst Peril and Progress: Conservation of Diversity and Patent Law’ in R. Bogers, L. Craker and D. Lange (eds.) *Medical and Aromatic Plants* (Springer, 2006); M. Blakeney, ‘Bioprospecting and Biopiracy’ in B. Ong (ed.) *Intellectual Property Resources* (Marshall Cavendish, Singapore, 2004) (analysing different biopiracy cases and international legislation in PGR);for a different perspective see: BIO & IFPMA, *Analysis of the Examples of ‘Potential Cases of Biopiracy” Submitted by Peru in WIPO/GRTKF/8/12* (WIPO/GRTKF/IC/INF/21, 2010) [↑](#footnote-ref-277)
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280. The application is deemed to be withdrawn on 21.09.2012 see EPO Patent Application, EP1945237 Use of Extracts of Myrtle and Other Mediterranean Agent Towards Yeast and Yeast-Like Microorganism [↑](#footnote-ref-281)
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300. n 145, p 46; n 284, p 4 [↑](#footnote-ref-301)
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310. Lin, n 287, p 108 [↑](#footnote-ref-311)
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351. n Intruduction of Thesis, pp 38-40 [↑](#footnote-ref-352)
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354. Trade Agreement Between the EU and its Members, of the One Part, and Colombia and Peru, of the Other Part (EU/CO/PE/1 en) [↑](#footnote-ref-355)
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379. The initiative took place from 1932 to 1948; in 1938, this public-private partnership opened and equipped a modern lab in the province of Villavicencio for the production of vaccines; see P. Mejia-Rodriguez, ‘De Ratones, Vacunas y Hombres: El Programa de Fiebre Amarilla de la Fundación Rockefeller en Colombia, 1932-1948’ [2004] 24 *DYNAMIS* 119-155 [↑](#footnote-ref-380)
380. Ibid., p 136 [↑](#footnote-ref-381)
381. E. Ordoñez (ed.), *Visión Histórica de la Farmacia en Colombia* (Colección Farma, Grupo Editorial Apsis, Bogotá, 2007) [↑](#footnote-ref-382)
382. BPR Benchmark, n 377, p 53; Espicom Business Intelliegence, “Colombia: World Pharmaceutical Market” (Espicom, 2011) [↑](#footnote-ref-383)
383. For further information on the influence of developed countries, especially the US, on Colombia’s affairs in the 1950s and 1960s see J. Henderson, *Modernization in Colombia: the Laureano Gomez years, 1889-1965* (University Press of Florida, 2001); E. Saenz-Rovner, *Colombia Años* (Universidad Nacional de Colombia, 2002); E. Saenz-Rovner, ‘La Misión del Banco Mundial en Colombia, El Gobierno de Laureano Gomez (1950-1951) y La Asociación Nacional de Industriales (ANDI)’ [2001] *Revista Cuadernos de Economia <*<http://www.fce.unal.edu.co/media/files/documentos/Cuadernos/35/v20n35_saenz_2001.pdf>> accessed 05.02.2012  [↑](#footnote-ref-384)
384. Saenz-Rovner (2001), n 383, p 45 [↑](#footnote-ref-385)
385. H. Forero, *Momentos Históricos de la Medicina en Colombia* (Universidad Nacional de Colombia, 2009) <<http://www.bdigital.unal.edu.co/638/>> accessed 26.01.2012 [↑](#footnote-ref-386)
386. Benchmark, n 377, p 52-53 [↑](#footnote-ref-387)
387. AFIDRO, ‘Historia Afidro’ (Afidro Website, 2012) <http://www.afidro.com/noticias.php?idsec=48> accessed 27.01.2012 [↑](#footnote-ref-388)
388. Ibid. [↑](#footnote-ref-389)
389. Ibid. [↑](#footnote-ref-390)
390. J. Sepúlveda-Mora, *Caracterización Opcional del Sector Farmacéutico en Colombia, enfoque por Entornos* (Servicio Nacional de Aprendizaje, SENA, Medellín-Colombia, 2008) [↑](#footnote-ref-391)
391. ASINFAR, ‘Institucional’ (ASINFAR website, 2012) <http://asinfar.com/index.php?option=com_content&view=article&id=1&Itemid=3> accessed 27.01.2012 [↑](#footnote-ref-392)
392. R. Archer, ‘Party Strength and Weakness in Colombia’s War-time Democracy’ (Paper Presented at the XVIth International Congress, Latin American Studies Association, Washington D.C., 1991) <<http://lasa.international.pitt.edu/members/congress-papers/lasa1991/files/ArcherRonald.pdf>> accessed 31.01.2012; L. Boudon, ‘Party System Deinstitutionalization: the 1997-98 Colombian Elections in Historical Perspective’ [2000] 42 *Journal of Interamerican Studies and World Affairs* 33-57 [↑](#footnote-ref-393)
393. Other social and political measures included housing, social welfare and urban and rural reforms, see A. Catanase, ‘Planning in a State of Siege: The Colombian Experience’ [1973] 49 *Land Economies* 35-43 [↑](#footnote-ref-394)
394. Information collected by T. López and F. Castaño from the Colombia Industrial Property Office for the studies on technology transfer of the Andean Common Market in C. Vaitsos, ‘Patents Revisited: Their Function on Developing Countries’ [1972] 9 *The Journal of Development Studies* 71-97 [↑](#footnote-ref-395)
395. Ibid., p 78 [↑](#footnote-ref-396)
396. Ibid., p 90 [↑](#footnote-ref-397)
397. S, Sell, *Power and Ideas: North-South Politics of Intellectual Property and Antitrust* (State University of NY, 1998) [↑](#footnote-ref-398)
398. Article 538, Title II, Chapter I, Decree 410 of 1971 Colombian Codex of Commerce [↑](#footnote-ref-399)
399. The ACN was created by the Andean Sub-Regional Integration Agreement or Cartagena Agreement signed on 26 May 1969 and modified by the Trujillo Protocol of 1996; although there were five members of the ACN (Colombia, Bolivia, Ecuador, Peru and Venezuela), different commercial and ideological approaches between Venezuela and other members led Venezuela to resign from the ACN in 2006; for further information on the history, legislation and organization of the ACN see: G. Pico Mantilla, *Codigo de la Comunidad Andina* (Eumed.net, 2006); J. Briceño & A. Bustamante (eds.), *La Integración Latinoamericana: Entre el Regionalismo Abierto y la Globalization* (Universidad de los Andes, Venezuela, 2002); M. Pacheco-Suárez, *Los Organos de la Comunidad Andina y su Papel en el Logro Efectivo de la Participación Civil en el Proceso de Integración* (Universidad Andina Simón Bolivar de Bolivia, 2000) [↑](#footnote-ref-400)
400. Decision 85 of the Andean Community of Nations approved on 27th May of 1974 in Lima, Peru; the Decision 85 adopted a similar wording to the Colombian Codex of Commerce see: n 398 [↑](#footnote-ref-401)
401. Benchmark, n 377, pp 53-54 [↑](#footnote-ref-402)
402. M. Angulo & S. Mosquera, ‘Diseño de una Estrategia para La Exportación de Medicamentos Genéricos a los Estados Unidos, Desde una Compañía Farmacéutica Colombiana A Través del apalancamiento de Socio Comercial Americano’ (PG Dissertation, Universidad del Norte, 2008) <<http://manglar.uninorte.edu.co/bitstream/10584/126/1/32653027.pdf>> accessed 26.01.2012 [↑](#footnote-ref-403)
403. n section 2 Chapter 1 [↑](#footnote-ref-404)
404. M. Patarroyo et al., ‘A Synthetic Vaccine Protects Humans Against Challenge with Asexual Blood Stages of Plamodium falciparum Malaria’ [1988] 332 *Nature* 158-161 [↑](#footnote-ref-405)
405. T. Teucher et al., ‘A Chemically Synthesized Subunit Malaria Vaccine is safe and Immunogenic in Tanzanians Exposed to Intense Malaria Transmission’ [1994] 12 *Vaccine* 328-336; see also, M. Tanner et al., ‘SPf66-The First Malaria Vaccine’ [1995] 11 *Parasitology Today* 10-13 [↑](#footnote-ref-406)
406. P. Guerin et al., ‘Malaria: Current Status of Control, Diagnosis, Treatment, and a Proposed Agenda for Research and Development’ [2002] 2 *The Lancet Infectious Diseases* 564-573 [↑](#footnote-ref-407)
407. U. D’Alessandro et al., ‘Efficacy Trial of Malaria Vaccine SPf66 in Gambia Infants’ [1995] 346 *The Lancet* 462-467; K. Bojang et al., ‘An Efficacy Trial of the Malaria Vaccine SPf66 in Gambian Infants-Second Year of Follow Up’ [1997] 16 *Vaccine* 62-67 [↑](#footnote-ref-408)
408. F. Nosten, ‘Randomised Double-Blind Placebo Controlled Trial of SPf66 Malaria Vaccine in Children in Northwestern Thailand’ [1996] 348 *Lancet* 701-707 [↑](#footnote-ref-409)
409. P. Graves & H. Gelband, ‘Vaccines for Preventing Malaria (SPf66)’ [2006] 2 *Cochrane Database of Systematic Review*  [↑](#footnote-ref-410)
410. n subsection 2.1 Chapter 1 [↑](#footnote-ref-411)
411. n subsection 2.1.5 Chapter 1 [↑](#footnote-ref-412)
412. J. Sepúlveda-Mora, ‘Notas Académicas y Profesionales: Consolidación y Estructura de la Mesa Sectorial de Salud Equipo Técnico del Subsector Farmacéutico’ [2006] *Vitae* 88-89 [↑](#footnote-ref-413)
413. The Colombian Social Security System is established by Act 100 of 1993 (Ley 100) Social Security System in Health <<http://www.secretariasenado.gov.co/senado/basedoc/ley/1993/ley_0100_1993.html#T%C3%8DTULO%20PRELIMIN>> accessed 12.04.2012  [↑](#footnote-ref-414)
414. Article 157 Act 100 of 1993 [↑](#footnote-ref-415)
415. The CR monthly fee is 12.5% of the employee’s and self-employed’s monthly income. In the case of employees, 8.5% is paid by employers and 4% by employees; whereas the self-employed have to pay 12.5% of their monthly income; see Articles 202-210 Act 100 of 1993 [↑](#footnote-ref-416)
416. The SR is funded by the CR and provided by subsidised health insurance companies; see Articles 211-227 of Act 100 of 1993 [↑](#footnote-ref-417)
417. Articles 162-169 of Act 100 of 1993 [↑](#footnote-ref-418)
418. For further discussion on Colombian health system see: The Economist, ‘Colombia’s Health Reforms: Shock Treatment’ (Feb 4th The Economist Printed Edition, 2010); for further information on how the Colombia health system operates and challenges, see: A. Glassman et al. (eds.) *From Few to Many: Ten Years of Health Insurance Expansion in Colombia* (Inter-American Development Bank, New York, 2009) <<http://idbdocs.iadb.org/wsdocs/getdocument.aspx?docnum=35026183>> accessed 29.01.2012; J. Londono & J. Frenk, ‘Structure Pluralism: Towards an Innovative Model for Health System Reform in Latin-America’ [1997] 41 *Health Policy* 1-36; and P. Aceves, ‘Colombia: General System of Social Security in Health’ (Joint Learning Network for Universal Health Coverage, 2011) <<http://jointlearningnetwork.org/content/general-system-social-security-health>> accessed 30.01.2012; F. Ruiz et al., ‘Progressive Segmented Health Insurance: Colombia Health Reform and Access to Health Services’ [2007] 16 *Health Economy* 3-18; D. Masis-Pinto, “Colombia: Good Practices in Expanding Health Care Coverage” in P. Gottret et al. (eds), *Good Practices in Health Financing: Lesson from Reforms in Low-and Middle-Income Countries* (The World Bank, 2008) <<http://siteresources.worldbank.org/INTHSD/Resources/376278-1202320704235/GoodPracticesHealthFinancing.pdf>> accessed 30.01.2012 [↑](#footnote-ref-419)
419. Departamento Nacional de Estadísticas (DANE), “Encuesta Nacional de Calidad de Vida” (DANE, 2013) <<http://www.dane.gov.co/files/investigaciones/condiciones_vida/calidad_vida/Boletin_Prensa_ECV_2012.pdf>> accessed 23.11.2013 (47.5% of Colombians who are in the health system were in the CR and 52.2% were in the SR) [↑](#footnote-ref-420)
420. Espicom, n 382, p 1 and 30 [↑](#footnote-ref-421)
421. WTO, ‘Trade Policy Review: Colombia’ (Reported by the Secretariat of the WTO, WT/TPR/S/18, 1996) [↑](#footnote-ref-422)
422. C. Correa, “Reforming the Intellectual Property Rights System in Latin America” [2002] 23 *World Economy* 851-872; R. Salazar-Manriquez, “The Andean Community’s Intellectual Property Regime” in M. Rodríguez et al. (eds.) *The Andean Community and the United States: Trade and Investment Relations in the 1990s* (1998, Inter-American Dialogue and the Organization of American States, Washington D.C.) <<http://www.thedialogue.org/uploads/CAF/IAD_CAF_OAS_1998_Publication/Chapter_14.pdf>> accessed 06.02.2012 [↑](#footnote-ref-423)
423. Decision 311 of 1991 Common Regime on Industrial Property as signed on November 8, Caracas [↑](#footnote-ref-424)
424. Decision 344 of 1993 Common Regime on Industrial Property as signed on October 21, Bogotá [↑](#footnote-ref-425)
425. The World Health Organization defines essential medicines as those medicines ‘that satisfy the health care needs of the majority of the population: they should therefore be available at all times in adequate amounts and in appropriate dosage forms at a price’ in R. Smith et al., ‘Trade, TRIPs and Pharmaceuticals’ [2009] 373 *The Lancet* 684-691; for further information on what dugs are included in the list see: ‘WHO Model List of Essential Medicines 18th List’ (WHO, 2013) <<http://www.who.int/medicines/publications/essentialmedicines/en/index.html>> accessed 03.01.2014 [↑](#footnote-ref-426)
426. This term refers to when patent protection has expired so a medicine can be manufactured without paying royalties to whoever used to own the patent [↑](#footnote-ref-427)
427. See R. Hartog, ‘Essential and Non-Essential Drugs Marketed by the 20 Largest European Pharmaceutical Companies in Developing Countries’ [1993] 37 *Social Science & Medicine* 897-904; M. Reich, ‘The Global Drug Gap’ [2000] 287 *Science* 1979-1981 [↑](#footnote-ref-428)
428. For a general discussion on second indication see n section 1 Chapter 1 [↑](#footnote-ref-429)
429. Decision 344 of 1993 [↑](#footnote-ref-430)
430. Article 78 Decision 344 of 1993 [↑](#footnote-ref-431)
431. Decision 486 of 2000 Common Regime on Industrial Property as signed on September 14, Lima [↑](#footnote-ref-432)
432. See Protocol of Amendment of the US-Colombia FTA Signed on 28, June 2007. For further discussion on the policy making process of the US-Colombia FTA, and the influence of US in Colombian health issues and IPRs see J. Von Braun, *The Domestic Politics of Negotiating International Trade: Intellectual Property Rights in US-Colombia and US-Peru Free Trade Agreements* (Routledge, 2012). [↑](#footnote-ref-433)
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436. Departamento Nacional de Planeacion (DNP), ‘Documento Sectorial: Cadena Farmacéutica y Medicamentos’ (Agenda Interna para la Productividad y la Competitividad-DNP, 2007) <<http://metono032009.wikispaces.com/file/view/farmaceutica.pdf>> accessed 07.02.2012 [↑](#footnote-ref-437)
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445. For further information on INVIMA see: Decree 677 of 1995; J. Vásquez-Velásquez et al., ‘Regulación en el Mercado Farmacéutico Colombiano’ [2010] 15 *Revista de Ciencias Sociales* 197-209; L. Zuleta-Jaramillo & J. Junca-Salas, ‘Efectos Económicos y Sociales de la Regulación sobre la Industria Farmacéutica Colombiana: el Caso de los Estudios de Bioquivalencia y Biodisponibilidad, de los Secretos Empresariales y las Buenas Prácticas de Manufactura’ (Fedasorrollo, 2001) <<http://bvs.per.paho.org/texcom/cd048228/indufarm.pdf>> accessed 08.02.2012 [↑](#footnote-ref-446)
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456. n 69, p 11 [↑](#footnote-ref-457)
457. n 69, p 54 [↑](#footnote-ref-458)
458. n 69, p 11 [↑](#footnote-ref-459)
459. n 117, p 19 [↑](#footnote-ref-460)
460. n Introduction of Thesis, pp 38-40 [↑](#footnote-ref-461)
461. n section 1 Chapter 1 [↑](#footnote-ref-462)
462. The analysis of the relationship between capacity and the global market shift is taken from the academic scholarship of Warren-Jones, n 34 [↑](#footnote-ref-463)
463. See for instance, *Natco Pharma Ltd v. Bayer Corporation*, n 105 [↑](#footnote-ref-464)
464. the drug development process is studied in detail in n, Introduction of Thesis, pp 4-10 [↑](#footnote-ref-465)
465. L. Helfer ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ [2003] 5 *Minnesota Intellectual Property Law Review* 47-61 [↑](#footnote-ref-466)
466. S. Safrin, ‘Hyperownership in a Time of Biotechnological Promise: the International Conflict to Control the Building Blocks of Life’ [2004] 98 *The American Journal of International Law* 641 [↑](#footnote-ref-467)
467. Paris Convention for the Protection of Industrial Property, 1883 as amended on September 28, 1979 [↑](#footnote-ref-468)
468. n section 1 Chapter 1 [↑](#footnote-ref-469)
469. For further information see D. Ritter, ‘Switzerland’s Patent Law History’ [2004] 14 *Fordham Intellectual Property Media and Entertainment Law Journal* 463-496 [↑](#footnote-ref-470)
470. For instance, see Section 22 of the Patents, Designs and Trade Marks Act 1883 (46&47 Vict. C 57) on compulsory licensing and local working requirements [↑](#footnote-ref-471)
471. W. Kingston, ‘Antibiotics, Invention and Innovation’ [2000] 29 *Research Policy* 679 [↑](#footnote-ref-472)
472. C. May & S. Sell, *Intellectual Property Rights: a Critical History (*Lynne Rienner, 2006); W. Hulme “On the History of Patent Law in the Seventeenth and Eighteenth Centuries” [1902] 18 LQR 280 [↑](#footnote-ref-473)
473. M. Halewood, ‘Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law’ [1997] 35 *Osgoode Hall Law Journal* 243 [↑](#footnote-ref-474)
474. See: F. Machlup & E. Penrose, ‘The Patent Controversy in the Nineteenth Century’ [1950] 10 *The Journal of Economic History* 1-29 L. Haber *The Chemical Industry During the Nineteenth Century* (Oxford University Press, 1958) [↑](#footnote-ref-475)
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476. Section 22 of the Patents, Designs and Trade Marks Act 1883 (46&47 Vict.c. 57) [↑](#footnote-ref-477)
477. A. Bloxam, ‘Patent Law in Relation to the Dyeing Industry’ in W. Gardner (ed.) *The British Coal-Tar Industry: Its Origin, Development and Decline* (Williams & Norgate, 1915) [↑](#footnote-ref-478)
478. M. Doane, ‘TRIPS and International Intellectual Property Protection in an Age of Advancing Technology’ [1994] 9 *American University International Law Review* 465 [↑](#footnote-ref-479)
479. n 472, pp 126-130 [↑](#footnote-ref-480)
480. n 472, pp 115-122 [↑](#footnote-ref-481)
481. For instance: the United Kingdom Intellectual Property Office (IPO), the European Patent Office (EPO) and the US Patent and Trademark Office (USPTO) [↑](#footnote-ref-482)
482. Article 2 Paris Convention; see also Articles 3-5 of Berne Convention (applying the same principle to copyright works) [↑](#footnote-ref-483)
483. Article 3 Paris Convention 1883 [↑](#footnote-ref-484)
484. Article 4 ibid. [↑](#footnote-ref-485)
485. M. Pflüger, ‘Paris Convention for the Protection of Industrial Property’ in T. Cottier and P. Véron (eds.), *Concise International and European IP Law: TRIPS, Paris Convention, European Enforcement and Transfer of Technology* (Kluwer Law International, 2008) [↑](#footnote-ref-486)
486. See original text of Paris Convention 1883 [↑](#footnote-ref-487)
487. n 485, 212 [↑](#footnote-ref-488)
488. D. Gervais, *The TRIPs Agreement: Drafting History and Analysis* (3rd ed. Sweet and Maxwell, 2008) [↑](#footnote-ref-489)
489. See Articles 228 to 232 of the Brazilian Patent Act (*Lei de Propriedade Industrial, Lei 9.279/96*) see also K.C. Shadlen, ‘The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil’ [2011] 39 *Policy & Society* 143 [↑](#footnote-ref-490)
490. See Convention Establishing the World Intellectual Property Organization as amended on September 28, 1979. This Convention states that WIPO assumes the administration of the executive body of both the Paris Convention and Berne Convention known as the Paris Union and Berne Union respectively. Therefore, WIPO aims to promote the protection of IPRs globally, this includes not only patents and copyright but also industrial designs, trademarks, etc. (Articles 2 to 4) [↑](#footnote-ref-491)
491. Patent Cooperation Treaty, 1970, Washington, as in force from April 1, 2000; Patent Law Treaty adopted in Geneva on June 1, 2000 [↑](#footnote-ref-492)
492. M. Cordray, ‘GATT v. WIPO’ [1993] *Journal of the Patent and Trademark Office Society* 121 [↑](#footnote-ref-493)
493. A. Sabatelli, ‘Impediments to Global Patent Law Harmonisation’ [1994-1995] *Northern Kentucky Law Review*, 579 [↑](#footnote-ref-494)
494. n 117, p 19 [↑](#footnote-ref-495)
495. n 116, pp 6 and 7 [↑](#footnote-ref-496)
496. n 117, p 70 [↑](#footnote-ref-497)
497. M. Gad, ‘Impact of Multinational Enterprises on Multilateral Rule Making: the Pharmaceutical Industry and the TRIPS Uruguay Round Negotiations’ [2003] 9 *Law and Business Review of the Americas* 667-698 [↑](#footnote-ref-498)
498. See K. Dam, ‘The Growing Importance of International Protection of Intellectual Property’ [1987] 21 *International Lawyer* 627, see: n 360, 470 [↑](#footnote-ref-499)
499. J. Reichman & C. Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPs and an Overview of the Practice in Canada and the US* (ICTSD UNCTAD, Issue Paper No 5, 2003) [↑](#footnote-ref-500)
500. Ibid., p 20 [↑](#footnote-ref-501)
501. Ibid., pp 21-22 [↑](#footnote-ref-502)
502. A. Sykes, ‘TRIPs, Pharmaceuticals, Developing Countries, and the Doha Solution’ (2002) John M. Olin Law & Economics Working Paper No. 140 [↑](#footnote-ref-503)
503. For general discussion on compulsory licensing, TRIPS, access to medicines and human rights see P. Torremans (ed.), *Intellectual Property and Human Rights* (Kluwer Law International, 2008); T. Kongolo, *Unsettled International Property Issues* (Wolters Kluwer, 2008); J. Harrison, *The Human Rights Impact of the World Trade Organization* (Oxford and Portland, Oregon, 2007); A. Attaran & L. White, ‘Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?’ [2001] 17 JAMA 1886-1892; A. Chapman, ‘A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science’ [1998] in WIPO/UNCHCR *Intellectual Property and Human Rights: A Panel Discussion to Commemorate the 50th Anniversary of the Universal Declaration on Human Rights,* Publication No. 762(E) <<http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/chapman.pdf>> accessed 03.09. 2011   [↑](#footnote-ref-504)
504. P. Drahos ‘Developing Countries and International Intellectual Property Standard-Setting’ [2005] 5 *Journal of World intellectual Property* 765-789; n subsection 1.1 Chapter 3 [↑](#footnote-ref-505)
505. R. Weissman, ‘A Long, Strange TRIPs: the Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries’ [1996] 17 *University of Pennsylvania Journal of International Economic Law* 1079-1132 [↑](#footnote-ref-506)
506. n 497, p 673 [↑](#footnote-ref-507)
507. F. Abbott, ‘Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework’ [1989] 22 *Vanderbilt Journal of Transnational Law* 689-745 [↑](#footnote-ref-508)
508. D. Matthews, *Globalising Intellectual Property Rights: the TRIPs Agreement* (Routledge, London, 2002) [↑](#footnote-ref-509)
509. Ibid., p 12 [↑](#footnote-ref-510)
510. n 488, p 8 [↑](#footnote-ref-511)
511. n 504, p 773; see also M. Levis, ‘Role, Perspectives and Challenges of the Generic Pharmaceutical Industry in Latent America’ in P. Roffe et al. (eds.), *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, 2006) [↑](#footnote-ref-512)
512. n 394, p 90 [↑](#footnote-ref-513)
513. See the Chand Report, chaired by Justice Bakshi Teck Chand of the Indian Supreme Court in 1948-1950, and the Ayyangar Report, led also by a Justice of the Supreme Court, Rajagopala Ayyangar in 1959; n subsection 2.1.1. of Chapter 1 [↑](#footnote-ref-514)
514. See n subsection 2.1.1 Chapter 1; see also W. Greene, *The Emergence of India’s Pharmaceutical Industry and Implications for the US Generic Drug Market* (2007) (Office of Economics Working Paper-US International Trade Commission) <<http://www.usitc.gov/publications/332/working_papers/EC200705A.pdf>> accessed 24.o9.2011; J. Lanjouw, ‘The Introduction of Pharmaceutical Product Patents in India’ (1997) Economic Growth Centre, Yale University, Centre Discussion Paper No. 775 <<http://www.nber.org/papers/w6366>> accessed 25.09. 2011 [↑](#footnote-ref-515)
515. n 508, p 14 [↑](#footnote-ref-516)
516. n 508,p 15-16 [↑](#footnote-ref-517)
517. n 508, p 16 [↑](#footnote-ref-518)
518. n 504, 774 [↑](#footnote-ref-519)
519. For further information on the history and content of TRIPs see: N. de Carvalho, *The TRIPs Regime of Patent Rights* (3rd ed. Wolters Kluwer, 2010); C. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPs Agreement* (Oxford University Press, 2007); W. Martin & L. Winters *The Uruguay Round and the Developing Countries* (The World Bank, 1996); M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPs Agreement* (Sweet & Maxwell, 1996); T. Stewart (ed.) *The GATT Uruguay Round: a Negotiating History (1986-1992)* (Kluwer Law International, 1999) [↑](#footnote-ref-520)
520. S. Ford ‘Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents’ [2000] 15 *American University International Law Review* 941-974 [↑](#footnote-ref-521)
521. D. Gervais, *The Trips Agreement: Drafting History and Analysis* (2nd ed. Sweet & Maxwell, 2003) [↑](#footnote-ref-522)
522. For further information on TRIPs-Plus and Doha see: C. Deere, *The Implementation Game: the TRIPs Agreement and the Global Politics of Intellectual Property Reforms in Developing Countries* (Oxford University Press, 2008); J. Cohen et al., “Addressing Legal and Political Barriers to Global Pharmaceutical Access: Options for Remedying the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the Imposition of TRIPs Standards” [2008] 8 *Health, Economics, Policy and Law* 229-256 (claiming that TRIPs-Plus mainly targets countries that have some pharmaceutical industry); D. Gervais (ed.), *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPs-Plus Era* (Oxford University Press, 2007); see also: B. Mercurio, “TRIPs-Plus Provisions in FTAs: Recent Trends” in L. Bartels & F. Ortino (eds.), *Regional Trade Agreements and the WTO Legal System* (2006, Oxford University Press); M. El-Said, “The Road from TRIPs-Minus, to TRIPs, to TRIPs-Plus: Implication of IPRs for the Arab World” [2005] 8 *The Journal of World Intellectual Property* 53-65 [↑](#footnote-ref-523)
523. Article 16.9 the US-Colombia FTAs, n 353 [↑](#footnote-ref-524)
524. For further discussion on second indications or uses in the US and Europe see E. Ventose, *Medical Patent Law-The Challanges of Medical Treatment* (Edward Elgar, 2011) [↑](#footnote-ref-525)
525. Morocco-US Free Trade Agreement (as signed in June 2004) Article 15.9(2); full text of the treaty is at <<http://www.ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text>> accessed 15.03.2012; see further information on US FTAs with developing countries in C. Fink and P. Reichenmiller, ‘Tightening TRIPs: Intellectual Property Provisions of US Free Trade Agreements’ in R. Newfarmer, *Trade, Doha and Development: A Window into the Issues* (the World Bank,2006) [↑](#footnote-ref-526)
526. Article 17.9(1) of the US-Australia Free Trade Agreement as signed in May 2004; full text of the treaty is at <http://www.dfat.gov.au/fta/ausfta/final-text/index.html> accessed 15.03.2012; [↑](#footnote-ref-527)
527. J. von Braun & M. Pugatch, ‘The Changing Face of the Pharmaceutical Industry and Intellectual Property Rights’ [2005] 8 *The Journal of World Intellectual Property Rights* 599-623 [↑](#footnote-ref-528)
528. C. Correa, ‘Unfair Competition Under the TRIPs Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals’ [2002] 3 *Chicago Journal of International Law* 69-85 (claiming that this mechanism does not provide protection to acts of unfair competition but rather it is a partial substitute for patent protection) [↑](#footnote-ref-529)
529. Z. Frias, 'Data Exclusivity, Market Protection and Paediatric Rewards', *Workshop for Micro, Small and Medium Sized Enterprises EMA* (2013) <http://www.ema.europa.eu/docs/en\_GB/document\_library/Presentation/2013/05/WC500143122.pdf> accessed July 15, 2014. [↑](#footnote-ref-530)
530. Article 16.10 (2) of the US - Peru Trade Promotion Agreement as signed in 2006; see full text at <<http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text>> accessed 30.10.2012 [↑](#footnote-ref-531)
531. Article 39.3 has its origins in Article 10 *bis* of the Paris Convention in which Members of the treaty are obliged to assure effective protection against acts of unfair competition; for a brief explanation of the scope of Article 10 *bis* see G. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (WIPO Publication N 611 (E), 1961) < <http://www.wipo.int/freepublications/en/intproperty/611/wipo_pub_611.pdf>> accessed 30.10.2012; G. Skillington & E. Solovy, ‘The Protection of Test and Other Data Required by Article 39.3 of the TRIPs Agreement’ [2003] 24 *Northwestern Journal of International Law & Business* 1-52; C. Correa, ‘Unfair Competition Under the TRIPs Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals’ [2002] 3 *Chicago Journal of International Law* 69-85 [↑](#footnote-ref-532)
532. n 527, p 599 [↑](#footnote-ref-533)
533. Correa, n 531, p 70 [↑](#footnote-ref-534)
534. n 34, p 21 [↑](#footnote-ref-535)
535. Article 15.9(6)(b)(c) of the US and Panama Trade Promotion Agreement as signed June 2007 full text available at <<http://www.ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text>> accessed 31.10.2012; Article 16.10(6)(b)(c) of the US and Peru Trade Promotion Agreement [↑](#footnote-ref-536)
536. n subsection 2.2.2 Chapter 1 [↑](#footnote-ref-537)
537. A. Kapczynski, ‘The Access to Knowledge Mobilization and the New Politics of Intellectual Property’ [2008] *The Yale Law Journal* 117 [↑](#footnote-ref-538)
538. P. Yu, ‘A Tale of Two Development Agendas’ [2009] 35 *Ohio Northern University Law Review* 465-573 [↑](#footnote-ref-539)
539. n 488 [↑](#footnote-ref-540)
540. See: WTO, ‘The General Council Decision On Implementation Issues and Concerns’ (WT/L/384, 19 December, 2000) on different aspects related to international trade [↑](#footnote-ref-541)
541. See Paragraph 17 and the Doha Declaration on the TRIPs Agreement and Public Health [↑](#footnote-ref-542)
542. The Ministerial Declaration also set up a working programme in Paragraph 18 on the establishment of a multilateral system of notification and registration for wines and spirits based on Article 23 of TRIPs as well as the possible extension of Article 23 to products other than wines and spirits [↑](#footnote-ref-543)
543. Paragraph 19 of the Doha Ministerial Declaration also mentions the discussion on traditional knowledge [↑](#footnote-ref-544)
544. n 503 [↑](#footnote-ref-545)
545. Paragraph 1 Doha Declaration on the TRIPs Agreement and Public Health [↑](#footnote-ref-546)
546. Paragraph 1, ibid. [↑](#footnote-ref-547)
547. Council for TRIPs (2002), n 6, Paragraph 1 [↑](#footnote-ref-548)
548. S. Frankel, ‘Challenging TRIPs-Plus Agreements: the Potential Utility of Non-Violation Disputes’ [2009] 12 *Journal of International Economic Law* 1023-1065; C. Correa, ‘Investment Protection in Bilateral and Free Trade Agreements’ [2004-2005] 26 *Michigan Journal of International Law* 331-353; D. Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPs-Plus World: the Free Trade Area of the Americas* (Geneva, QUNO, 2003); S. Sell, “Industry Strategies for Intellectual Property and Trade: the Quest for TRIPs and Post-Trips Strategies” [2002] 10 *Cardozo Journal of International and Comparative Law* 79-108; P. Drahos, ‘BITs and BIPs: Bilateralism in Intellectual Property’ [2001] 4 *The Journal of World Intellectual Property* 791-808 (Drahos also includes Section 301 of the US Trade Act as a bilateral mechanism to secure further protection for pharmaceutical products) [↑](#footnote-ref-549)
549. See n subsections 1.1. and 1.2 Chapter 3 [↑](#footnote-ref-550)
550. See n section 2 Chapter 1 [↑](#footnote-ref-551)
551. n 116, p 285 [↑](#footnote-ref-552)
552. Reichman and Maskus have paid particular attention to developing countries as stewards of competitive rules in their countries to prevent IPRs abuse in the light of TRIPs; ibid.; see also R. Whish & D. Bailey, *Competition Law* (7th Edition, Oxford University Press, 2009); for further discussion on competition law in the EU and the UK see M. Furse, *Competition Law of the EC and UK* (6th Edition, Oxford University Press, 2008); for further discussion on the link between IPRs and competition law see: G. Guidini, *Innovation, Competition and Consumer Welfare in Intellectual Property Law* (Edward Elgar, 2010); S. Anderman (ed.), *The Interface Between Intellectual Property Rights and Competition Policy* (Cambridge University Press, 2009); Federal Trade Commission, “Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition” (US Department of Justice and FTC, 2007) <<http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf>> accessed 13.01.2013 [↑](#footnote-ref-553)
553. R. Hermann, “Developing Countries are not Making the Most of TRIPs Flexibilities Because of Political Pressure” [2012] *British Medical Journal* December 2011 [↑](#footnote-ref-554)
554. This is Rwanda, ibid., p 1 [↑](#footnote-ref-555)
555. TRIPs did not derogate from the Paris Convention and other IPRs-related treaties, but clarified and extended the scope of IPRs protection; see Article 2 TRIPs [↑](#footnote-ref-556)
556. J. Straus, ‘Implications of the TRIPs Agreement in the Field of Patent Law’ in F. Karl and G. Schricker (eds.), *From GATT to TRIPs: the Agreement on Trade-Related Aspects of Intellectual Property Rights* (IIC Studies in Industrial Property and Copyright Law, Max Planck Institute, 1996) [↑](#footnote-ref-557)
557. Article 27.2 of TRIPs Article 53(a) of EPC; and Article 6 (1) of Directive 94/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions (Biotech Directive) [↑](#footnote-ref-558)
558. For instance methods of medical and veterinarian treatment are excluded from patentability to secure that health care professionals can carry out a treatment on medical grounds and not from economic considerations. See *Wellcome/Pigs* T (116/85) [1988] EPOR, paragraph 3.7. In the US, see *Ex parte Brinkerhof (*24 Off. Gaz. Pat. 349, Comm'r Pat. Off. 1883) *Palin vs. Singer*  (36 USPQ 2d 1050), the Physician’s Immunity Statute 1996 (35 U.S.C. §287(c)(1)) see also *Mayo vs. Prometheus* [2012] US\_ 566 which denied a patent over a method of giving a medical treatment to a patient. For further information on the scope of this exclusion and exceptions in Europe see E. Ventose, ‘Patent Protection for Therapeutic Methods Under the European Patent Convention’ [2010] EIPR 120-131; regarding the background and implications of the Physician’s Immunity Statute in the US, see J. Rundle ‘The Physician’s Immunity Statute: A Botched Operation or a Model Procedure’ [2008] 34 *The Journal of Corporation Law* 944-966; for a comparative analysis of different jurisdictions on this issue see A. Sims ‘The Case Against Patenting Methods of Medical Treatment’ [2007] EIPR 43-5; for a general discussion see P. Pennant, “Patentability of Medical Treatment” [1981] 2 EIPR 64; J. Pila, ‘Methods of Medical Treatment within Australian and United Kingdom Patents Law’ [2001] 24 *UNSW Law Journal* 420; K. Panchen, ‘Patentability in the Field of Therapy and Diagnosis’ [1991] 22 IIC 879 [1991]; for a point of view from a developing country see Article 10 on therapeutic methods and Article 18 on plants and animals in the Brazilian Patent Act (*Lei da Propriedade Industrial*); and S. Scholze, ‘Os Direitos de Propiedad Intelectual e a Biotecnologia’ [1998] 15 *Cadernos de Ciencia & Tecnologia* 41-66 [↑](#footnote-ref-559)
559. ; n 521, paragraph 2.253; see also UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press, 2005) [↑](#footnote-ref-560)
560. n subsection 1.2 Chapter 3 [↑](#footnote-ref-561)
561. n 521, paragraph 2.261; this concept is much more elaborate for countries that followed the French Civil Law system. For instance in Colombia, a private contract will have no legal effect if it is against *ordre public,* see F. Hinestrosa *Tratado de las Obligaciones: Concepto, Estructura, Vicisitudes* (Universidad Externado de Colombia, 2007) [↑](#footnote-ref-562)
562. For an analysis of the EPO standards on *ordre public* and morality, particularly in biotechnology see A. Warren-Jones, ‘Finding a 'Common Morality Codex' for Biotech: A Question of Substance’ [2008] 6 IIC 638-661;F. Francioni (ed.), *Biotechnologies and International Human Rights* (Hart Publishing, 2007); P. Drahos, ‘Biotechnology Patents, Markets and Morality’ [1999] 21 EIPR 441-449; R. Ford, ‘The Morality of Biotech Patents: Different Legal Obligations in Europe?’ [1997]19 EIPR 315-318; J. Straus, ‘Patenting Human Genes in Europe - Past Development Prospects for the Future’ [1995] 26 IIC 920-950; D. Beyleveld & R. Brownsword, *Mice, Morality and Patents* (Common Law Institute of Intellectual Property, London 1993); S. Sterckx (ed.), *Biotechnology, Patents and Morality* (Ashgate Publishing Ltd., 1997); see also R. Moufang, ‘Patenting of Human Genes, Cells and Parts of the Body? - the Ethical Dimension of Patent Law’ [1994] 25 ICC 487-515; R. Merges, ‘Intellectual Property in Higher Life Forms: the Patent System and Controversial Technologies’ [1987-1988] 47 *Maryland Law Review* 1051-1075; for a developing country perspective see E. Gonzalez, ‘Patentes Sobre Genes Humanos’ [2004] Derecho y Vida XXXVII <<http://www.scribd.com/doc/32020434/Patentes-Sobre-Genes-Humanos-EMILSSEN-GONZALEZ-DE-CANCINO>> accessed 25.09.2011 [↑](#footnote-ref-563)
563. n 75, pp 31-67 [↑](#footnote-ref-564)
564. n 76 [↑](#footnote-ref-565)
565. n Introduction of Thesis, pp 17-18 [↑](#footnote-ref-566)
566. Biopiracy is the way that IPRs promote the abusive exploitation of genetic resources. There is no benefit sharing (MATs) and/or PIC [↑](#footnote-ref-567)
567. n 73, p 85 [↑](#footnote-ref-568)
568. n Introduction of Thesis, p 36 [↑](#footnote-ref-569)
569. A. Taubman, ‘Genetic Resources’ in S. Von Lewinski (ed.) *Indigenous Heritage and Intellectual Property* (2nd ed., Kluwer Law International, 2008) [↑](#footnote-ref-570)
570. n section 2 Chapter 3 [↑](#footnote-ref-571)
571. C. Seville, *EU Intellectual Property Law and Policy* (Elgar European Law, 2009) [↑](#footnote-ref-572)
572. n 557 [↑](#footnote-ref-573)
573. UK Patent Act 1977 as amended (c.37) [↑](#footnote-ref-574)
574. However, it is also important to mention that the US does not follow this division between discovery and invention as the US Code considers both of them to be inventions (US Patent Act, 35 USCS Sects. 1-376). The US employs a different approach to natural resources with the doctrine of ‘products of nature’. For further discussion on the US legislation and judiciary decisions regarding products of nature doctrine see J. Conley & R. Makowski, ‘Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part I)’ [2003] 85 JPTOS 301-334; J. Conley & R. Makowski, ‘Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II)’ [2003] 85 JPTOS 371-398; J. Utermann, ‘Reflections on Patent Protection of Products of Nature Part Two’ [1978] 9 *International Law Review of Industrial Property & Copyright* 409; J. Utermann, ‘Reflections on Patent Protection of Products of Nature Part One’ [1978] 9 *International Law Review of Industrial Property & Copyright* 523; M. Jacob, ‘Patentability of Natural Products’ [1970] 52 *Journal of the Patent Office Society* 473-478; M. Davis ‘The Patenting of Products of Nature’ [1995] 21 *Rutgers Computer & Technology Law Journal* 293-347; K. Bosicevic, ‘Distinguishing ‘Products of Nature’ from Products Derived from Nature’ [1987] 69 JPTOS 415-427 [↑](#footnote-ref-575)
575. See G. Van Overwalle, ‘Legal and Ethical Aspects of Bio-Patenting: Critical Analysis of the EU Biotechnology Directive’ in P. Drahos (ed.) *Death of Patents*, Oxon (Lawtext Publishing, 2005) A. Warren-Jones, *Patenting rDNA: Human and Animal Biotechnology in the UK and* Europe (Lawtext, 2001); Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics, London, 2002); U. Schatz, ‘Patentability of Genetic Engineering Inventions in European Patent’ [1998] 29 IIC 2-16; S. Bostyn, ‘The Patentability of Genetic Information Carriers’ [1999] 1 IPQ 1-36; A. Oser, ‘Patenting (partial) Gene Sequences taking Particular Account of the EST’ [1999] 30 ICC 1-18; G. Van Overwalle, *The Legal Protection of Biotechnological Inventions in Europe and in the United States: Current Legal Framework and Future Developments* (University Press Leuven, 1997) [↑](#footnote-ref-576)
576. Jacob, n 574, pp 477-478 [↑](#footnote-ref-577)
577. [1874] 90 U.S. 566, WL 17379 (U.S.N.Y.) [↑](#footnote-ref-578)
578. Ibid., p 593 [↑](#footnote-ref-579)
579. Ibid., p 594 [↑](#footnote-ref-580)
580. [1864] 66 E.R. 836 [↑](#footnote-ref-581)
581. n 577, p 596 [↑](#footnote-ref-582)
582. n 91 [↑](#footnote-ref-583)
583. J. Harkness, ‘Dicta on Adrenalin (e): Myriad Problems with Learned Hand’s Product-of-Nature: Pronouncements in *Parke-Davis v. Mulford*’ [2011] 93 *Journal of the Patent and Trademark Office Society* 363-395 [↑](#footnote-ref-584)
584. n 91, p 103 [↑](#footnote-ref-585)
585. See *Kuehmsted v. Farbenfabriken of Elberfeld Co* [1910] 171 F.887 (considering that the therapeutic value of a new chemical product (aspirin) makes it different from a prior chemical product); see also L. Demaine & A. Fellmeth “Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent” [2002] 55 *Stanford Law Review* 303, in p 351 [↑](#footnote-ref-586)
586. *Merck vs. Chase* [1967]155 USPQ 139 in Jacob, n 574, p 476 [↑](#footnote-ref-587)
587. *Código de Propriedade Industrial* Lei No 5.772 de 1971 [↑](#footnote-ref-588)
588. n subsection 1.1 Chapter 3 [↑](#footnote-ref-589)
589. n subsection 1.2 and section 3 Chapter 3 [↑](#footnote-ref-590)
590. n 569, p 190 [↑](#footnote-ref-591)
591. n section 2 Chapter 3 [↑](#footnote-ref-592)
592. For further information regarding the drafting process of the Biotech Directive. A. Plomer et al. *Stem Cell Patents: European Patent Law and Ethics Report*. (Report for the European Commission, 2006) <<http://www.nottingham.ac.uk/law/StemCellProject/project.report.pdf>> accessed 05.09.2011 [↑](#footnote-ref-593)
593. [1980] 447 U.S. 303 [↑](#footnote-ref-594)
594. [1991] US 927.F.2d 1200 [↑](#footnote-ref-595)
595. Ibid., p 1203 [↑](#footnote-ref-596)
596. Ibid., p 1207 [↑](#footnote-ref-597)
597. n subsection 3.3 Chapter 3 [↑](#footnote-ref-598)
598. [1996] 6 OJ EPO 388 [↑](#footnote-ref-599)
599. Ibid., paragraph 6.3.4 [↑](#footnote-ref-600)
600. Nuffield Council, n 575, p xi [↑](#footnote-ref-601)
601. A. Warren-Jones, ‘Patenting DNA: A Lot of Controversy Over a Little Intangibility’ [2004] 12 *Medical Law Review* 97-124 and R. Crespi, ‘Patenting and Ethics: a Dubious Connection’ [2003] 85 JPTOS 31-47; see also T. Baldwin, ‘Ethics and Patents for Genetic Diagnostic Tests’ in G. van Overwalle, *Gene Patents and Public Health*, (Etablissements Emile Bruylant, 2007) [↑](#footnote-ref-602)
602. Nuffield Council, n 575 , 56 [↑](#footnote-ref-603)
603. Ibid., p 59 [↑](#footnote-ref-604)
604. HM Treasury, *Gowers Review of Intellectual Property* (2006) [↑](#footnote-ref-605)
605. Warren-Jones, n 601, p 99 [↑](#footnote-ref-606)
606. Ibid., p 124 [↑](#footnote-ref-607)
607. Since developed countries have been constantly granted patents on biotechnological inventions, there is the fear that patents could prevent others from making further developments in the technology when the claims are either too broad or too narrow; for further discussion see R. Eisenberg , ‘Patenting the Human Genome’ [1990] *Emory Law Journal* 721; see also M. Heller & R. Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ [1998] *Science* 698; and S. Leung, ‘The Commons and Anticommons in Intellectual Property’ [2010] *UCL Jurisprudential Review* 16 [↑](#footnote-ref-608)
608. n 61 [↑](#footnote-ref-609)
609. n 61, p 5 [↑](#footnote-ref-610)
610. n 61, p 16 [↑](#footnote-ref-611)
611. A. Rai & R. Cook-Deegan, ‘Moving beyond “isolated” gene patents’ [2013] 341 *Science* 137‐138; A. Kesselheim et al., ‘Gene Patenting-The Supreme Court Finally Speaks’ [2013] Editorial 10 July *New England Journal of Medicine* 1-7; A. Hirshfel, ‘Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.’ (USPTO memo, 2013) <<http://patentdocs.typepad.com/files/uspto-myriad-memorandum.pdf>> accessed 04.01.2014 (reporting that the USPTO required its patent examiners to deny patents on isolated genes in the light of the Supreme Court Decision) [↑](#footnote-ref-612)
612. For further information see Trilateral Co-operation website <http://www.trilateral.net/index.html> [↑](#footnote-ref-613)
613. Trilateral Co-operation of the US, European and Japanese Patent Offices, reported in 1988, 7 *Biotechnology Law Review* 159-193 [↑](#footnote-ref-614)
614. For instance, Trilateral Project DR2 Biotechnology, *Trilateral Search Guide Book in Biotechnology* (Ver 1 Publication, 2007) < <http://www.trilateral.net/projects/biotechnology/guide1.pdf> > accessed 06.09.2012; Trilateral Project 24.1, *Biotechnology Comparative Study on Biotechnology Patent Practices Comparative Study Report* < <http://www.trilateral.net/projects/biotechnology/practices.pdf> > accessed 06.09.2012; see also P. Gubb, ‘The Trilateral Cooperation’ [2007] 6 *Journal of Intellectual Property Law & Practice* 397-401; K. Kankanala, *Genetic Patent Law and Strategy* (Manupatra, 2007); D. Schertenleib, ‘The Patentability and Protection of DNA-based Inventions in the EPO and the European Union’ [2003] 25 EIPR125-138 [↑](#footnote-ref-615)
615. P. Drahos, ‘Trust Me: Patent Offices in Developing Countries’ [2008] 34 *American Journal of Law & Medicine* 151-174 [↑](#footnote-ref-616)
616. Ibid., pp 157-158 [↑](#footnote-ref-617)
617. C. Correa, ‘Internationalisation of the Patent System and New Technologies’ [2002] 20 *Wisconsin International Law Journal* 523; G. Dutfield et al., *Exploring the Flexibilities of TRIPs to Promote Biotechnology Capacity Building and Appropriate Technology Transfer* (2006, Queen Mary University, London); for an update version of Duffield’s work on exploring flexibilities of WTO for developing countries see G. Dutfield et al., ‘Exploring the Flexibilities of TRIPs to Promote Biotechnology in Developing Countries’ in C. Correa (ed.), *Research Handbook on the Protection of Intellectual Property Rights Under WTO Rules* (2010, Edward Elgar, US) [↑](#footnote-ref-618)
618. Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Developments Policy* (London, 2002) [↑](#footnote-ref-619)
619. UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (2011, United Nations, NY and Geneva) [↑](#footnote-ref-620)
620. n 4, p 4 [↑](#footnote-ref-621)
621. Article 15 (b) Decision 486; see also E. Archila, ‘Radiografía del Patentamiento del Genoma Humano’ [2000] 1 *Propiedad Inmaterial* 81-92 [↑](#footnote-ref-622)
622. n, section 2 Chapter 3 [↑](#footnote-ref-623)
623. Joint Communication from the African Group, ‘Taking Forward the Review of Article 27.3(b) of the TRIPs Agreement’ (WTO Document IP/C/W/404, 2003) [↑](#footnote-ref-624)
624. Communication from the European Communities, ‘Review of Article 27.3(b) of the TRIPs Agreement, and the Relationship between the TRIPs Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore’ (WTO Documents IP/C/W/383, 2003) [↑](#footnote-ref-625)
625. UNCTAD-ICTSD, n 569, p 397 [↑](#footnote-ref-626)
626. Prejudicial Interpretation of Articles 1,6 paragraph (b) and 7 of Decision 344 of ACN 21-(Proceso 21-IP-2000) ATJ [↑](#footnote-ref-627)
627. n section 2 Chapter 3 [↑](#footnote-ref-628)
628. Disclosure of origin was originally proposed by Hendrickx, Gadgil and Devasia, but it was India that introduced this issue in the Conference of Parties of the CBD in 1995; see Conference of Parties of the CBD, *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity* (UNEP/CBD/COP/2/19, 1995). For discussions carried out by the Conference of Parties of the CBD in this issue see: the Conference of Parties of the CBD, *The Convention on Biological Diversity and the Agreement Related Intellectual Property Rights (TRIPs): Relationships and Synergies* (UNEP/CBD/COP/3/23, 1996); for a summary of the discussions in the Council for TRIPs see: the Secretary of WTO, *The Relationship Between the TRIPs Agreement and the Convention on Biological Diversity* (the Council For Trade-Related Aspects of Intellectual Property Rights, IP/C/W/368/Rev.1, 2006); see also F. Hendrickx et al., ‘Access to Genetic Resources: A Legal Analysis’ in V. Sanchez & C. Juma (eds.) *Biodiplomacy: Genetic Resources and International Relations* (ACTS Press, Nairobi, 1993); M. Gadgil & P. Devasia, ‘Intellectual Property Rights and Biological Resources: Specifying Geographical Origins and Prior Knowledge of Use’ [1995] 69 *Current Science* 637-639; for a different analysis of different disclosure of origin M. Blakeney, ‘Proposal for the Disclosure of Origin of Genetic Resources in Patent Applications’ (2004) Background paper for Smithsonian/UNU-IAS Roundtable on certificates of Origin <<http://www.economia.uniroma2.it/conferenze/icabr2005/papers/Blakeney.pdf>> accessed 21.08.2012; see also G. Dutfield, ‘Sharing the Benefits of Biodiversity: Is there a Role for the Patent System’ [2002] 5 *The Journal of World Intellectual Property* 899-931 [↑](#footnote-ref-629)
629. J. Straus, ‘How to Break the Deadlock Preventing a Fair and Rational Use of Biodiversity’ [2008] 11 *The Journal of World Intellectual Property* 229-295 [↑](#footnote-ref-630)
630. C. Correa, *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement* (Occasional Paper No 12, Friends World Committee for Consultation, Quaker UN Office, 2003); De Carvalho, ‘Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent’ in Patent Application without Infringing the TRIPs Agreement: the Problem and the Solution: Patent Law and Policy Symposium – Re-Engineering Patent Law: the Challenge of New Technologies [2000] 2 *Washington University Journal of Law and Policy* 371-401; see also M. Girsberger, ‘Disclosure of the Source of Genetic Resources and Traditional Knowledge’ in International Expert Workshop on Access to Genetic Resources and Benefit Sharing (2004) Mexico, Cancun <<http://www.canmexworkshop.com/documents/final/English.pdf>> accessed 10.06.2010; J. Santamauro, ‘Reducing the Rhetoric: Reconsidering the Relationship of the TRIPs Agreement, CBD and Proposed new Patent Disclosure Requirements Relating To Genetic Resources and Traditional Knowledge’ [2007] 29 *European Intellectual Property Review* 91-99. [↑](#footnote-ref-631)
631. V. Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press, US, 1997) [↑](#footnote-ref-632)
632. S. Murphy, ‘Biotechnology and International Law’ (2001) Washington University Law School, Public Law and Legal Theory Working Paper No. 08 <<http://papers.ssrn.com/paper.taf?abstract_id=266470>> accessed 25.06.2011 [↑](#footnote-ref-633)
633. Ibid., pp 26-53 [↑](#footnote-ref-634)
634. Scientific American Worldview, ‘2013 Scientific American Worldview Overall Scores’ (2013) <<http://www.saworldview.com/wv/scorecard/2013-scientific-american-worldview-overall-scores/>> accessed 25.11.2013 [↑](#footnote-ref-635)
635. n section 2 Chapter 1 [↑](#footnote-ref-636)
636. n section 1 Chapter 2 [↑](#footnote-ref-637)
637. n 73, p 85 [↑](#footnote-ref-638)
638. Sustainable use of biodiversity is part of a broader commitment, which is to achieve sustainable development regarding not only biological diversity but also natural resources such as oil and coal; whereas conservation involves the mandate to protect ecosystems and natural habits and components of biological diversity which are collected in, for instance, botanical gardens, zoos and university collections (Articles 8, 9 and 10 of the CBD); see the Addis Ababa Principles and Guidelines of 2007 which establishes a set of 14 practical principles to accomplish sustainable use; for conceptual and historical background on conservation and sustainability see the International Union for Conservation of Nature and Natural Resources (IUCN), *World Conservation Strategy: Living Resources Conservation for Sustainable Development* (IUCN-UNEP-WWF, 1980) <<http://data.iucn.org/dbtw-wpd/edocs/WCS-004.pdf>> accessed 01.04.2013 [↑](#footnote-ref-639)
639. For further discussion on NP see M. Buck & C. Hamilton, ‘The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity’ [2011] 20 *Review of European Community & International Environmental Law* 47-61; E. Morgera et al. (eds.), *The Nagoya Protocol on Access and Benefit-Sharing in Perspectives* (Matinus Nijhoff Publishers, Leiden, 2013); J. Vogue et al., ‘The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources’ [2011] 7 *Law, Environment and Development Journal* 52-65 [↑](#footnote-ref-640)
640. Commentators such as Ruiz have expanded the scope of the regulation on access to genetic resources and benefit sharing to include issues and international instruments that are related to genetic resources, such as farmers’ rights and FAO’s regulation on plant genetic resources for food (i.e. ITPGRF); M. Ruiz, ‘The International Regime on Access to Genetic Resources and Benefit Sharing: In Search of the Right Path” [2006] 17 *Policy and Environmental Law Series* 1-4 [↑](#footnote-ref-641)
641. n, section 1 Chapter 1 [↑](#footnote-ref-642)
642. See D. Schroeder & B. Pisupati, *Ethics, Justice and the Convention on Biological Diversity* (UNEP, Cape Town, 2010); see also J. Cabrera & K. Garforth, “Sustainable Biodiversity Law: Global Access, Local Benefits” (A CISDL Legal Research Paper, 2003) <<http://cisdl.org/biodiversity-biosafety/public/docs/abs.pdf>> accessed 04.04.2013 [↑](#footnote-ref-643)
643. N. Chishakwe & T. Young, ‘Access to Genetic Resources, and Sharing the Benefits of their Use: International and Sub-regional Issues’ (2003) Working Paper Developed as Requested by the Southern African Development Community <<http://www.weavingaweb.org/absdocuments/eng_SADC.pdf>> accessed 04.01.2014; T. Hodges & A. Daniel, ‘Promises and Pitfalls: First Steps on the Road to the International ABS Regime’ [2005] 14 *Reciel* 148-160 [↑](#footnote-ref-644)
644. Third paragraph of the CBD’s Preamble [↑](#footnote-ref-645)
645. This is also known as a stewardship obligation of conservation and sustainability over the exploitation of biodiversity, which means that developing countries rich in biodiversity should take into account conservation and sustainability in the exploitation of their biodiversity. This stewardship obligations is reflected in the CBD as this treaty requires States to adopt and develop a series of measures that involve, for instance, developing plans and strategies for the conservation and sustainable use of biodiversity (Article 6 of the CBD) as well as identifying and monitoring components of biological diversity (Article 7 of the CBD). For further discussion see: L. William & C. Mitchell, ‘Replacing Private Property: The Case For Stewardship’ [1996] 55 *The Cambridge Law Journal* 566-600; see also: C. Rodgers, ‘Nature’s Place? Property Rights, Property Rules and Environmental Stewardship’ [2009] 68 *The Cambridge Law Journal* 550-574; D. Beyleveld & R. Brownsword, ‘Principle, Proceduralism, and Preoccupation in a Community of Rights’ [2006] 19 *Ratio Juris* 141-168; R. Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford University Press, 2008). [↑](#footnote-ref-646)
646. Common heritage has been employed in international law when it has been difficult, controversial or inconvenient to allocate ownership, particularly the seabed. For further information on Common Heritage see: C. Joyner, ‘Legal Implications of the Concept of the Common Heritage of Mankind’ [1986] 35 *International and Comparative Law Quarterly* 190­199; B. Larschan & B. Brennan, ‘Common Heritage of Mankind Principles in International Law’ [1982-1983] *21 Columbia Journal of Transnational Law* 305-337; for further information on Common Heritage and the seabed see Articles 136 and 137 of the United Nations Convention on the Law of the Sea as signed at Montego Bay on 10th December 1982; for further Reading on this issue see: D. Rothwell, *The International Law of the Sea* (Hart Publishing, 2010); and Y. Tanaka, *The International Law of the Sea* (Cambridge University Press, 2012); another territory in which it has been difficult to assert property is the Antarctica since there are different countries that claim sovereignty and have economic and political interests in the area (e.g. Russia, the US); for further information see the Antarctic Treaty (as signed up in December 1959); Protocol on Environmental Protection to the Antarctic Treaty (the Madrid Protocol) as adopted in 1991, in force 1998, Madrid (suspending certain commercial activities in the Antarctic area); on the relationship between this treaties and the ABS regime see: S. Johnston, *The Relationship Between and International Regime on ABS and the ATS and UNCLOS* (Commissioned Study, UNEP/CBD/WG-ABS/7/INF/3/Part 3, 2009) [↑](#footnote-ref-647)
647. Decision 523 Regional Biodiversity Strategy for the Tropical Andean Countries as signed in Lima, Peru on 17th of July 2002; for general information on the Andean Community policy and legislation see: A. Seiler & G. Dutfield, ‘Regulating Access and Benefit Sharing: Basic Issues, Legal Instruments, Policy Proposals’ (2001) Study Commissioned by the Federal Republic of Germany in Preparation for the 1st Meeting of the Ad Hoc Working Group on Access and Benefit Sharing in Bonn <<http://www.bfn.de/fileadmin/MDB/documents/access.pdf>> accessed 03.01.2014 [↑](#footnote-ref-648)
648. Originally known as Commonwealth Agriculture Bureaux (CAB), in 1986 CAB transformed into CAB International (CABI) for further information see <http://www.cabi.org/about-cabi/>; for further information on the role of these international organisations in the CBD see: B. Groombridge (ed.), *Global Biodiversity: Status of the Earth’s Living Resources* (Chapman & Hall, London, 1992); B. Arts, *The Political Influence of Global NGOs: Cases Studies on the Climate and Biodiversity Conventions* (International Books, Netherlands, 1998) [↑](#footnote-ref-649)
649. For further information on taxonomy see: n 9 [↑](#footnote-ref-650)
650. The Global Taxonomy Initiative included organisations such as FAO, the UN Environment Programme, the International Union for Conservation, the European Strategy Forum for Research Infrastructure; for more information on the Global Taxonomy Initiative see <http://www.cbd.int/gti/> [↑](#footnote-ref-651)
651. The core of the CHM is the use of the World Wide Web (www) in order to classify, organise and find information related to conservation of biodiversity and sustainable use of its components. This web-based mechanism acts as a channel of communication between the national and regional levels, and the Secretariat of the CBD. The information collected may include all national biodiversity-related information necessary to give support to stakeholders (companies, governments, NGOs, etc.); hence they could accomplish the obligations imposed by the CBD; for further information see CBD (2006) ‘The Programme of Work of the Clearing House Mechanism up to 2010’ [Online] Available: <http://www.cbd.int/chm/work/> accessed: 13.04.2010 [↑](#footnote-ref-652)
652. See paragraph 4 (c) of Conference of the Parties of the CBD, *Access and Benefit-Sharing* (1994, COP, Decision IV/8); see also paragraphs 28 and 107-108 of Conference of Parties of the CBD, *Report of the Panel of Experts on Access and Benefit-Sharing* (1999, UNEP/CBD/COP/5/8) [↑](#footnote-ref-653)
653. The 2004 Action Plan on Capacity Building for Access to Genetic Resources and Benefit Sharing (2004, COP, Decision VII/19F) [↑](#footnote-ref-654)
654. The Conference of Parties of the CBD has also paid attention to capacity in terms of biosafety through the Cartagena Protocol. See Cartagena Protocol on Biosafety to the Convention on Biological Diversity as adopted in 1991 in Montreal; there has been a good number of reports and action plans in capacity building in biosafety; see for instance Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), *Capacity Building (Articles 22 and 28)*(3  / UNEP/CBD/ICCP/3/6, 2002); see also the Conference of Parties of the CBD, *Framework and Action Plan for Capacity Building for the Implementation of the Cartagena Protocol on Biosafety* (UNEP/CBD/BS/COP-MOP/6/18, 2012) [↑](#footnote-ref-655)
655. L. Glowka et al., *A Guide to the Convention on Biological Diversity* (IUCN, Gland, Switzerland, 1994) [↑](#footnote-ref-656)
656. Ibid., pp 21-21 [↑](#footnote-ref-657)
657. Ibid., p 16 [↑](#footnote-ref-658)
658. For instance see Preamble, Articles 6, 7, 8, 10, 12(c) of the CBD [↑](#footnote-ref-659)
659. n Introduction Thesis, pp 17-18; n section 3 Chapter 3 [↑](#footnote-ref-660)
660. The International Institute for Sustainable Development, ‘Summary of the Ninth Meeting of the Working Group on Access and Benefit Sharing of the Convention on Biological Diversity’ [2010] 9 *The Earth Negotiation Bulletin* <http://www.iisd.ca/download/pdf/enb09503e.pdf> accessed: 08.08.2012. There were also NGOs which claimed that the definition of derivatives during the negotiations of the NP did not close the ‘digital loophole’ as it did not include ‘genetic information stored or transmitted’ in a digital form; see The ETC Group, *Synthetic Biology: Creating Artificial Life Forms. Briefing and Recommendations for CBD Delegates to COP 10* (the ETC Group, 2010) <<http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_COP10SynbioBriefing081010.pdf>> accessed 09.08.2012; for further information on synthetic biology, the NP, its implementation and the impact for synthetic biology research see M. Bagley & A. Rai, *The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts* (Synthetic Biology Project, Wilson Centre, 2013): see also C. Conde-Gutierrez, ‘Governing Synthetic Biology in the Light of the Access and Benefit Sharing Regulation (ABS)’ [2014] 41 *Law and the Human Genome Review* 63-87 [↑](#footnote-ref-661)
661. F. Casas-Castaneda, ‘Genetic Resources and Property Rights. Tangible and Intangible Property Rights. The Issue of Derivatives’ (2004) International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Mexico, Cancun, 2004 <<http://www.canmexworkshop.com/documents/final/English.pdf>> accessed 10.06.2010 [↑](#footnote-ref-662)
662. M. Tvedt & O. Rukundo, *Functionality of an ABS Protocol* (Fridtjof Nansen Institute, 2010) <<http://www.fni.no/doc&pdf/FNI-R0910.pdf>> accessed 23.08.2012 [↑](#footnote-ref-663)
663. See for instance Guidelines 8, 16 (b)(vi), 24, 41, 44 (1); n subsection 1.3 Chapter 4; for further analysis on the term ‘utilisation of genetic resources’ see M. Tvedt & T. Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD* (IUCN, Gland, Switzerland, 2007) [↑](#footnote-ref-664)
664. T. Greiber et al., *An Explanatory Guide to the Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing* (IUCN Environmental Policy and Law Paper No. 83, 2012) <<https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf>> accessed 10.04.2013 [↑](#footnote-ref-665)
665. K. Bavikatte & B. Tobin, ‘Cutting the Gordian Knot: Resolving Conflicts over the Term “Utilisation”’ [2010] 4 *Bridges Trade BioRes Review* [↑](#footnote-ref-666)
666. For further information of how the negotiations on the protocol were carried out see UNEB CBD, *Report of the Fourteenth Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice* (UN Doc UNEP/CBD/COP/10/3, Nagoya, Japan, 2010); and UNEB CBD, *Report of the Second Part of the Ninth Meeting of the Ad Hoc Open-Ended Working Group On Access and Benefit Sharing* (UN Doc. UNEP/CBD/COP/10/5/ad. Nagoya, Japan, 2010) [↑](#footnote-ref-667)
667. Buck & Hamilton, n 639, pp 55-57 [↑](#footnote-ref-668)
668. n 664, pp 66-68 [↑](#footnote-ref-669)
669. M. Tvedt, ‘Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment’ [2006] 9 *The Journal of World Intellectual Property* 189-212: T. Swanson, ‘Why is there a Biodiversity Convention?’ [1999] 75 *International Affairs* 307-331 [↑](#footnote-ref-670)
670. BIO, ‘Views and Proposals of the BIO and the PhRMA for the Eighth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing’ (BIO, 2009) <<http://www.bio.org/advocacy/letters/comments-8th-meeting-convention-biological-diversity-cbd-ad-hoc-open-ended-working->> accessed 23.07.2012 [↑](#footnote-ref-671)
671. For more information on the implementation measures of the CBD at the national and regional level see <https://www.cbd.int/abs/measures/default.shtml> [↑](#footnote-ref-672)
672. For further discussion on disclosure of origin see: n subsection 3.4 Chapter 3 [↑](#footnote-ref-673)
673. For further information on the history of the IRCC see G. Garrity et al., ‘Studies on Monitoring and Tracking Genetic Resources: An Executive Summary’ [2009] 1 *Standards in Genomic Sciences* 78-86; for further information on the history of the certificate see in D. Cunningham et al., ‘The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Preliminary Results of Comparative Analysis of Tracking Material in Biological Resources Centers and of Proposal for Certification Scheme’ (2004) Working Paper, UNU-IAS <[https://www.cbd.int/doc/meetings/abs/abswg-03/information/abswg-03-inf-05-en.doc>](https://www.cbd.int/doc/meetings/abs/abswg-03/information/abswg-03-inf-05-en.doc%20%3e%20) accessed 21.08.2012; for a summarised version of the proposal see: D. Cunningham et al., ‘Tracking Genetic Resources and International Access and Benefit Sharing Governance: the Role of Certificates of Origin’ (Background paper for Smithsonian/UNU-IAS Roundtable on certificates of Origin, 2004) <<http://www.ias.unu.edu/binaries2/Certificates_of_origin_backgr_paper.doc>> accessed 21.08.2012 [↑](#footnote-ref-674)
674. n 664, pp 172-175 [↑](#footnote-ref-675)
675. The Conference of Parties, *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use* (UNEP/CBD/COP/3/22, 1996) [↑](#footnote-ref-676)
676. Decrees 1375 and 1376 of 2013 [↑](#footnote-ref-677)
677. G. Dutfield, ‘Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What’s left to Discuss’ in M. David & D. Halbert (eds.) *The Sage Handbook of Intellectual Property* (2014, Sage) [↑](#footnote-ref-678)
678. ICG, *Joint Recommendation on Genetic Resources and Associated Traditional Knowledge: Document Submitted by the Delegations of Canada, Japan, Norway, the Republic of Korea and the US* (2014, WIPO/GRTKF/28/7) [↑](#footnote-ref-679)
679. See website: <http://www.tkdl.res.in/>; for further discussion see: J. Gaudilliere, ‘An Indian Path to Biocapital? The Traditional Knowledge Digital Library, Drug Patents, and the Reformulation Regime of Contemporary Ayurveda’ [2014] *East Asian Science, Technology and Society* 2717469 [↑](#footnote-ref-680)
680. G. Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge , Drug Discovery and Patent-Based Biopiracy' [2011] 33 EIPR 238-244 [↑](#footnote-ref-681)
681. *Merrell Dow Pharmaceuticals Inc v. HN Norton & Co Ltd* [1996] R.P.C. 76 (HL) in Dutfield, Ibid., pp 242-243 [↑](#footnote-ref-682)
682. n 680, p 243, see also: Board of Patent Appeals and Interferences of USPTO, *Ex Parte* Pfizer, Inc. (2009) at <<http://ipwatchdogs.com/cases/viagra_bpai_decision.pdf>> accessed 20.09.2014 [↑](#footnote-ref-683)
683. see official website: <https://absch.cbd.int/Art10_groups.shtml> [↑](#footnote-ref-684)
684. For further information on different MATs rules and agreements in different national jurisdiction see T. Young et al. (eds.), *Contracting for ABC: the Legal and Scientific Implications of Bioprospecting Contracts* (IUCN, Gland, Switzerland, 2009) [↑](#footnote-ref-685)
685. See Annex of NP Monetary and Non-monetary Benefits. Monetary benefits might include fees for access, up-front payments, milestones payments, payment of royalties, etc.; non-monetary benefits include sharing of research and development results, admittance to *ex situ* facilities, etc. [↑](#footnote-ref-686)
686. The GEF was a US$ 1 billion pilot project of the World Bank Organization. Founded in 1991, the GEF coordinates different stakeholders to grant projects on environmental sound projects in more than 182 countries; for further information visit GEF’s web page: <http://www.thegef.org>; for further discussion on the history and role of GEF see: Z. Young, ‘NGOs and the Global Environmental Facility: Friendly Foes?’ [1999] 8 *Environmental Politics* 243-267; C. Streck, ‘The Global Environment Facility: A Role Model for International Governance?’ [2001] 12 *Global Environmental Policy* 71-94 [↑](#footnote-ref-687)
687. For further information on the relationship between economic development and the ABS regime see V. Boisvert & A. Coron, ‘The Convention on Biological Diversity: An Institutionalism Perspective of the Debates’ [2002] 36 *Journal of Economic Issues* 151-166; for a developed country’s perspective see also D. Eugene, ‘The 1992 Convention on Biological Diversity the Continuing Significance of US Objection at the Earth Summit’ [1993] 26 *Geo. Wash. J. Int’l L. &Econ* 479-537 [↑](#footnote-ref-688)
688. Cragg et al. n 46, p 1408 [↑](#footnote-ref-689)
689. C. Richerzhagen & K. Holm-Mueller, ‘The Effectiveness of Access and Benefit Sharing in Costa Rica: Implications for National and International Regimes’ [2005] 53 *Ecological Economics* 445-460; for further information on INBio, Bioprospecting and Access to Genetic Resources in Costa Rica see J. Cabrera, ‘Access to Genetic Resources, Protection of Traditional Knowledge, and Intellectual Property Rights: Lessons Learned from the Costa Rica Experience’ [2003] 10 *Gene Conserve* 128-151 [↑](#footnote-ref-690)
690. C. Tinker, ‘A “New Breed” of Treaty: The United Nations Convention on Biological Diversity’ [1995] 12 *Pace Environmental Law Review* 191-218 [↑](#footnote-ref-691)
691. D. Eugene, n 687, p 517; for further information on transfer of technology see R. Findlay, ‘Relative Backwardness, Direct Foreign Investment and the Transfer of Technology: A Simple Dynamic Model’ [1979] 92 *The Quarterly Journal of Economics* 1-16; for general information on the basics of transfer of technology and its different models see Radošević, S, ‘Technology and Modes of Technology Transfer’ in *International Technology-Transfer and Catch-Up in Economic Development* (Edward Elgar, Cheltenham, 1999); for a discussion on transfer of technology and the WTO see B. Hoekman, ‘Transfer of Technology to Developing Countries: Unilateral and Multilateral Policy Options’ [2005] 33 *World Development* 1587-1602 [↑](#footnote-ref-692)
692. G. Dutfield, ‘Sharing the Benefits of Biodiversity: Access Regimes and Intellectual Property Rights’ (Science, Technology and Development Discussion Paper No. 6, Centre for International Development and Belfer Center for Science and International Affairs, Harvard University, Cambridge, MA, US) [↑](#footnote-ref-693)
693. The fact that WIPO is not an international organization related to free trade and access to markets (TRIPs actually is related to trade) has facilitated the inclusion of this issue in the WIPO agenda; for further discussion on the link between trade and IPRs, and the role of WIPO see: n subsection 1.2 of Chapter 3 [↑](#footnote-ref-694)
694. For further information on the IGC see <http://www.wipo.int/tk/en/igc/> and on the Council for TRIPs see <http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm> [↑](#footnote-ref-695)
695. This is the WIPO’s Committee that held the discussion that led to the PLT; for further information see <http://www.wipo.int/meetings/en/topic.jsp?group_id=61> [↑](#footnote-ref-696)
696. Proposal by the Delegation of Colombia, *Protection of Biological and Genetic Resources* (WIPO, SCP/3/10, 1999) [↑](#footnote-ref-697)
697. D. Vivas-Eugui, *Bridging the Gap on Intellectual Property and Genetic Resources in WIPO’s Intergovernmental Committee* (ITSD Programme on Innovation, Technology and Intellectual Property, Issue Paper No. 34, 2012) [↑](#footnote-ref-698)
698. Standing Committee of Patents, *Report of the Third Session* (WIPO SCP/3/11, 1999) [↑](#footnote-ref-699)
699. IGC, *Report of First Season* (WIPO/GRTKF/IC/1/13, 2001) [↑](#footnote-ref-700)
700. IGC, *Consolidated Document Relating to Intellectual Property Rights and Genetic Resources* (Facilitators’ draft, WIPO, Rev 2, 2013) [↑](#footnote-ref-701)
701. WIPO, *Adoption of the General Report and of the Individual Report of each Governing Body* (A/54/13, 2015) [↑](#footnote-ref-702)
702. See discussion on Doha negotiations in subsection 1.3.2 Chapter 3 [↑](#footnote-ref-703)
703. Ibid. [↑](#footnote-ref-704)
704. Communication from the US, *Access to Genetic Resources Regime of the US National Parks* (WTO, IP/C/W/393, 2005); IGC, *Access to Genetic Resources Regime of the United States National Parks: Document Submitted by the Delegation of the United States of America* (IGC, WIPO/GRTKF/IC/4/13, 2002) [↑](#footnote-ref-705)
705. Reported by the Director-General, *Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPs Agreement to Products Other Than Wines and Spirits and Those Related to the Relationship Between the TRIPs Agreement and the Convention On Biological Diversity* (WTO, WT/GC/W/633, 2011) [↑](#footnote-ref-706)
706. L. Helfer, ‘Regime Shifting: the TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking’ [2004] 29 *The Yale Journal of International Law* 1-83; see also L. Laxman & A. Ansari, ‘The Interface between TRIPs and CBD: Efforts Towards Harmonisation’ [2012] 11 *Journal of International Trade Law and Policy* 108-132 [↑](#footnote-ref-707)
707. n 466, pp 641, 685 [↑](#footnote-ref-708)
708. K. Raustiala & D. Victor, ‘The Regime Complex for Plant Genetic Resources’ [2004] *International Organization* 58; 277-309 [↑](#footnote-ref-709)
709. S. Finston, ‘Discussion Paper: Relevance of Genetic Resources to the Pharmaceutical Industry’ (2004, International Expert Workshop on Access to Genetic Resources and Benefit Sharing Cancun, Mexico) <http://www.canmexworkshop.com/documents/final/English.pdf> accessed 23.04.2010; see also S. Finston, ‘The Relevance of Genetic Resources to the Pharmaceutical Industry’ [2005] 8 *The Journal of World Intellectual Property* 141-155; [↑](#footnote-ref-710)
710. G. Cragg et al., n46, p 1416 [↑](#footnote-ref-711)
711. n 77, p 168 [↑](#footnote-ref-712)
712. Eugene, n 687, p 217 [↑](#footnote-ref-713)
713. n 117, p 70 [↑](#footnote-ref-714)
714. This treaty has been signed up by Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama, but has not been ratified yet; for further information see: Cabrera, J., et al, *Overview of National and Regional Measures on Access to Genetic Resources and Benefit-Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol* (CILSDL, Switzerland, 2012) [↑](#footnote-ref-715)
715. Articles 2 and 6 of the Costa Rican Biodiversity Act 7788 of 1998 [↑](#footnote-ref-716)
716. Article 6 of the Costa Rican Biodiversity Act [↑](#footnote-ref-717)
717. El Salvador has only enacted legislation regarding the management of natural resources such as oil, wood, etc., although it vaguely mentions access to genetic resources. The Environment Act 233 of 1998 establishes that users should obtain PIC from the authority which holds the genetic resources, yet there is no mention of benefit sharing and MATs as established by the CBD; however, El Salvador has already commissioned experts to draft a new legislation that will comply with the NP and the Central American protocol; see J. Cabrera, *Propuesta de Contenidos de una Ley de Acceso a Recursos Genéticos y Bioquímicos para el Salvador* (Documento de Consultoria, Fundación Nacional para el Desarrollo, 2009) [↑](#footnote-ref-718)
718. Article 5 of Decision 391 [↑](#footnote-ref-719)
719. Article 6 of Decision 391 [↑](#footnote-ref-720)
720. Ibid. [↑](#footnote-ref-721)
721. n 557 [↑](#footnote-ref-722)
722. Section 57 of the 2009 Act Relating to the Management of Biological, Geological and Landscape Diversity (Nature Diversity Act) [↑](#footnote-ref-723)
723. R. Wynberg, ‘Access and Benefit-Sharing Agreements in the Commercial Development of Hoodia’ in S. Laird & R. Wynberg, *Access and Benefit-Sharing in Practice: Trends in Partnership Across Sectors* (Secretariat of the CBD, Technical Series N 38, 2008) [↑](#footnote-ref-724)
724. Ibid., p 94 [↑](#footnote-ref-725)
725. Botswana has a draft IPRs bill in which some aspects of access to genetic resources and benefit sharing are established but it has not been enacted. See: Botswana Fourth National Report to the CBD (Botswana Government, 2009) <<http://www.cbd.int/doc/world/bw/bw-nr-04-en.pdf>> accessed 21.07.2013 [↑](#footnote-ref-726)
726. For further information on the Global Multilateral Benefit-Sharing Mechanism and trans-boundary situations after the NP see M. Tvedt, *A Report from the First Reflection Meeting on the Global Multilateral Benefit-Sharing Agreement* (Fridtjof Nansen Institute, Norway, 2011) [↑](#footnote-ref-727)
727. R. Wynberg, ‘Rhetoric, Realism and Benefit-Sharing: Use of Traditional Knowledge of Hoodia Species in the Development of an Appetite Suppressant’ [2004] 7 *The Journal of World Intellectual Property* 851-876 [↑](#footnote-ref-728)
728. Pfizer withdrew clinical trials in 2003; however, the biotechnological company Unilever stepped in, but the latter also abandoned the project as Unilever’s clinical studies revealed that products that employ hoodia did not meet its standards of safety and efficacy; according to Kamau, solely in the US there is more than 5 patent applications on hoodia; see Unilever, 'Sustainable Development 2008: An Overview' (2008) <http://www.unilevernigeria.com/Images/Unilever\_Sustainable\_Development\_Overview2008\_v3\_tcm199-163522.pdf> accessed July 17 2014. E. Kamau, “Common Pools of Traditional Knowledge and Related Genetic Resources: A Case Study of San-Hoodia” in E. Kamau & G. Winter (eds.), *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law* (Routledge, NY, 2013); see also D. Schroeder & J. Lucas (eds.), *Benefit Sharing: From Biodiversity to Human Genetics* (Springer, Netherlands, 2013) [↑](#footnote-ref-729)
729. n 727, p 864 [↑](#footnote-ref-730)
730. n section 3 Chapter 3 [↑](#footnote-ref-731)
731. [1990] 51 Cal 3d 120 [↑](#footnote-ref-732)
732. Ibid., p 12 [↑](#footnote-ref-733)
733. Ibid. [↑](#footnote-ref-734)
734. For instance, in the UK different high profile cases and public inquiries (e.g. Royal Liverpool Children and Bristol Royal Infirmary where tissues and organs were retained without PIC) have shaped the discussion on this issues; see the UK Human Tissue Act 2004 (c 30); for further discussion on this issue see C. Lenk et al. (eds.), *Human Tissue Research: A European Perspective on the Ethical and Legal Challenges* (Oxford University Press, 2011); R. Weir & R. Olick, *The Stored Tissue: Biomedical Research, Ethics, and Law in the Era of Genomic Medicine* (Oxford University Press, 2004) [↑](#footnote-ref-735)
735. M. Lin, 'Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act.' [1996] 22 *American Journal of Law & Medicine* 109; for further discussion see: J. Weeden, Genetic Liberty, Genetic Property: Protecting Genetic Information' [2006] 4 *Ave Maria Law Review* 611; A. Prince, 'Comprenhensive Protection of Genetic Information: One Size Privacy or Property Model May Not Fit All' [2014] *Brooklyn Law Review* 175. [↑](#footnote-ref-736)
736. For instance see Indian Biological Diversity Act 2002 (Sections 3,5,7 and 19 (1)) and Biological Diversity Rules (Rule 12, 14, 17-19); and Article 69-75 of the Costa Rican Biodiversity Act 7788 [↑](#footnote-ref-737)
737. Section 3 of the Indian Biological Diversity Act [↑](#footnote-ref-738)
738. Articles 16 and 17 Decision 391 of the ACN [↑](#footnote-ref-739)
739. Decrees 1375 and 1376 of 2013 [↑](#footnote-ref-740)
740. BIO & PhRMA, ‘Comments, BIO and PhRMA on Issues to be Addressed by the Technical and Legal Experts Group on Compliance’ (BIO & PhRMA, 2008) <<http://www.bio.org/advocacy/letters/comments-bio-and-phrma-issues-be-addressed-technical-and-legal-experts-group-compli>> accessed 03.01.2014 [↑](#footnote-ref-741)
741. Ibid. [↑](#footnote-ref-742)
742. These particularly cases are studied in more detail in Chapter 5 [↑](#footnote-ref-743)
743. G. Cragg and D. Newman, ‘Access Issues Related to the US National Cancer Institute’s (NCI) Natural Products Drug Discovery and Development Program’ in T. Young et al. (eds.), n 684, see also R. Dalton, ‘Bioprospects Less Than Golden’ [2004] 429 *Nature* 598-600 [↑](#footnote-ref-744)
744. BIO & IFPMA, ‘Joint Submission On Regional, National And Community Policies, Measures And Experiences Regarding Intellectual Property And Genetic Resources’ (WIPO Document WIPO/GRFTKF/IC/16/INF/21, 2010) [↑](#footnote-ref-745)
745. Ibid. p 2 [↑](#footnote-ref-746)
746. S. Laird & R. Wynberg, n 723, pp 28-37 [↑](#footnote-ref-747)
747. Further information on biopiracy see: n 276 [↑](#footnote-ref-748)
748. IFPMA, *Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilisation* (IFPMA, Switzerland) <<http://www.ifpma.org/fileadmin/content/Innovation/Biodiversity%20and%20Genetic%20Resources/IFPMA_Guidelines_Access_to_Genetic_Resources.pdf>> accessed 27.07.2013  [↑](#footnote-ref-749)
749. BIO, *Guidelines for BIO Members Engaging in Bioprospecting* (BIO, Washington DC) <<http://www.bio.org/sites/default/files/Guidelines%20for%20BIO%20Members%20Engaging%20in%20Bioprospecting_0.pdf>> accessed 27.07.2013; see also BIO & PhRMA, ‘Views and Proposals of BIO and PhRMA for the Eighth Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing’ (BIO & PhRMA, 2009) [↑](#footnote-ref-750)
750. Ibid., Guidelines II to VII [↑](#footnote-ref-751)
751. n 128 [↑](#footnote-ref-752)
752. The reason for implementing the NP at the EU Level is that it will be against the EU market policy to let each member of the EU adopt separate rules, hence this will create significant costs and barriers for EU researches and companies ‘in natural based products and services’. For the EU Commission, if a common approach is not taken and countries are allowed to create non-harmonised legislation, it could go against the EU internal market, as established in the Lisbon Treaty. This indicates that EU countries are on the way to creating a regulation in which they aim to minimize any economic and administrative burdens of the NP by taking a common approach to users’ measures; see Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, December 2007 [↑](#footnote-ref-753)
753. Bulgaria has only one article that refers to access to genetic resources, i.e. Article 66 of the Biological Diversity Act (Promulgated, State Gazette No 77/9.08.2002) <<http://www.cbd.int/doc/measures/abs/msr-abs-bg-en.pdf>> accessed 28.07.2013; France is considering implementing providers’ measures as it has a colony (Guyana) in a biodiversity region, see Sous-section 3 Code de L’environnement <<http://www.cbd.int/abs/measures/measure.shtml?id=73739>> accessed 28.07.2013; finally, Spain has mentioned the possibility of implementing provider measures in its biodiversity strategy, see Cuarto Informe Nacional sobre la Diversidad Biologica <<http://www.cbd.int/doc/world/es/es-nr-04-es.pdf>> accessed 28.07.2013 [↑](#footnote-ref-754)
754. See European Commission, *Impact Assessment* (Commission Staff Working Document, SWD 292 final, 2012) [↑](#footnote-ref-755)
755. In order to recognise those best practices, users of genetic resources have to submit the best practices they have adopted, accompanied by information on procedures, tools and mechanisms, to the Commission, who decides whether those practices comply with the Regulation (see Article 8 of the EU Regulation) [↑](#footnote-ref-756)
756. Case-377/98 Netherlands v. Parliament and Council [1998] 1 ECJ 7149 [↑](#footnote-ref-757)
757. Recitals are, in principle, guidelines in the EU legislation for implementation at a national level [↑](#footnote-ref-758)
758. Danish Act 412 (31/5/2000) amending the Patent Act (consolidated Patent Act 926 22/9 2000); Section 8c of the Norwich Patents Act (Act No. 9 of 15 December, 1967, as last amended by Act No. 20 of May 2004); Article 49a of the Swiss Federal Law on Patents for Inventions of June 25, 1954 (status as of July 1, 2009) [↑](#footnote-ref-759)
759. Section 34a of (German) Patent Law as amended by the Law of July 31, 2009 [↑](#footnote-ref-760)
760. Rule 5a of the Regulation (2004:162) Amending the Patents Decree [↑](#footnote-ref-761)
761. Article 15(6) of Patent Law of 1984 as amended on December 22, 2008 [↑](#footnote-ref-762)
762. IEEP, *Study to Analyse Legal and Economic Aspects of Implementing the Nagoya Protocol on ABS in the EU* (IEEP, 2012) [↑](#footnote-ref-763)
763. See § 166 of the Norwich General Civil Penal Code; and paragraph 163 of the Danish Penal Code [↑](#footnote-ref-764)
764. Articles 49a and 81a [↑](#footnote-ref-765)
765. Proposal Submitted by Switzerland, *Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications* (2007, Working Group on Reform of the PCT, Ninth Session, PCT/R/W/9/5) [↑](#footnote-ref-766)
766. Ibid., paragraph 15 [↑](#footnote-ref-767)
767. n section 2 Chapter 4 [↑](#footnote-ref-768)
768. ## Nature Diversity Act (Act No. 100 of June 19, 2009 relating to the Management of Biological, Geological and Landscape Diversity)

     [↑](#footnote-ref-769)
769. Ibid., Section 60 [↑](#footnote-ref-770)
770. Ibid., Section 69 [↑](#footnote-ref-771)
771. Ibid., Section 73 [↑](#footnote-ref-772)
772. Ibid., Section 75 [↑](#footnote-ref-773)
773. M. Tvedt & O. Fauchald, ‘Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway’ [2011] 14 *The Journal of World Intellectual Property* 383-402 [↑](#footnote-ref-774)
774. n subsection 1.1 Chapter 1 [↑](#footnote-ref-775)
775. n section 2 Chapter 4 [↑](#footnote-ref-776)
776. K. Kurien & A. Das, ‘Nagoya Protocol and its Implications on Pharmaceutical Industry’ (BEROE, 2011) < <http://www.beroeinc.com/insights/whitepapers/nagoya-protocol-and-its-implication-pharmaceutical-industry>> accessed 28.07.2013 [↑](#footnote-ref-777)
777. n section 1 Chapter 4 [↑](#footnote-ref-778)
778. For further information on Costa Rica’s INBio see: R. Gomez, ‘The Link Between Biodiversity and Development: Lessons from Bioprospecting Programs in Costa Rica’ in C. McManis, *Biodiversity and the Law: Intellectual Property Biotechnology and Traditional Knowledge* (Earthscan, UK, 2007); C. Richerzhagen, *Protecting Biological Diversity: the Effectiveness of Access and Benefit Sharing* (Routledge, UK, 2010) [↑](#footnote-ref-779)
779. Richerzhagen, n 778, pp 160-170 [↑](#footnote-ref-780)
780. Submission by Costa Rica, ‘Information on Experience Developing and Implementing Articles 15 of the Convention at the National Level, Including Obstacles and Lessons Learned’ in Secretary of the CBD, *Compilation of Submissions by Parties on Experiences in Developing and Implementing Article 15 of the Convention at the National Level and Measures Taken to Support Compliance with Prior Informed Consent and Mutually Agreed Terms* (UNEP/CBD/WG/ABS/5/INF/2, 2005); see Articles 5 and 6 of the CBD; n subsection 1.1 Chapter 4 [↑](#footnote-ref-781)
781. Richerzhagen, n 778, p 162 [↑](#footnote-ref-782)
782. E. Pennis, ‘Costa Rica’s INBio Facing Government Bailout’ [2013] *Science Insider* April 22 [↑](#footnote-ref-783)
783. see further information on this project at <http://linington.chemistry.ucsc.edu/ICBG/index.html> [↑](#footnote-ref-784)
784. T. Kursar et al., ‘Securing Economic Benefits and Promoting Conservation through Bioprospecting’ [2006] 56 BioScience 1005-1012 [↑](#footnote-ref-785)
785. see list of projects at <http://www.icbg.org/groups/panama.php> [↑](#footnote-ref-786)
786. see list of articles in different journals since 1999 at <http://linington.chemistry.ucsc.edu/ICBG/publications.html> [↑](#footnote-ref-787)
787. for further information on the different projects of the ICBD visit <http://www.icbg.org/groups/> [↑](#footnote-ref-788)
788. See Act 99 of 1993 (or Environmental Act), Decree 1600 by which is Regulated the National Environmental System related to the National Systems of Environmental Research and Environmental Information; and Decree 1603 of 1994 by which is Organised and Established the Research Institutes of Biological Resources Alexander Von Humboldt, the Research Amazonia Institute (SINCHI, Spanish acronym) and the Environmental Pacific Research John Von Neumann); for further information on the Institute see: <http://www.humboldt.org.co/iavh/instituto/quienes-somos> [↑](#footnote-ref-789)
789. n subsection 1.1 Chapter 4 [↑](#footnote-ref-790)
790. T. Kursar, ‘What are the Implications of the Nagoya Protocol for Research on Biodiversity?’ [2011] 61 *BioScience* 256-257 [↑](#footnote-ref-791)
791. A. Artuso, ‘Bioprospecting, Benefit Sharing and Biotechnological Capacity Building’ [2002] 30 *World Development* 1355-1368 [↑](#footnote-ref-792)
792. A. Grajal, ‘Biodiversity and the Nation State Regulating Access to Genetic Resources Limits Biodiversity Research in Developing countries’ [1999] 13 *Conservation Biology* 6-10 [↑](#footnote-ref-793)
793. ICBG, ‘Principles for Accessing Genetic Resources, the Treatment of Intellectual Property and the Sharing of Benefits Associated with ICBG-Sponsored Research’ (ICBG Website, 2013) <<http://www.icbg.org/program/principles.php>> accessed 15.11.2013 [↑](#footnote-ref-794)
794. n 748 and 749 [↑](#footnote-ref-795)
795. n 34 [↑](#footnote-ref-796)
796. n 1 [↑](#footnote-ref-797)
797. n 1, Conpes (2012), p 17 [↑](#footnote-ref-798)
798. n subsections 2.1.2-2.1.3 Chapter 1; and n subsection 2.3 Chapter 2 [↑](#footnote-ref-799)
799. n 626, p11 [↑](#footnote-ref-800)
800. For further information see R. Barcelo, ‘El Sistema de Patentes en Colombia’ [2007] 1 *Clio America* 203-337: G. Cavalier, *Compilacion Historica de Las Leyes Colombianas sobre Propiedad Industrial: Expedidas desde 1823 hasta 1971* (Asociacion Cavelier del Derecho, Bogotá, 2002); J. Pabón, *De los Privilegios a la Propiedad Intelectual: la Proteción en Colombia a las Obras Literarias, Artisticas y Científicas en el Siglo XX* (Universidad Externado de Colombia, Bogotá, 2010); and, E. Santa, *Regimen de Propiedad intellectual y Prensa* (Imprenta Nacional, Bogotá, 1962) [↑](#footnote-ref-801)
801. See Article 14 of Decision 486 [↑](#footnote-ref-802)
802. The US-Colombia Trade Promotion Agreement as signed in November 2006; full text of the treaty is at <<http://www.ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text>> [↑](#footnote-ref-803)
803. n subsection 1.3. Chapter 3 [↑](#footnote-ref-804)
804. The last two Colombian governments have highlighted the importance of genetic resources for the economic and technological development of the country; see: n section 1 Chapter 2 [↑](#footnote-ref-805)
805. See paragraphs 1, 5 and 9 of the Prologue and Article 2 of Decision 391 [↑](#footnote-ref-806)
806. As stated in Chapter 3, in the granting process of a patent, it is required that the applicant describes the invention (disclosure) in such a way that an ordinarily skilled person can replicate it; developing countries rich in biodiversity such as Colombia ask for an extra requirement within the disclosure, i.e. whoever uses genetic resources should disclose all information related to the origin of the genetic resources and demonstrate that such information was extracted following the legislation on access to genetic resources and benefit sharing; for discussion of disclosure of origin in TRIPs see: n subsection 3.4 Chapter 3; in the ABS regime and WIPO see: n section 3.2 Chapter 4 [↑](#footnote-ref-807)
807. See Decision 523, n 647 [↑](#footnote-ref-808)
808. A. Hoare & R. Tarasofsky, ‘Asking and Telling: Can “Disclosure of Origin” Requirements in Patent Applications Make a Difference?’ [2007] 10 *The Journal of World Intellectual Property* 149-169 [↑](#footnote-ref-809)
809. n section 2 Chapter 1 [↑](#footnote-ref-810)
810. See Article 1 of the constitutive agreement of the Cartagena Agreement, n 399 [↑](#footnote-ref-811)
811. Chile was a country founder member of the ACN but renounced its membership on 30 October 1976; whereas Venezuela was added to the Cartagena Agreement on 30 October 1973, but renounced its membership on 22 April 2006. [↑](#footnote-ref-812)
812. See Article 1-4 of the Treaty which creates the Tribunal of Justice of the ACN as subscribed on 28 May 1979 and modified by the Trujillo Protocol; for further information on the Andean legal system see: G. Pico Mantilla, n 399; for an analysis of the applicability of the Andean legislation into the Colombian legal system see: L. Plata-López, ‘Naturaleza Jurídica de las Normas Comunitarias Andinas’ [2009] 31 *Revista de Derecho* 196-223 [↑](#footnote-ref-813)
813. Article 5-6 of the Cartagena Agreement, n 399 [↑](#footnote-ref-814)
814. There are three sets of institution in the ACN: (1) intergovernmental institutions such as the Presidential Council, the Andean Council of Ministers of International Affairs and the Commission; (2) communitarian organisations which are the Tribunal of Justice, the Andean Parliament, the Secretary of the ACN, the Latin American Development Bank, the Latin American Fund, the Andean Organisation of Health and the Andean University Simon Bolivar; and (3) institutions that represent civil society, such as the Consultative Business Council, Consultative Labour Council, Consultative Indigenous People Council and the Andean League for the Defence of the Rights of Consumers; see Article 6 of the Cartagena Agreement, n 399 [↑](#footnote-ref-815)
815. Articles 11-14 of the Cartagena Agreement, n 399 [↑](#footnote-ref-816)
816. Articles 15-22 ibid. [↑](#footnote-ref-817)
817. Articles 21-28 ibid. [↑](#footnote-ref-818)
818. Articles 40-41 ibid. and the Treaty that creates the Tribunal of Justice of the ACN (see: n 651) [↑](#footnote-ref-819)
819. Although the legislation on copyrights and related rights was passed in record time, the Constitutional Court of Colombia declared that the Bill was unconstitutional because of errors in the legislative procedure before the Colombian Parliament; see: n subsection 2.3 Chapter 2 [↑](#footnote-ref-820)
820. El Pais, “Colombia Lista Para Prender Motor del TLC con EE.UU” [2012] *El Pais* April 15 <<http://www.elpais.com.co/elpais/colombia/noticias/colombia-esta-lista-para-prender-motor-del-tlc-con-eeuu>> accessed 23.12.2012; for further information on the influence of the US in the sub-region in terms of IPRs see: L. Helfer et al., “Islands of Effective International Adjudication: Constructing an Intellectual Property Rule of Law in the Andean Community” [2009] 103 *The American Journal of International Law* 1-47; R. Salazar-Manriquez, n 422, pp 213-214 [↑](#footnote-ref-821)
821. Ministerio de Comercio, ‘Exportaciones Colombianas Enero-diciembre de 2014’ (Mincomercio, 2015) <<file:///Users/Carlos/Downloads/oee_mab_exportacionesdiciembre2014.pdf> > accessed 24.04.2015 [↑](#footnote-ref-822)
822. n subsection 1.2 Chapter 3 [↑](#footnote-ref-823)
823. n subsection 2.3 Chapter 2 [↑](#footnote-ref-824)
824. The ATJ highlighted this point in its first IPRs case in 1988, see Prejudicial Interpretation of Articles 5 (c) and 85 of Decision 85 of ACN (Proceso 1-IP-1988) ATJ; see also, G. Pico Mantilla, *Jurisprudencia Andina* (Tribunal de Justicia del Acuerdo de Cartagena-Roca, Quito-Ecuador, 2009) [↑](#footnote-ref-825)
825. For further discussion on China and India’ patent policy see: n section 2 Chapter 1; on TRIPs see: n subsection 1.2. Chapter 3 [↑](#footnote-ref-826)
826. 48th Period of Ordinary Season of the Commission of the Andean Community of Nations 15 and 16 December Lima, Peru (COM/XLVIII/di/10, Nov. 21/88) [↑](#footnote-ref-827)
827. Prejudicial Interpretation of Articles 5 (c) and 22 of Decision 85 of the Commission of the ACN (Process 7-IP-89) ATJ [↑](#footnote-ref-828)
828. Articles 4 (b) and (c) Decision 85 [↑](#footnote-ref-829)
829. Articles 32 to 40 ibid. [↑](#footnote-ref-830)
830. Article 34 ibid. [↑](#footnote-ref-831)
831. Chapter 2 provides further details on how the Colombian pharmaceutical industry has evolved; see: n subsection 2.2 Chapter 2 [↑](#footnote-ref-832)
832. As analysed in Chapter 2, the Colombian scientist Manuel Patarroyo was able to sequence the *Plasmodium falciparum* in order to create an anti-malaria vaccine. Although it was effective in pre-clinical and clinical trials (phase I) in intensive malaria areas such as Tanzania, clinical trials (phases II and III) carried out in Africa and Asia proved that it was ineffective; n subsection 2.2 Chapter 2 [↑](#footnote-ref-833)
833. n 394, p 83 [↑](#footnote-ref-834)
834. For further history on the Andean common legislation on IPRs see M. Pachon & Z. Sanchez, “El Régimen Andino de la Propiedad Industrial” (Ediciones Jurídicas Ibáñez, Bogotá, 1995); A. Díaz, *America Latina y el Caribe: La Propiedad Intelectual de los Tratados de Libre Comercio* (CEPAL, Chile, 2008) <<http://www.eclac.org/publicaciones/xml/4/32614/LCG2330-Pindiceintro.pdf>> accessed 28.12.2012; M. Uribe, *Datos de Prueba y Acceso a los Medicamentos* (Universidad Nacional, Bogotá, 2011); M. Uribe, *La Transformación de la Propiedad Intelectual* (Ediciones Doctrina y Ley, Bogotá, 2005); n sections 2.2 and 2.3 Chapter 2 [↑](#footnote-ref-835)
835. Article 4 (c) of Decision 85 [↑](#footnote-ref-836)
836. The WHO defines essential medicines as those “that satisfy the health care needs of the majority of the population: they should therefore be available at all times in adequate amounts and in appropriate dosage forms at a price that individuals and the community can afford” in R. Smith et al., “Trade, TRIPs and Pharmaceuticals” [2009] 373 *The Lancet* 684-691 For further information on what medicines are included in the list see: WHO, n 425 [↑](#footnote-ref-837)
837. Article 65 of TRIPs states that developing countries such as Colombia could delay the implementation of TRIPs up to 2000 in the case of IPRs such as copyright and trademarks, but it allows the possibility of delaying this period for five years more in the case of pharmaceutical products (Article 65 (4)). As Decision 486 does not only regulate patents but also industrial designs, geographical indications, trademarks, etc. [↑](#footnote-ref-838)
838. n subsection 1.1 Chapter 3 [↑](#footnote-ref-839)
839. Ibid. [↑](#footnote-ref-840)
840. n subsection 1.3 Chapter 3 [↑](#footnote-ref-841)
841. Articles 33 and 34 of Decision 85 [↑](#footnote-ref-842)
842. Article 39 ibid. [↑](#footnote-ref-843)
843. This follows the wording of Article 28 of TRIPs; this provision was established within the Andean community in Article 37 of Decision 311 and then Article 38 of Decision 344 [↑](#footnote-ref-844)
844. Decree 4302 of 2008 by which is established the Procedure for the Declaration of the Existence of the Public Interest in Accordance with the Provisions of Article 65 of Decision 486 of the Andean Community Commission <<http://www.wipo.int/wipolex/es/text.jsp?file_id=190459>> accessed 01.02.2013 [↑](#footnote-ref-845)
845. Articles 4 and 8 of Decree 4302 of 2008 [↑](#footnote-ref-846)
846. J. Reyes-Villamizar, ‘Licencias Obligatorias: Posición de la Industria Farmacéutica Colombiana a propósito de las Flexibilidades planteadas por el Documento CDIP de la OMPI - 08/2010’ [2010] Wipo News and Events <<http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12/wipo_ip_bog_12_ref_topic11c.pdf>> accessed 04.01.2014; see also S. Gómez-Fierro, ‘Análisis del Sistema de Patentes Colombiano en Relación con los Medicamentos y la Salud Publica’ (Tesís de Maestría Universidad Nacional de Colombia, 2011) <<http://www.bdigital.unal.edu.co/6992/>> accessed 03.01.2013 [↑](#footnote-ref-847)
847. The Ministry of Social Protection of Colombia did not issue compulsory licensing for the drug Kaletra in Resolution 5283 of 2008 of the Ministry of Social Protection. However, the Ministry of Social Protection reduced the price of some medicines by employing control prices and parallel imports; parallel imports in Colombia have worked as a way to persuade originators to reduce prices For instance, Roche reduced the prices of nine medicines in 2010 to avoid parallel imports of their medicines which were marketed in other Andean countries (see: Portafolio, ‘Multinacional Farmacéutica Roche le Ofrecio al Gobierno Reducir el Precio de Nueve Medicamentos’ (Portafolio 17 May Bogotá, 2010) <<http://www.portafolio.co/archivo/documento/CMS-7705538>> accessed 12.01.2013)); further information on parallel imports see n 7 and Article 6 TRIPs which establishes that exhaustion of rights is not regulated within this treaty; see also C. Heath, “Parallel Imports and International Trade” (ATRIP Annual Meeting, WIPO, Geneva, 1999) <<http://www.wipo.int/mdocsarchives/ATRIP_GVA_99/ATRIP_GVA_99_6_E.pdf>> accessed 12.01.2013; P. Kanavos & J. Costa-Font, ‘Pharmaceutical Parallel Trade in Europe: Stakeholder and Competition Effects’ [2005] 20 *Economic Policy* 753-796; T. Valleti & S. Szymanski, ‘Parallel Trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis’ [2006] 55 *The Journal of Industrial Economics* 499-526 [↑](#footnote-ref-848)
848. In 2012 the Indian Controller of Patents issued a compulsory licence for a pharmaceutical product because the medicine was not affordable for the public and the patent was not produced locally in India; this decision was upheld by an Indian court in 2013; n subsection 2.1.3 Chapter 1 [↑](#footnote-ref-849)
849. n section 2 Chapter 2 [↑](#footnote-ref-850)
850. Although the US-Colombian FTA took 7 years to draft (2004-2011), it has its beginnings in 1994 when the US hosted the First Summit of the Americas. In the Summit it was agreed that most of the countries of the Americas would create the Free Trade Area of the Americas (FTAA) (see Summit of Americas Plan of Action, First Summit of the Americas, Miami, Florida December 9-11, 1994 <<http://www.summit-americas.org/miamiplan.htm>> accessed 13.01.2013); see the first draft of the Chapter on IPRs in FTAA-Free Trade Area of the Americas, Draft Agreement, Buenos Aires, April 2001 <<http://www.ftaa-alca.org/FTAADraft/draft_e.asp>> accessed 13.01.2013). As the US was not able to make any progress with the countries of the region, it decided to negotiate on a bilateral basis [↑](#footnote-ref-851)
851. n subsection 1.3.1.2 Chapter 3 [↑](#footnote-ref-852)
852. Ibid. [↑](#footnote-ref-853)
853. Decree 2085 of 2002 which regulates Aspects of the Information Provided to obtain Sanitary Registration Regarding New Chemical Entities in the area of Medicines <<http://www.presidencia.gov.co/prensa_new/decretoslinea/2002/septiembre/19/dec2085190902.pdf>> accessed 01.02.2013 [↑](#footnote-ref-854)
854. Decree 677 of 1995 which partially regulates the Sanitary Registration, Licensing Regime, Quality Control and Health Surveillance Regime of Medicines, Cosmetics, Pharmaceuticals based Natural Resources, Toiletries, Hygiene and Cleaning and other Products for Domestic use and other Provisions on the Matter <<http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=9751>> accessed 01.02.2013 [↑](#footnote-ref-855)
855. M. Pérez, *Tribunal de Justicia de la CAN, Propiedad Intelectual y Salud Publica* (2006, Serie Magister, v 67, Abya-Yala, Quito) pp 70-73; Uribe (2011), n 834, p 51 [↑](#footnote-ref-856)
856. Judicial Action for breaching of the Andean Region Legislation against the Republic of Colombia (Process No 22-AI-2002) ATJ [↑](#footnote-ref-857)
857. As explained in Chapter 3, this type of protection has its origins in the concept of “unfair competition” in Article 10 *bis* of the Paris Convention in which some countries considered that the misappropriation of undisclosed data constitutes an act of ‘unfair competition’ (see: n 393). In the particular case of Colombia, competition law is not regulated at the Andean level, but as national legislation; see legislation on competition law: Article 333 of the 1991 Colombian Constitution, Act 1340 of 2009 (Competition Act) and Decree 2153 of 1992. For further information on competition law and IPRs see: n 552; for further information on competition law in Colombia see: J. Cortazar, *Hacia un Nuevo Derecho de la Competencia en Colombia. Análisis crítico y prospectiva* (2003, Doctrina y Ley, Bogotá); and M Velandia, *Derecho de la Competencia y del Consumo* (2008, Universidad Externado de Colombia, Bogotá); see also D. de la Cruz Camargo, “Límites al Uso de la Patente, Desde el Punto de Vista del Derecho de la Competencia: A Propósito del Caso Microsoft” [2008] 24 *Con-texto Revista de Derecho y Economía* 131 [↑](#footnote-ref-858)
858. n 821, p 6 [↑](#footnote-ref-859)
859. Pérez, n 855, p 73 [↑](#footnote-ref-860)
860. Judicial Action for breaching of the Andean Region Legislation against the Republic of Colombia (Proceso 114-AI-2002) ATJ [↑](#footnote-ref-861)
861. Ibid., p 2 [↑](#footnote-ref-862)
862. Ibid., p 4 [↑](#footnote-ref-863)
863. Ibid. [↑](#footnote-ref-864)
864. Ibid., pp 45-46 and 51 [↑](#footnote-ref-865)
865. The first draft of the FTA (2001) already mentioned undisclosed data protection which is not substantively different from the final text of the US-Colombia FTA (Article 16.10.2); n 687 [↑](#footnote-ref-866)
866. Uribe (2011), n 36, p 75 [↑](#footnote-ref-867)
867. Decision 632 of 2006 on the Clarification of the Second Part of Article 266 of Decision 486 of 2000 as signed on 6 April 2006, Lima, Peru; it is also important to mention that it was the Colombian delegation who introduced undisclosed data protection in the negotiation process of Decisions 344 and 486. For further information see pp 41-42 Proceso 114-AI-2004 and Acta Final del Septuagesimo de la Comision Andina, realiza en Lima, Peru 14 Septiembre de 2000 [↑](#footnote-ref-868)
868. n subsection 1.2 Chapter 1 [↑](#footnote-ref-869)
869. Pérez n 855, p 66 [↑](#footnote-ref-870)
870. Ibid. [↑](#footnote-ref-871)
871. Venezuela was at that time a member of the CAN; n 811 [↑](#footnote-ref-872)
872. See Judicial Action by the Secretary of the ACN for breaching of the Andean Region Legislation against the Republic of Peru (Process No 07-AI-1999) ATJ; Judicial Action by the Secretary of the ACN for breaching of the Andean Region Legislation against the Republic of Venezuela (Process N0 01-AI-2001) ATJ; and Judicial Action by the Secretary of the ACN for breaching of the Andean Region Legislation against the Republic of Ecuador (Process No 34-AI-2001) ATJ [↑](#footnote-ref-873)
873. Superintendencia de Industria y Comercio Resolucion 112 del 18 de enero de 2000 [↑](#footnote-ref-874)
874. *Pfizer Research and Development Company vs. Superintendencia de Industria y Comercio* (2008, Council of State, Ref: 2000-066008) [↑](#footnote-ref-875)
875. Mojica-Ante and Alberto-Villamil, n 434, p 7 s; M. Pérez, n 855, pp 70-73 [↑](#footnote-ref-876)
876. See SIC, “Datos Química Farmacéutica 2005-2011” (SIC, Bogotá, 2012) <<https://docs.google.com/open?id=1P6KL_9ufMtQOj3CU9LsF6t5qKpiKv510nA8IRG2zZF7Vd_BoUcI0Mv2PFaEy>> accessed 07.02.2012 ; and, SIC, “Datos Biotecnología 2005-2011” (SIC, Bogotá, 2012)<<https://docs.google.com/spreadsheet/ccc?key=0ApN85vGW_nzSdHVnMzBwek5WWl8xRGpxbnlBYVZlbVE&hl=en&pli=1#gid=0>> accessed 02.07.2012 [↑](#footnote-ref-877)
877. F. De Paula Gómez, ‘TLC y Precios de Medicamentos’ (2012, AFIDRO, Press communication of AFIDRO’s President) <<http://www.afidro.org/img/documento/TLC%20y%20precio%20de%20medicamentos.pdf>> accessed 14.01.2013 [↑](#footnote-ref-878)
878. AFIDRO, ‘Balance Social de la Industria Farmacéutica de Investigación y Desarrollo en Colombia’ (2006, AFIDRO Coordinacion Social) <<http://www.afidro.com/img/documento/FolletoAFIDRO-FinalFinal-DEF.PDF>> accessed 13.01.2013 [↑](#footnote-ref-879)
879. n 362, p 57 [↑](#footnote-ref-880)
880. n Section 1 Chapter 2 [↑](#footnote-ref-881)
881. SIC, *Propiedad Industrial 2020* (SIC, 2012) [↑](#footnote-ref-882)
882. SIC, ‘Solicitudede de Patentes, Diseños Industriales y Esquemas de Trazado en Colombia por País de Origen’ (SIC, 2015) <<http://www.sic.gov.co/drupal/recursos_user/estadisticas/paisorigen/StatPlanet_IE_security_bypass.html>> accessed 28.04.2015 [↑](#footnote-ref-883)
883. n 826, p 5 [↑](#footnote-ref-884)
884. See Paragraphs 2,6 and 7 of Decision 523, n 647 [↑](#footnote-ref-885)
885. Ministerio del Medio Ambiente et al., *Politica Nacional de Biodiversidad* (1997, MinAmbiente, Bogota) <<http://www.minambiente.gov.co/documentos/politica_nacional-biodiversidad.pdf>> accessed 18.01.2013; see also Minesterio de Ambiente y Desarrollo Sostenible, *Politica Nacional para la Gestión Integral de la Biodiversidad y sus Servicios Ecosistémicos* (2011, Ministerio de Medio Ambiente y Desarrollo Sostenible) <<http://www.andi.com.co/Archivos/file/Vicepresidencia%20Desarrollo%20Sostenible/politicanacionalbiodiversidad.pdf>> accessed 04.01.2014 [↑](#footnote-ref-886)
886. M. Gomez-Lee, *Protección de los Conocimientos Tradicionales en las Negociaciones TLC* (2004, Universidad Externado de Colombia, Bogotá)  [↑](#footnote-ref-887)
887. A. Hernández, “Biopiratería y Propiedad Intelectual” [2002] 67 *Revista la Tadeo* 116-120 [↑](#footnote-ref-888)
888. Third Complementary Disposition of Decision 391 [↑](#footnote-ref-889)
889. J. Chavez (ed.), *Análisis Jurídico Sobre el Régimen de Acceso y Distribución de Beneficios en Colombia: Problemas y Posibles Soluciones* (2006, Instituto Alexander Von Humboldt, Bogotá) [↑](#footnote-ref-890)
890. G. Nemogá et al. (eds.), *La Investigación Sobre Biodiversidad en Colombia: Propuesta de Ajustes al Régimen de Acceso a Recursos Genéticos y Productos Derivados, y a la Decisión Andina 391 de 1996* (2010, Universidad Nacional de Colombia, Bogotá) [↑](#footnote-ref-891)
891. As part of its mandate, the Constitutional Court of Colombia has to make a constitutional revision of any international treaty to which Colombia subscribes. In the case of the CBD and Act 165 of 1994, a constitutional examination was carried out in 1994 in which this Court found that the CBD complied with the Colombian Constitution as guarantors of the protection of the environment (Constitutional Court, Sentence C-519 of 1994, <<http://www.corteconstitucional.gov.co/relatoria/1994/C-519-94.htm>> accessed 24.05.2015 [↑](#footnote-ref-892)
892. See paragraph 4 Article 3 of Decision 486 [↑](#footnote-ref-893)
893. n subsection 1.1 Chapter 4 [↑](#footnote-ref-894)
894. Article 5 of Decision 391 [↑](#footnote-ref-895)
895. Council of State, Sentence No 997 of 1997 [↑](#footnote-ref-896)
896. n sections 1.2 and 1.3 Chapter 4 [↑](#footnote-ref-897)
897. Article 6 paragraph 2 of Decision 391 [↑](#footnote-ref-898)
898. Decree 2811 of 1974, National Codex of Renewable Resources and Protection of the Environment; for further discussion on the regulation of biological resources in Colombia see G. Nemogá & A. Chaparro, *Regimenes de Propiedad Sobre Recursos Biológicos, Genéticos y Conocimiento Tradicional* (2005, Universidad Nacional de Colombia, Bogotá); F. Vallejo et al., *Guia Práctica para el Acceso a: Los Recursos Biológicos, los Recursos Genéticos y/o sus Productos Derivados, y el Componente Tangible* (2009, Universidad Nacional de Colombia, Bogotá); see also L. Villar Borda et al., *Evaluación y Perspectivas del Código Nacional de Recursos Naturales de Colombia en sus 30 Años de Vigencia* (2004, Universidad Externado de Colombia, Bogotá) [↑](#footnote-ref-899)
899. See Articles 42 and 43 of the National Codex of Renewable Resources and Protection of the Environment; the Constitutional Court, when deciding on the constitutionality of Articles 42 and 43, found that the Colombian Constitution does not forbid private property but demands that if there is private property over renewable natural resources it should have an ‘ecological function’; this means that in these cases, private property should be employed with due regard to sustainability and conservation of the environment; Constitutional Court, Sentence C-126 of 1998 <<http://www.secretariasenado.gov.co/senado/basedoc/cc_sc_nf/1998/c-126_1998.html#1>> accessed 20.01.2013 [↑](#footnote-ref-900)
900. n 95, pp 13-14 [↑](#footnote-ref-901)
901. See Articles 2 (c), 4 (b), 6, 14, 23 and 26 (b) of Decision 391 [↑](#footnote-ref-902)
902. Articles 1 and 2 of Decree 391 [↑](#footnote-ref-903)
903. Paragraphs 1 and 2 of Article 2 of Decision 391 [↑](#footnote-ref-904)
904. See Paragraphs 16 and 17 of Article 1 of Decision 491; for further discussion on the nature of genetic resources in Article 2 of the CBD, the Bonn Guidelines and the NP see: n subsection 1.2 Chapter 4 [↑](#footnote-ref-905)
905. M. Ruiz, *Guía Explicativa de la Decisión 391 y una Propuesta Alternativa para Regular el Acceso a los Recursos Genéticos en la Sub-región Andina* (2008, Deutsche Gesellschaft für Technische Zusammenarbeit and Sociedad Peruana de Derecho Ambiental, Lima-Peru) <<http://cdam.minam.gob.pe:8080/bitstream/123456789/358/1/CDAM0000211.pdf>> accessed 24.01.2013 [↑](#footnote-ref-906)
906. As explained in Chapter 4, the conditions for access to genetic resources and benefit sharing are included in MATs (Article 15.7 of the CBD); this agreement is reached by users of genetic resources and a governmental authority; n subsection 1.3.2 Chapter 4 [↑](#footnote-ref-907)
907. n 626; although this ruling was over Decision 344, which was amended by Decision 486, the wording of Article 6 (b) is similar to Article 15 (b) of Decision 486 [↑](#footnote-ref-908)
908. n 61, p 10 [↑](#footnote-ref-909)
909. For further discussion on exclusion on ethical grounds in developing countries see: n subsection 3.4 Chapter 3; for a comparative analysis between the US Supreme Court decision and the ATJ ruling see C. Conde-Gutiérrez & L. Diaz, ‘Productos de la Naturaleza y el Caso Association for Molecular Pathology v. Myriad Genetics, Inc.’ [2013] 17 *La Propiedad Inmaterial* 263-281 [↑](#footnote-ref-910)
910. Constitutional Court of Colombia, Sentence C-137 of 1996, <<http://www.corteconstitucional.gov.co/relatoria/1996/C-137-96.htm>> accessed 24.01.2013; see also G. Nemogá & A. Chaparro, n 898, p 37 [↑](#footnote-ref-911)
911. Genetic resources that come from humans are not included within the nature of genetic resources in the ABS regime, see, n 135 [↑](#footnote-ref-912)
912. US and Colombia Governments- “Understanding Regarding Biodiversity and Traditional Knowledge” (November 22, 2006) <<http://www.ustr.gov/sites/default/files/uploads/agreements/fta/colombia/asset_upload_file953_10182.pdf>> accessed 24.01.2013 [↑](#footnote-ref-913)
913. For further information on the nature of side letters in FTAs with the US see R. Cruz-Miramontes, ‘The North American Free Trade Agreement and the So-Called “Parallel Letters”’ [2005] 3 *Mexican Law Review;* for side letters on public health and IPRs see P. Roffe & C. Spennemann, ‘The Impact of FTAs on Public Health Policies and TRIPs Flexibilities’ [2006] 1 *International Journal of Intellectual Property Management* 75-9; and C. Fink and P. Reichenmiller, ‘Tightening TRIPs: Intellectual Property Provisions of US Free Trade Agreements’ in R. Newfarmer, *Trade, Doha and Development: A Window into the Issues* (the World Bank,2006) [↑](#footnote-ref-914)
914. Trade Agreement Between the EU and its Members, of the One Part, and Colombia and Peru, of the Other Part (EU/CO/PE/1 en) [↑](#footnote-ref-915)
915. Article 201 ibid. [↑](#footnote-ref-916)
916. n subsection 3.2 Chapter 4 [↑](#footnote-ref-917)
917. Ibid. [↑](#footnote-ref-918)
918. Paragraph 2, Article 81 of the Colombia Constitution requires the State to oversee access to genetic resources; Article 5 (21) of Act 99 of 1993 (or Environmental Act) indicates that it is the Ministry of Environment which is the local authority in charge of the regulation on access to genetic resources [↑](#footnote-ref-919)
919. See Articles 26 and 27 of Decision 391 and Articles 4-9 of Resolution 620 [↑](#footnote-ref-920)
920. Article 28 of Decision 391 and Articles 9-12 of Resolution 620 [↑](#footnote-ref-921)
921. Articles 29-31 of Decision 391 and Articles 11-20 of Resolution 620 [↑](#footnote-ref-922)
922. Articles 31-37 of Decision 391 [↑](#footnote-ref-923)
923. Ministerio de Medio Ambiente (2011), n 885, p 32 [↑](#footnote-ref-924)
924. A. Chaparro et al., ‘La Investigación sobre Recursos Biológicos y Genéticos en el País: Grupos Registrados en Colciencias’ p 31 in G. Nemogá et al. (eds.), n 890 [↑](#footnote-ref-925)
925. O. Duarte-Torres, ‘La Bioprospección como un Mecanismo de Cooperación Internacional para Fortalecimiento de Capacidades en Ciencia y Tecnología en Colombia’ [2009] 38 *Ci. Inf. Brasilia* 96-110 [↑](#footnote-ref-926)
926. Ibid., p 100 [↑](#footnote-ref-927)
927. Ibid., p 105 [↑](#footnote-ref-928)
928. Ibid. [↑](#footnote-ref-929)
929. File number 2571 of Ministry of Environment in Public Registration Office (*Registro Público de Acceso a Recursos Genéticos*) <<http://www.minambiente.gov.co/documentos/DocumentosBiodiversidad/licencias/Varios/registro_rge_061011.pdf>> accessed 29.01.2013; for a complete compilation of all the steps of this case before the Colombia Ministry of Environment see G. Nemogá & D. Rojas-Díaz, ‘Algunas Lecciones Sobre el Acceso a Recursos Genéticos en Colombia: Dos Estudios de Caso’ [2009] 14 *Actualidad Biológica Colombiana* 137-160 [↑](#footnote-ref-930)
930. G. Nemogá & D. Rojas-Díaz, ‘Desencuentros Institucionales sobre la Investigación en Diversidad Genética’ [2010] 12 *Revista Colombiana de Biotecnología* 4-8 [↑](#footnote-ref-931)
931. Ibid., p 4 [↑](#footnote-ref-932)
932. Nemogá & Rojas (2009), n 929, p 145 [↑](#footnote-ref-933)
933. Ibid., pp 141-144 [↑](#footnote-ref-934)
934. Ibid., p 144 [↑](#footnote-ref-935)
935. Ibid. [↑](#footnote-ref-936)
936. Ibid., p 145 [↑](#footnote-ref-937)
937. Ibid. [↑](#footnote-ref-938)
938. Ibid., p 146 [↑](#footnote-ref-939)
939. Ibid. [↑](#footnote-ref-940)
940. n 767, p 5 [↑](#footnote-ref-941)
941. Ibid. [↑](#footnote-ref-942)
942. See Superintendencia de Industria y Comercio (SIC), *Resolution Number 2936 of May 2011* which upholds SIC, *Resolution* *19617 of April 2010* [↑](#footnote-ref-943)
943. File number 2571, Ministry of Environment, n 128, p 2 [↑](#footnote-ref-944)
944. n subsection 1.2.1 and 3.1.2 Chapter 4 [↑](#footnote-ref-945)
945. Ministerio de Medio Ambiente (2011), n 885, p 90 [↑](#footnote-ref-946)
946. Ministerio de Ambiente y Desarrollo Sostenible, *Informe de Gestión 2013*(Ministerio de Ambiente y Desarrollo Sostenible, 2013) <<https://www.minambiente.gov.co/images/Atencion_y_particpacion_al_ciudadano/Rendici%C3%B3n_de_cuentas/informe_gestion_mads_2013.pdf>> accessed 23.02.2015 [↑](#footnote-ref-947)
947. MATs in agriculture include: (a) a research on promising tropical species for the development of a competitive and self-sustaining agroindustry of derivate and isolated natural products (File number RG 0005-3444 of Ministry of Environment in Public Registration Office; (b) development of biopesticides and biofertilisers from isolated bacteria (*Musa sp*.) (File number RGE 0116 of Ministry of Environment in Public Registration Office); (c) evaluation of solubilisation capability of inorganic phosphate and acid phosphate of *Aspergillus spp* (File number RGE 0070-24 of Ministry of Environment in Public Registration Office); (d) development of genetic markets for the identification of genome sequences related to the improvement of palm oil (File number RGE 0127 of Ministry of Environment in Public Registration Office); for further information on agriculture and regulation on access to genetic resources see: C. Roa-Rodríguez, ‘Acceso a Recursos Biotecnológicos en Área Andina: Asunto de Gobernancia y Derechos de Propiedad’ (Powerpoint Presentation, 2012) ≤<http://ciat.cgiar.org/wp-content/uploads/2012/12/2007_10_08_C_Roa.pdf>≥ accessed 02.02.2015 [↑](#footnote-ref-948)
948. MATs in the chemistry industry are: (a) bioleaching of iron in kaolinite for the production of white cement (File number RGE 0070-24 of Ministry of Environment in Public Registration Office); (b) microbial and enzymatic discoloration of synthetic colorants for textiles from native fungus (File number RGE 0070-24 of Ministry of Environment in Public Registration Office); (c) designing of a system with microorganism degradatives of TNT and PENT (File number RGE 0118 of Ministry of Environment in Public Registration Office) [↑](#footnote-ref-949)
949. Superintendencia de Industria y Comercio (SIC), *Resolution Number 3654 of June 2012* which upholds SIC, *Resolution* *60646 of October 2011* [↑](#footnote-ref-950)
950. Ibid., p 1 [↑](#footnote-ref-951)
951. Ibid., pp 2-3 [↑](#footnote-ref-952)
952. Ibid., p 6 [↑](#footnote-ref-953)
953. SIC, *Request 45- Exp 12.124171* (SIC, February 2015) [↑](#footnote-ref-954)
954. see document from the patent applicant Lloreda Camacho & Abogados, ‘Re: Identificación de Marcadores Moleculares Asociados con Compsosicion de Acido Graso en Plantes’ (Exp: 12124171, May, 2015) ≤<http://docsrodas.sic.gov.co:81/DocumentosRad/NavegacionDocs/VerDocs.php?ano_radi=12&nume_radi=124171&cont_radi=&cons_radi=8>≥ accessed 23.05.2015 [↑](#footnote-ref-955)
955. n Section 3.2 Chapter 4 [↑](#footnote-ref-956)
956. n Conclusions Chapter 4 [↑](#footnote-ref-957)
957. Posada et al. carried out research into 150 patents granted by the EPO, the USPTO and the Japanese Patent Office in which it was found that there were around 50 that might have possibly been obtained without benefit sharing; however, Colombian authorities have not opened criminal or administrative investigations; J. Chavez et al., ‘El Acceso Ilegal de Recursos Genéticos y Conocimientos Tradicionales-Estudio de Caso Colombia’ (2006, Iniciativa para la Prevencion de la Biopiratería, Sociedad Peruana de Derecho Ambiental (SPDA) and Instituto Humboldt Colombia); Gomez-Lee, n 886, p 53-59 [↑](#footnote-ref-958)
958. A. Chaparro & P. Vanegas, ‘La investigación sobre Recursos Biológicos y Genéticos en el País: Instituciones del Sina’ in G. Nemogá et al. (eds), n 890, pp 42-52 [↑](#footnote-ref-959)
959. Ibid., p 51 [↑](#footnote-ref-960)
960. A. Chaparro et al., “La Investigación sobre Recursos Biológico y Genéticos en el País: Grupos Registrados en Colciencias” in G. Nemogá et al. (eds), n 890, pp 21-42 [↑](#footnote-ref-961)
961. Ibid., p 33 [↑](#footnote-ref-962)
962. n 889, p 14 [↑](#footnote-ref-963)
963. n 808, p 157 [↑](#footnote-ref-964)
964. G. Nemogá & D. Rojas-Díaz, ‘Regímenes Paralelos de Investigación sobre Recursos Biogenéticos’, in G. Nemogá et al. (eds.) n 890, p 91 [↑](#footnote-ref-965)
965. n 4, p 9 [↑](#footnote-ref-966)
966. Ibid. [↑](#footnote-ref-967)
967. n Introduction of Thesis, pp 38-40 [↑](#footnote-ref-968)
968. n Introduntion of Thesis, pp 41-42 [↑](#footnote-ref-969)
969. Ibid. [↑](#footnote-ref-970)
970. n conclusions Chapter 1 [↑](#footnote-ref-971)
971. n conclusions Chapter 2 [↑](#footnote-ref-972)
972. See the different studies in Introduction that illustrates the importance that genetic resources, including traditional knowledge associated with genetic resources, still have for the pharmaceutical industry; see n, Introduction Thesis, pp 15-18 [↑](#footnote-ref-973)
973. n Introduction Thesis, pp 38-40 [↑](#footnote-ref-974)
974. n conclusion Chapter 5 [↑](#footnote-ref-975)
975. n section 1. Chapter 2 [↑](#footnote-ref-976)
976. n subsection 1.2 Chapter 3 [↑](#footnote-ref-977)
977. n subsection 2 Chapter 4 [↑](#footnote-ref-978)
978. n section 3 Chapter 3; n section 2 Chapter 4 [↑](#footnote-ref-979)
979. See for instance the discussion on orphan drugs in section 1 Chapter 1 [↑](#footnote-ref-980)
980. n subsections 1.2 and 1.3 Chapter 3 [↑](#footnote-ref-981)
981. n section 2 Chapter 4 [↑](#footnote-ref-982)
982. Ibid. [↑](#footnote-ref-983)
983. n section 2 Chapter 4 [↑](#footnote-ref-984)
984. n section 1 Chapter 1; see also the difference between generic drugs and illegal generic drugs in Warren-Jones, n 34. This refers to generic drugs that are pharmaceutical products that get into the market after patent protection on an originator drug has to come to an end. Warren-Jones names Illegal generics those medicines that are manufactured despite the fact that there is an existing patent on an originator; however, they are not either fake drugs that could harm the health of patients [↑](#footnote-ref-985)
985. n subsection 2.2.2 Chapter 1 [↑](#footnote-ref-986)
986. For further discussion see: n subsection 2.1.3 Chapter 1 [↑](#footnote-ref-987)
987. n 34, subsection 1.2 [↑](#footnote-ref-988)
988. n 4, pp 182-185 [↑](#footnote-ref-989)
989. n subsection 2.3 Chapter 2 [↑](#footnote-ref-990)
990. n subsection 2.4 Chapter 5 [↑](#footnote-ref-991)
991. Ibid. [↑](#footnote-ref-992)
992. n section 2 Chapter 4 [↑](#footnote-ref-993)
993. n section 1 Chapter 5 [↑](#footnote-ref-994)
994. n 34, subsection 1.2 [↑](#footnote-ref-995)
995. n conclusions Chapter 1 [↑](#footnote-ref-996)
996. n Section 1 Chapter 3 [↑](#footnote-ref-997)
997. n 116 p 285 [↑](#footnote-ref-998)
998. Ibid., p 6 [↑](#footnote-ref-999)
999. n Introduction Thesis, pp 38-40 [↑](#footnote-ref-1000)
1000. n section 2 Chapter 5 [↑](#footnote-ref-1001)
1001. n subsection 1.2 Chapter 1 [↑](#footnote-ref-1002)
1002. n subsection 1.2 Chapter 5 [↑](#footnote-ref-1003)
1003. Ibid. [↑](#footnote-ref-1004)
1004. For further discussion on the cost of R&D in second indication see: n 89 [↑](#footnote-ref-1005)
1005. Chapter 2 finds that AFIDRO has vaguely reported to have invested US$ 24 million between 2000 and 2006; yet, there is no more data in this regard [↑](#footnote-ref-1006)
1006. Correa, n 196, p 21 [↑](#footnote-ref-1007)
1007. n section 3.4 Chapter 3 [↑](#footnote-ref-1008)
1008. Ibid. [↑](#footnote-ref-1009)
1009. n section 2.4 Chapter 5 [↑](#footnote-ref-1010)
1010. n, section 2.4 Chapter 5 [↑](#footnote-ref-1011)
1011. n subsection 3.4 Chapter 3 and n subsection 2.4 Chapter 5 [↑](#footnote-ref-1012)
1012. n section 2 Chapter 4 [↑](#footnote-ref-1013)
1013. Ibid. [↑](#footnote-ref-1014)
1014. Ibid. [↑](#footnote-ref-1015)
1015. n 77, p 168 [↑](#footnote-ref-1016)
1016. Ibid. [↑](#footnote-ref-1017)
1017. n subsection 1.2 Chapter 4 [↑](#footnote-ref-1018)
1018. Ibid. [↑](#footnote-ref-1019)
1019. n subsection 1.2 Chapter 4 [↑](#footnote-ref-1020)
1020. n subsection 2.2 Chapter 5 [↑](#footnote-ref-1021)
1021. n subsection 1.2 Chapter 4 [↑](#footnote-ref-1022)
1022. n subsection 2.4 Chapter 5 [↑](#footnote-ref-1023)
1023. n subsection 1.1 Chapter 4 [↑](#footnote-ref-1024)
1024. n section 1 Chapter 4 [↑](#footnote-ref-1025)
1025. n subsection 2.3 Chapter 5 [↑](#footnote-ref-1026)
1026. The three steps are (1) admission and formal review of users’ application; (2) publication and public registration of the user’s application; and (3) evaluation and negotiation of MATs; ibid. [↑](#footnote-ref-1027)
1027. n subsection 2.4 Chapter 5 [↑](#footnote-ref-1028)
1028. n subsection 2.4 Chapter 5 [↑](#footnote-ref-1029)
1029. Ibid. [↑](#footnote-ref-1030)
1030. Ibid. [↑](#footnote-ref-1031)
1031. n subsection 1.3.1 Chapter 4 [↑](#footnote-ref-1032)
1032. Ibid. [↑](#footnote-ref-1033)
1033. Ibid. [↑](#footnote-ref-1034)
1034. n subsection 1.3.1 Chapter 4 [↑](#footnote-ref-1035)
1035. n subsection 3.4 Chapter 3 and n section 2 Chapter 4 [↑](#footnote-ref-1036)
1036. n subsection 2.2 Chapter 5 [↑](#footnote-ref-1037)
1037. Ibid. [↑](#footnote-ref-1038)
1038. n subsection 2.4 Chapter 5 [↑](#footnote-ref-1039)
1039. See Articles 46 and 47 of Decision 391 [↑](#footnote-ref-1040)
1040. n Introduction of Thesis, pp 4-10 [↑](#footnote-ref-1041)
1041. n section 4.1 Chapter 4 [↑](#footnote-ref-1042)
1042. n Introduction of Thesis [↑](#footnote-ref-1043)
1043. n section 2.4 Chapter 5 [↑](#footnote-ref-1044)
1044. n section 3.2 Chapter 4 [↑](#footnote-ref-1045)
1045. n subsection 3.1.2 Chapter 4 [↑](#footnote-ref-1046)
1046. Ibid. [↑](#footnote-ref-1047)
1047. n subsection 3.2 Chapter 4 [↑](#footnote-ref-1048)
1048. n subsection 3.1.2 Chapter 4 [↑](#footnote-ref-1049)
1049. n subsection 2.4 Chapter 5 [↑](#footnote-ref-1050)
1050. n subsection 4.1 Chapter 4 [↑](#footnote-ref-1051)
1051. n subsection 4.1 Chapter 4, n section 2.4 Chapter 5 [↑](#footnote-ref-1052)
1052. For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively. [↑](#footnote-ref-1053)
1053. This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6. [↑](#footnote-ref-1054)
1054. “Other use" refers to use other than that allowed under Article 30 [↑](#footnote-ref-1055)
1055. For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition. [↑](#footnote-ref-1056)