

Access to Genetic Resources and Sustainable Innovation in the Health Industry and Health Research: A Colombian Legal Perspective

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To my wife and son, Daniela and Martin Emilio, who have taught me that
knowledge, as well as love, is a selfless act

Abstract

Colombia is one of the most biodiverse countries in the world and consequently has sought to employ genetic resources to further both its economic development and technological and scientific advancement. Colombia's implementation of the international regime on access to genetic resources and benefit sharing responds to the interests of the country in employing genetic resources for health research and also for the health industry. However, the relevant Colombian law leaves aside practices and knowledge that emanate from local, indigenous, and Afro-Colombian communities in adding value to biodiversity. Through an interdisciplinary analysis, this thesis adds a novel country case study to existing international socio-legal literature on the International Regime on Access to Genetic Resources and Benefit Sharing, showing its deficiencies when considered at national and local levels. Further, drawing on a Capability Approach, the thesis aims to suggest an alternative approach for Colombia, making the normative claim that such an approach would create a more inclusive model of innovation in the use of biodiversity.

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, its true source of wealth dwelled in its ethnic and biological diversity, 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.

List of Cases

Andean Community of Nations

Prejudicial Interpretation of Articles 5 (c) and 22 of Decision 85 of the Commission of the Andean Community of Nations (1989) 7-IP-89

Colombia

- C-058 of 1994, Constitutional Court
- C-1051 of 2012
- C-143 of 2015, Constitutional Court
- C-882 of 2011, Constitutional Court
- SU-133 of 2017, Constitutional Court
- SU-510 of 1998
- T-380 of 1993, Constitutional Court
- T-406 of 1992, Constitutional Court
- T-426 of 1992, Constitutional Court
- T-496 of 1996, Constitutional Court
- T-539 of 2015, Constitutional Court
- T-881 of 2002, Constitutional Court
- Sentence No 997 of 1997, Council of State
- Superintendencia de Industria y Comercio (SIC), *Resolution Number 3654 of June 2012* which upholds SIC, *Resolution 60646 of October 2011*

EU and EUROPEAN PATENT OFFICE

- Case-377/98 Netherlands v. Parliament and Council [1998] 1 ECJ 7149
- Bioactive Fraction of Petiveria Alliacea, Pharmaceutical Composition Containing Same, and Combination with Immunostimulants for Treating Cancer EP2522356 (A2)'

UK

- *Merrell Dow Pharmaceuticals Inc v. HN Norton & Co Ltd* [1996] R.P.C. 76 (HL)

List of Legislation

International

- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organization, signed in Marrakech, Morocco April 15, 1994
- 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 UN Convention on Biological Diversity at its sixth meeting, in The Hague in April 2002
- 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 UN Convention on Biological Diversity at its tenth meeting, in Nagoya, Japan in October 2010
- The International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the Food and Agriculture Organisation Conference through Resolution 3/2001
- UN Convention on Biological Diversity, Rio de Janeiro, as adopted in June 1992
- International Union for the Protection of New Varieties of Plants

Andean Legislation

- Decision 391 of 1996 on the Common Regime on Access to Genetic Resources
- Decision 486 of 2000 on the Common Industrial Property Regime
- Decision 523 Regional Biodiversity Strategy for the Tropical Andean Countries as signed in Lima, Peru on July 17, 2002
- The Andean Subregional Integration Agreement (Cartagena Agreement)
- The Trujillo Protocol of 1996

- Treaty which creates the Tribunal of Justice of the Andean Community of Nations as subscribed on May 28, 1979

Colombia

- Act 1333 of 2009, Colombian Environmental Sanctioning Procedure
- Act 1751 of 2015
- Decree 1320 of 1998
- Decree 677 of 1995
- Decrees 1375 and 1376 of 2013
- Resolution 1348 of 2014
- Resolution 620 of 1997 by which is Implemented the Andean Community of Nations Decision 391 of 1996
- The US-Colombia Free Trade Agreement
- 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)
- US and Colombia Governments- “Understanding Regarding Biodiversity and Traditional Knowledge” (November 22, 2006)

Europe

- Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions
- Regulation (EU) No 511/2014 of the European Parliament and of the Council of April 16, 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

Peru

- Ley que Establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos (Ley 27811 de 2012)

Abbreviations

BIO	Biotechnological Industry Organisation
CAB	Commonwealth Agriculture Bureaux
CGIAR	Consultative Group on International Agricultural Research
CSIR	Council for Scientific and Industrial Research (South Africa)
Colciencias	Departamento Administrativo de Ciencia, Tecnología e Innovación
EU	European Union
INBio	Costa Rica's National Biodiversity Institute
JPO	Japanese Patent Office
NP	Nagoya Protocol
OECD	Organization for Economic Co-operation and Development
PBS	Plan de Beneficios en Salud
R&D	Research and Development
SAI	State Members and the Andean System of Integration or SAI
SIC	Superintendencia de Industria y Comercio (Colombian Intellectual Property Rights Office and Antitrust Office)
SMES	Small and Medium Enterprises
TRIPs	Agreement on Trade-related Aspects of Intellectual Property Rights 1994
UN	United Nations
UNAM Mexico	Universidad Nacional Autonoma de Mexico
US	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Table of Contents

Abstract	I
Acknowledgements	III
List of Cases	V
List of Legislation	VII
Abbreviations	IX
Table of Contents	XI
Chapter One: Introduction	1
Colombia’s place in the world and its implementation of the International Regime on Access to Genetic Resources and Benefit Sharing	3
The Key Research Question	6
The Approach and Method of the Thesis	6
Who Will Be Interested in the Research?	16
The Scope of the Thesis	18
The Thesis Road Map	22
Chapter Two: A Review of the International Regime on Access to Genetic Resources and Benefit Sharing	29
Introduction	29
The Wording of the International Regime on Access to Genetic Resources and Benefit Sharing: From the UN Convention on Biological Diversity to the Nagoya Protocol	35
Conservation, Sustainable use, Sovereignty, Developing Countries Rich in Biodiversity’s Stewardship Role and Developed Countries’ Obligations in the UN Convention on Biological Diversity	35
The Third Objective of the UN Convention on Biological Diversity: The Cornerstone of the International Regime on Access to Genetic Resources and Benefit Sharing	39
The Definition of Genetic Resources.....	40
Genetic Resources in the Wording of the Article 2 of the CBD	40
Genetic Resources in the Bonn Guidelines and the Nagoya Protocol	42
The Legal and Administrative Mechanisms for Access to Genetic Resources and Benefit Sharing	48
Prior Informed Consent.....	49
Indigenous and Local Communities’ Prior Informed Consent.....	49
Mutually Agreed Terms and Benefit Sharing.....	51
The Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing	53
Balance of Power among Countries and Intellectual Property in the International Regime on Access to Genetic Resources and Benefit Sharing.....	57

The Problematic Aspect of Finding a Solution to the Issues of Biopiracy and Compliance of the International Regime on Access to Genetic Resources and Benefit Sharing.....	59
The Complexities and “Messiness” behind the Use of Biodiversity.....	66
Improving Compliance in the Implementation of the Nagoya Protocol: Lessons from the EU.....	69
Conclusions	75
<i>Chapter Three: The Particularities of the Colombian Legal System</i>	<i>79</i>
Introduction	79
The Colombian Constitution 1991: Reconciling Economic Development and International Trade with Communities’ Rights.....	82
The 1991 Colombian Constitution and the Rights of indigenous, Afro-Colombia, and local communities	84
The Access and Benefit Sharing Regime in the Andean Community and Colombia	91
The Andean Community of Nations, the Colombian Constitutional Regime and ABS Implementation	92
Harmonising the Andean Legislation in Colombian Constitutional and Legal System	94
The Constitutionality of the Andean Community’s Legislation in Colombia.....	94
Regulating Particular Aspects of Decision 391 in Colombia: Property Regime over Colombia’s Biodiversity, and the Scope of the Definitions of Biological Resources, Genetic Resources and Traditional Knowledge.....	96
The Procedure	99
Mechanisms of Compliance: From Administrative and Criminal Sanctions to Disclosure of Origin in Patents	101
The Andean and Constitutional Protection of Communities’ Practices and Knowledge Associated with Genetic Resources	104
The Difficulties in Protecting Communities Rights in the Light of Colombian Government Administrative Decisions	106
Conclusions	110
<i>Chapter Four: Making Genetic Resources and Traditional Knowledge Public: A Tale of Innovation and Access in Colombia</i>	<i>113</i>
Introduction	113
The Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing and Holders of Technology	118
Innovation Policy behind the Exploitation of Genetic Resources	125
Colombian Innovation Policy and Bioprospecting.....	127
From Public to Private: The Cases of the Dividivi and Anamú in Colombia	132
The Anamú	152

Lessons from the Dividivi and the Anamú	156
Conclusions	162
<i>Chapter Five: Communities' Traditional Knowledge and Practices at the Service of the Herbal Industry in Colombia....</i>	164
Introduction	164
The Two Paths of the Natural Products Market in Colombia: the Growing Herbal Industry and the Urban Markets	170
The Colombian Herbal Industry.....	173
<i>Del campo a la plaza y de la plaza a la casa: the role of Urban Markets in the Use of Medicinal Plants in Colombia.....</i>	<i>180</i>
Yerbas la Mona and Oscar Sanabria.....	187
Oscar Sanabria	197
Documenting Information on Medicinal Plants.....	206
Conclusions	212
<i>Chapter Six: Sustainable and Inclusive Innovation in Health Research and Health Industry</i>	215
Introduction	215
Sen's Capability Approach and the Capability for Sustainable Innovation.....	221
The Capability for Sustainable Innovation in Health Research and the Health Industry	230
Why the Capability Approach?	235
The List of Functionings	240
Possessing Genetic Resources for Benefit Sharing	241
Being Able to Take Part in the Industrial Application of Genetic Resources and the Benefits that Arise from it	242
Being Able to Add Value to Health Research and the Health Industry.....	242
Conclusions	243
<i>Chapter Seven: The Capability for Sustainable Innovation for the Health Industry and Health Research: Amending Colombia's Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing</i>	244
Introduction	244
Possessing Genetic Resources for Benefit Sharing: Addressing the Problem of Placing Practices and Knowledge into the Public Domain	252
Being Able to Take Part in the Industrial Application of Genetic Resources and the Benefits that Arise from it.....	258
Being Able to Add Value to Health Research and Health Industry ..	264
Conclusions	271

<i>Appendix I Schedule of interviews</i>	<i>275</i>
<i>Appendix II Participants Consent Form</i>	<i>279</i>
<i>Appendix III Information Sheet for Candidates.....</i>	<i>286</i>
<i>Participant Information Sheet September 2019 (Plant Sellers).....</i>	<i>286</i>
<i>Participant Information Sheet September 2019 (Researchers)</i>	<i>289</i>
<i>Appendix IV Ethics Approval</i>	<i>293</i>
<i>Appendix V: Decision 391 of 1996 Common Regime on Access to Genetic Resources (Non-official translation)</i>	<i>294</i>
<i>Appendix VI: Decision 486 of 2000 Common Intellectual Property Regime (Non-official translation)</i>	<i>305</i>
<i>Bibliography.....</i>	<i>309</i>

Chapter One: Introduction

For each hour you spend reading this thesis, Colombia – one of the most megadiverse countries in the world – loses 25 hectares of tropical forest. This adds up to approximately 219.973 hectares per year.¹ It is the equivalent of the size of major cities such as Mexico City or Bangkok. Additionally, more than 1,200 species in Colombia are threatened by extinction, of which 798 are plants and 313 are mammals and birds.² Along with these genetic resources, Colombia's biodiversity³ includes natural non-renewable resources, such as oil and minerals. The causes of Colombia's biodiversity loss are a combination of various activities representing the complexities of Colombian socio-economic reality. For instance, conflict in Colombia is fuelled by the growth of coca leaf for illegal drug production and by illegal mining of minerals, such as gold. These activities devour water and land in the most biodiverse areas of the country.⁴ However, it is not only illegal activities that affect Colombia's ecosystems. Activities that are key for the economic development of the country, such as oil extraction, animal husbandry, agriculture, and construction of infrastructure (e.g. roads, dams, housing projects, and so on), are also primary causes of biodiversity loss.⁵

The loss of biodiversity through such a variety of legal and illegal economic activities also reflects other challenges facing countries such as Colombia. The places in which oil extraction and mining (either legal or illegal) take place are in general the poorest in Colombia, where local elites are also the most

¹ Ministerio de Ambiente, 'Avances Estrategia Integral de Control de La Deforestación y Gestión de Bosques: Bosques Territorio de Vida' <www.minambiente.gov.co> accessed July 8 2018.

² Instituto Humboldt, 'Biodiversidad Colombiana: Números Para Tener En Cuenta' (*Instituto Humboldt*, 2017) <<http://www.humboldt.org.co/es/boletines-y-comunicados/item/1087-biodiversidad-colombiana-numero-tener-en-cuenta>> accessed July 8 2018.

³ Article 2 of the United Nations Convention on Biological Diversity defined biological diversity or biodiversity as "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."

⁴ Ministerio de Ambiente (n 1), p 5

⁵ *ibid.*

corrupt.⁶ Violence, fuelled by illegal activities that consume biodiversity, has caused almost eight million people to be internally displaced during Colombia's long history of conflict.⁷ In turn, the displacement of people triggers further poverty and violence in urban areas, where victims of conflict have struggled to fit into the different dynamics of cities. Among those most affected are local, indigenous, and Afro-Colombian communities who have particular spiritual, social, and economic relationships with the country's environment.

While historians discuss why such a rich country in biodiversity has such recurrent patterns of violence as it negotiates a path towards economic growth,⁸ Colombia's national authorities have struggled to channel such an abundance of biodiversity towards peaceful and sustainable development. There are many tales of what has gone wrong in terms of employing non-renewable natural resources, such as oil and gold, for economic development, as well as the degradation of Colombian biodiversity to meet demands for the ever-persistent problem of drug consumption in the developed world;⁹ but this thesis focuses on a different tale, one in which the country aspires to employ its biodiversity, especially genetic resources, to pursue an ambitious technological and scientific agenda to advance its economic development and make sustainable use of such diversity.

⁶ JP Soler, *Locomotora Minero-Energética: Mitos y Conflictos Socio Ambientales* (CENSAT Agua Viva Amigos de la Tierra Colombia 2012).

⁷ More recently, apart from internal displacement, the figures of refugees have also peaked due to the exodus of Venezuelan cause by the economic collapse of the neighbouring country; UN Refugee Agency, 'UNHCR Population Statistics - Data - Overview' (UNHCR, 2018) <http://popstats.unhcr.org/en/overview#_ga=2.243524421.1747780701.1531058317-1147107829.1531058317> accessed 8 July 2018.

⁸ See for instance Frank Safford and Marco Palacios, *Colombia: Fragmented Land, Divided Society (Latin American Histories)* (Oxford Univ Press, Oxford 2001).

⁹ See for instance: Aldo Civico, "'We Are Illegal, but Not Illegitimate.'" Modes of Policing in Medellín, Colombia' (2012) 35 *PoLAR: Political and Legal Anthropology Review* 77; Francisco E Thoumi, *Illegal Drugs, Economy, and Society in the Andes* (Woodrow Wilson Center Press 2003); Steven Dudley, *Walking Ghosts: Murder and Guerrilla Politics in Colombia* (Routledge 2004).

Colombia's place in the world and its implementation of the International Regime on Access to Genetic Resources and Benefit Sharing

Although Colombia faces difficult challenges, the country enjoys a growing and vital economy. Indeed, it is expected that the economy will keep a gradual pace of development in the coming years (2019-2020), as there is currently a relatively low unemployment rate alongside steady and controlled inflation.¹⁰ Colombia's economic profile has led it to be placed alongside larger economies in terms of development. Recently, for instance, Colombia joined the Organisation for Economic Co-operation and Development (OECD), through which the most economically developed countries in the world share data and experiences, disseminate good practice, and establish market-oriented policies.

The aspiration of becoming a key player at the international level has led to Colombia having a great interest in employing its biodiversity as a tool in its economic development. The Colombian National Development Plan or *Plan Nacional de Desarrollo* points explicitly to the importance of biodiversity and its components, including genetic resources, for both the economic development and technological innovation of the country and its economy.¹¹ As a result, Colombia has great expectations of making the utilisation of biodiversity a key aspect of the activities of sectors such as health research and the health industry.

Towards this goal, Colombia demands that those who employ the country's biodiversity and its components, particularly genetic resources, require prior informed consent from national authorities, and must reach an agreement with the country to share the benefits arising from the utilisation of genetic resources. The sharing of benefits can take the form of monetary benefits (e.g.

¹⁰ OECD, 'Developments in Individual OECD and Selected Non-Member Economies: Colombia', *OECD Economic Outlook* (OCDE 2018) <<http://www.oecd.org/eco/outlook/economic-forecast-summary-colombia-oecd-economic-outlook.pdf>> accessed 12 March 2019.

¹¹ Departamento Nacional de Planeación, *Plan Nacional de Desarrollo 2014-2018 2015 Tomo I*.

royalties, intellectual property rights, joint ownership) or non-monetary benefits, such as transfer of technology and training.¹²

Although the access to genetic resources and benefit sharing might sound like a straightforward transaction, in reality, the use of biodiversity for research and industry is far more complex. In fact, despite the expectations of employing genetic resources as a key aspect in the economic and technological development of the country, there is not a single story of commercial success from the use of Colombian biodiversity. Yet, Colombia keeps those expectations high, as it has developed an important national scientific and technological infrastructure.

As a result, Colombia has facilitated the rules on access to genetic resources for specific users, such as publicly funded projects in universities and research centres (i.e. local researchers), which are part of Colombia's scientific and technological network. In that way, Colombian law and policy aims to encourage local researchers to carry out bioprospecting activities within the extensive biodiversity the country enjoys. Bioprospecting initiatives involve the activities of scanning and scoping biodiversity for the collection of new biochemical compounds for specific industries, particularly the pharmaceutical industry, as well as finding "leads" in the practices and knowledge of communities associated with genetic resources. Furthermore, Colombia encourages local researchers to assert property rights over the products and processes derived from genetic resources. Local researchers are encouraged to do so through patents, a form of protection of intellectual property that grants exclusive rights over inventions, including those based upon genetic resources. In that way, holders of patents retain a right to either exploit their own invention (manufacture, distribute, and so on) or license other stakeholders to do so.

¹² The classification is taken from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (2002), which is part of the International Regime on Access to Genetic Resources

In addition, there are other sectors that, despite the fact that they benefit from the use of Colombian biodiversity, are exempted *de facto* from the International Regime on Access to Genetic Resources and Benefit Sharing. This is the case for the Colombian herbal industry, a growing national business which produces and manufactures phytomedicines, i.e. bioactive natural products that have pharmacological action and are derived from native and introduced plants. Rather than carrying out bioprospecting to define pharmaceutical effects of naturally occurring substances, this industry relies on knowledge and practices from local, indigenous communities. Reliance on this knowledge and practice supports both the production of herbal products and, crucially, the demonstration of their safety and effectiveness.

Colombian implementation of the International Regime on Access to Genetic Resources and Benefit Sharing is in line with Colombia's aspiration to become a key player in the international arena. The country claims that the use of biodiversity for health research and the health industry has a strategic value for economic development.¹³ Yet, as this thesis will uncover, there are complexities behind the use of biodiversity which reveal that such aspirations could have the effect of relegating, or at least rendering vulnerable, rights of people from local and indigenous communities, who through their knowledge and practices add value to the understanding of biodiversity for research and industry. Since knowledge and practices from those communities are not recognised as key aspects that add value to the industrial application of and research into Colombia's biodiversity, the country has not established effective mechanisms of protection. This is despite the fact that Colombia has acquired international compromises in the International Regime on Access to Genetic Resources and Benefit Sharing to involve those communities in the decision-making process.

But the question of what would be an effective policy for Colombia to promote sustainable innovation in its health industry and in health research is not only about acknowledging and protecting communities' knowledge and practices.

¹³ See Paragraphs 4 and 8 of the Preface of the Decision 391 on the Common Regime on Access to Genetic Resources of 1996.

Ultimately, it is a question about justice. As already noted in the first lines of this thesis, the exploitation of natural resources to meet international demand for commodities, and the illegal trade of drugs, are the main causes of harm to those who share an historical, spatial, and spiritual connection with Colombia's biodiversity. Of course, the use of biodiversity for scientific and technological advancement cannot be systematically compared with the extraction of natural resources and illegal drug trafficking, but since it is presented as a way to achieve sustainable use of biodiversity,¹⁴ Colombia should also consider those communities' practices and knowledge when it adopts policies that aim to secure such a sustainable use of biodiversity.

The Key Research Question

Against this background, the thesis aims to answer the following research question: How should Colombia, a developing country rich in biodiversity, implement the International Regime on Access to Genetic Resources and Benefit Sharing in order to recognise the contribution from local, indigenous, and Afro-Colombian communities' practices and knowledge in adding value to the use of genetic resources for the health industry and health research?

The Approach and Method of the Thesis

To that end, this thesis centres on an in-depth analysis of the various ways in which the contributions of local, indigenous, and Afro-Colombian communities to knowledge and understanding of the properties of Colombia's biodiversity has been ignored in health research and the health industry in the country. This is so, even though that industry and its research draws upon genetic resources. According to the aims of the International Regime on Access to Genetic Resources and Benefit Sharing, as we will see in more detail in the

¹⁴ See for instance the Colombian policy on the use of biotechnology for the use of sustainable development: Consejo Nacional de Política Económica y Social, 'Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad' (2011) <<https://colaboracion.dnp.gov.co/CDT/Conpes/Economicos/3697.pdf>> accessed 5 June 2018.

next chapter, it should therefore be part of Colombia's implementation of that international regime.

The primary focus of the research is on the Colombian regulatory framework that implements the International Regime on Access to Genetic Resources and Benefit Sharing. The analysis goes beyond an assessment of the legal texts according to the 'standard' methods of legal scholarship (sometimes known as the doctrinal or black letter approach). It also brings to bear scholarship from anthropological, ethnobotanic, and economic perspectives, and thus investigates the law from an interdisciplinary point of view. It adds data from a small dataset of original semi-structured interviews with representative actors in Colombia, as well as observations and photographs of the places in which the interviews took place. The thesis cross-references data available from published anthropological and ethnobotanical research with legal databases, such as for marketing approvals or patent applications. The aim is to provide a "deep" or "thick" analysis of the law and policy on the ground, in a single state, so as to strengthen our understanding of how the International Regime on Access to Genetic Resources and Benefit Sharing plays out in practice within a particular context.

Colombia makes a pertinent case study because its biodiversity is an aspect that the country as a whole considers part of its very own foundations, its national identity. It is an aspect that involves a long-time aspiration of making Colombia's biodiversity a key element in its economic and technological development. But such an aspirational objective in the use of Colombia biodiversity is rather a crossroad of different actors (e.g. local researchers, communities, government, national courts, etc.) and issues (sustainable use of biodiversity, economic development and so on) which is a pertinent example to illustrate the difficulties of regulating aspects related to a country's biodiversity.

Additionally, Colombia was chosen as the country for analysis for other specific reasons, a fundamental one being that Colombia is one of the most biodiversity-rich countries in the world because of its location in one of the

most megadiverse regions in the world; Colombia is in the north-west area of South America, where different “hot spots” converge; the Choco/Darren coast in the west coast, the tropical Andes, which begins in the centre and ends in the north coast of the country, and the Amazon rainforest in the south.¹⁵ 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.¹⁶ Also, to such indigenous diversity, Colombia has been the recipient of introduced species, including plants, which have had a profound impact in the country’s economy and cultural traditions.¹⁷ Colombia’s biodiversity also has a prominent interaction with the country’s diverse population that includes local (mestizo and peasants populations), indigenous, and Afro-Colombian communities;¹⁸ these communities, through their ancient knowledge and local practices, have revealed potential uses of introduced and native plants for key sectors such as the health industry. In addition, as Colombia enjoys a relatively stable economic development, the country seeks to make the use of biodiversity a key aspect in health industry and health research. Because of the convergence of those factors, it is the type of nation for which the International Regime on Access to Genetic Resources and Benefit Sharing seeks to secure fair access to genetic resources and the sharing of benefits in the context of the UN Convention on Biological Diversity. It is, in a sense, a ‘perfect’ test-case of the effectiveness of those international instruments in context.

The research ‘puzzle’ that the thesis tackles is to explore why, despite the aim of the International Regime on Access to Genetic Resources and Benefit

¹⁵ The most biodiversity-rich areas in the world are also the most threatened; as a result scientists have gathered together different areas in the world that account for most of the biodiversity, calling them ‘hot spots’ further information regarding biodiversity hot spots is at <https://www.conservation.org/How/Pages/Hotspots.aspx>

¹⁶ Norman Myers and others, ‘Biodiversity Hotspots for Conservation Priorities’ (2000) 403 *Nature* 853; Norman Myers, ‘Threatened Biotas: “Hotspots” in Tropical Forests’ (1988) 8 *The Environmentalist* 187.

¹⁷ Colombia cannot request users of genetic resources to comply with ABS Rules to introduced plants, but only native plants. Some of the key Colombian agriculture products are introduced plants such as coffee (*Coffea arabica*), sugar cane (*Saccharum offinnarum*), coconut (*Cocos nucifera*) and banana (*Musa paradisiacai*)

¹⁸ Milton Romero, Edersson Cabrera and Néstor Ortiz, ‘Informe Sobre El Estado de La Biodiversidad En Colombia 2006-2007’ [2008] Instituto de Investigación de Recursos Biológicos Alexander von Humboldt. Bogotá DC, Colombia.

Sharing to establish a compensation mechanism in which developing countries rich in biodiversity and communities within those countries are supposed to obtain benefit sharing, its implementation in Colombia has led its users, especially local researchers, to approach genetic resources as “raw materials” and indigenous communities’ contributions as mere “leads” in finding industrial applications in plants, rather than a benefit to be shared. To explore the Colombian case, the thesis employs an anthropological and ethnobotanical analysis of bioprospecting activities in other developing countries rich in biodiversity.

This literature points out the ways in which the International Regime on Access to Genetic Resources and Benefit Sharing treats all conditions and actors behind the use of biodiversity in a way that is too one dimensional and too simplistic. Thus, under the regime, benefit sharing is to be agreed for downstream stages of research and development (R&D). But this leaves “the rest of the research process largely intact”.¹⁹ Particularly, drawing on the work from authors such as Hayden, Osseo-Asare,²⁰ and Cloatre,²¹ this thesis explores how innovation and the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries rich in biodiversity is underpinned by a market-oriented approach which is biased towards holders of technology and the way they produce and commercialise knowledge and information.

The Colombian case is a specific example of this general observation, and the thesis also demonstrates how Colombia’s law and policy choices have created a sub-optimal situation for reaching the sustainable innovation that is claimed as Colombia’s hope for harnessing its biodiversity to economic ends, and for the health of its population. The examination of Colombia’s law and policy choices in the implementation of the International Regime on Access to

¹⁹ Cori Hayden, *When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico* (Princeton University Press 2003).

²⁰ Abena Dove Osseo-Asare, *Bitter Roots: The Search for Healing Plants in Africa* (University of Chicago Press 2014).

²¹ Emilie Cloatre, ‘Biodiversity, Knowledge and the Making of Rights: Reviewing the Debates on Bioprospecting and Ownership’ in M Bowman, P Davies and E Boodwin (eds), *Research Handbook in Biodiversity and Law* (Edward Elgar 2016).

Genetic resources is not limited exclusively to a documentary and interdisciplinary analysis. Throughout the final stages of this project, such an analysis led to a specific actors and networks which provided a better understanding of the way that stakeholders understand and approach to Colombia's law and policy on innovation and the use of biodiversity for health research and health industry. Consequently, the research adopted a qualitative research that demonstrates how those actors engage with Colombia' law and policy. It is also expected that the use of this methodology contributes to overcome the current limitation on legal scholarship that engage with fieldwork in Colombia in different areas of law, including intellectual property and environmental law.

The fieldwork involves conducting semi-structured interviews with seven people, who fall into two groups of representative stakeholders. These are: a research group in the field, based in Bogotá (Colombia) which has carried out extensive investigation in two medicinal plants, *Dividivi* (*Caesalpinia spinosa*) and *Anamú* (*Petiveria alliacea*), for industrial applications; and, providers of those medicinal plants, who are sellers of plants or *Yerbateros* in a well-known urban market in Bogotá (*La Plaza Samper Mendoza*). In addition, the author's observations in the urban market, captured in photographs, forms part of the data on which the analysis draws. Legal texts and policy documents are considered alongside data from the semi-structured interviews, and observations, to elicit more nuanced information about interactions and complexities on the ground in Colombia. The interviews and observations were carried out between September and October of 2019.

The interviews were recorded, and in the case of the interviews with the research group were transcribed; these interviews took place at the immunology labs in the Javeriana University and the home of its lead researcher. The transcripts of the recorded data from the interviews with the plant sellers (which are of variable quality because of background noise in the location) are supplemented by notes and photographs taken by the author of the surroundings of *Plaza Samper Mendoza*. Interview quotes, translated by the author, were employed extensively to provide an appropriate account of

the participants' discourse and to reveal the complexities behind the use of medicinal plants in practice.

The limitations of interview data of this type are well-established. The possibility of mistakes or misunderstandings arising through transcription and translation was mitigated in the case of this research by the author's mother tongue being the language in which the interviews were conducted, and the author being responsible for the transcription and translation. The author does not seek to over-claim or over-generalise from a small dataset taken from interviews with a specific research group, in a specific locality, at a specific time. However, the significance of this particular research group for the study lies in its claimed scientific and technical accomplishments in the use of medicinal plants in Colombia, as well as the professional and personal experiences of members of the group with the Colombian regulatory framework regarding access to genetic resources. Furthermore, the choice of location for interviews with market traders was justified by the necessity to corroborate the documentary analysis of the thesis, which point out how the law and policy behind the use of biodiversity do not capture the ways, traditions and costumes of those who work in the acquisition, transformation and trade of medicinal plants and knowledge related to them in the Colombian largest and most important market of plants.

As noted above, alongside the interview data, observational notes taken by the author during the interviewing process were also used to draw a better picture of the participants' life experience, interaction with other actors and places. One obvious limitation of this type of data is the dangers associated with cultural misunderstandings and misreadings: the fact that the author is a native of Colombia provides some mitigation of this limitation.

Other resources such as maps are also employed in this thesis to locate the reader in the different locations across the country in which the interactions among stakeholders and life experience of the participants can be contextualized geographically.

The final part of the thesis adds to that deep and “thick” analysis of the Colombian law and policy in context, by making a normative claim to justify a more inclusive regulation of innovation, in which practices and knowledge from indigenous communities are recognised and effectively protected. The implication of the aims of the International Regime on Access to Genetic Resources and Benefit Sharing is that this is what is required of countries that have agreed to its international norms. The normative part of the thesis draws from Sen’s Capability Approach.²² The Capability Approach seeks to make economic development inclusive, through an analysis of people’s wellbeing beyond economic terms, such as average income. The Capability Approach focuses on people’s conditions, i.e. what people are capable of doing and being, so they can live a life according to those doings and beings, (or so called functionings), making life worth living. In that way, the approach is able to incorporate, within an economic analysis, aspects of life which go beyond maximisation of wealth to entitle people and communities to pursue what they consider a good life. Although Sen’s main claim is to tackle poverty and improve people’s quality of life, his approach can also be an inspiration in interdisciplinary work such as this thesis because it allows to set up normative claims in the form of capabilities, which contains a list of conditions (i.e. functionings, what people are able to do or be); consequently, those conditions can be evaluated in order to define whether the proposed capability can be achieved.²³

For the particular case of the thesis, the argument is that there should be a capability for sustainable innovation in the health industry and in health research in Colombia. This claim departs from the standard view of Colombia’s policy on innovation, which has informed the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in the country. In the Andean nations, innovation has been constructed with a market-oriented perspective which measures and defines its scientific and

²² As originally proposed in Amartya Sen, ‘Equality of What?’ [1979] The Tanner Lecture on Human Values- Stanford University.

²³ Ingrid Robeyns, ‘The Capability Approach’ in Edward Zalta (ed), *The Stanford Encyclopedia of Philosophy* (Winter Edi, 2016) <<https://plato.stanford.edu/entries/capability-approach/>>.

technological infrastructure. This means that R&D in Colombia responds to a market logic, in which technology and science serves the purpose of bringing new products, process and services into the market. Translating this analysis into the thesis, local researchers, who are part of such an infrastructure, are evaluated and measured in terms of being able to produce new products, processes, and services derived from biodiversity, and bring them to the market. This means practices and knowledge from local, indigenous, and Afro-Colombian communities that add value to the use of biodiversity for health research and the health industry, but which do not follow a market-oriented perspective, are not considered innovative.

As those practices and knowledge are not seen as innovative in Colombia, this thesis argues that they are not properly acknowledged in R&D and industrial applications, nor effectively protected as Colombia implements the International Regime on Access to Genetic Resources and Benefit Sharing. As a result, knowledge and practices have been placed into the public domain, leading local researchers to appropriate them through, for instance, patents. Furthermore, the national herbal industry not only employs them as a source in the production of phytomedicines, but also uses them to prove safety and effectiveness of those products in order to obtain marketing authorisation from local authorities.

That is why this thesis argues that Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing should instead aim to achieve a capability for sustainable innovation in health research and the health industry, so as to include practices and knowledge of indigenous communities that add value to the use of biodiversity.

To explain what would achieve such a capability, this thesis puts forward an account of "functionings": What local, indigenous, and Afro-Colombian communities are capable of doing and being in R&D contexts. Attention to those functionings in Colombia's regulatory design when implementing the International Regime on Access to Genetic Resources and Benefit Sharing, the

thesis argues, would secure a more inclusive innovative health industry and health research sector in Colombia.

As it can be observed, this thesis makes Colombia's market perspective for health industry and health research on the use of biodiversity accountable for affecting communities' rights. Yet, this research does not distance itself completely from the view that biodiversity could lead Colombia to enhance its technical and scientific capability, as well as encouraging economic development, while protecting communities. This means that the protection of communities' practices and knowledge should be adequately integrated into the logic of the relevant markets in the use of biodiversity, i.e. the desire to bring new products and process into the market in order to impact positively countries' economic agendas. This can be observed in the wording of the UN Convention on Biological Diversity (CBD), the core treaty of the International Regime on Access to Genetic Resources, which provides a definition of sustainable use of biodiversity, as this treaty states that countries should exploit their biodiversity, including genetic resources, in a way and at a rate that secures the needs of present and future generations (Article 2 and 10 of the CBD). In other words, according to the CBD, sustainable use does not mean countries should desist from using biodiversity for research and industrial proposes, but should exploit it only in a form and manner that ensures that it would last.

Therefore, sustainable use demands countries to create adequate measures to preserve world's biodiversity, while they aim to achieve their economic interests. The same can be extended to communities' practices and knowledge associated with genetic resources. The implementation of the International Regime on Access to Genetic Resources cannot be contrary to countries' economic agendas, yet, it requires that the role of communities in the use of biodiversity is fully acknowledged. Although there is extensive critique on creating a balance between markets and economic development with

environmental and societal issues (i.e. “green capitalism” or *neodesarrollo*),²⁴ it is not only possible but also desirable. In fact, there are scholars such as Greene who brings into the discussion the ideas of market-oriented policies in the use of traditional knowledge without forgetting historical inequalities that affects indigenous communities.²⁵ This requires not only establishing mechanisms to protect and recognise the role of communities in the use of biodiversity for health industry and health research, but also actively involving those communities so as to empower them to make their own decisions.

Consequently, concepts such as sustainability and innovation in the use of biodiversity should be open to discussion to address communities’ concerns. It is precisely forums such as the UN Convention on Biological Diversity, and even the World Trade Organization, that have served as a platform to discuss economic and social aspects that affect the most vulnerable, including ethnic minorities and peasants.²⁶ This is even more relevant in places such as Colombia where divisive and polarised perspectives of the market economy have also fuelled Colombia’s long internal conflict. In fact, Colombia witnessed the rise of left guerrillas who opposed any form of capitalism, and State-backed forces, including paramilitary armies, which defended the *status quo*, leading to a ferocious civil war that lasted more than 50 years. In response, to be more precise, and to focus on the legal and constitutional settlement that followed, the Colombian Constitution of 1991 and the Constitutional Court of Colombia, the highest constitutional tribunal in the country, seek to create a balance between economic interests and societal concerns to secure an adequate path to peace and prosperity.

As a consequence, sustainable use of biodiversity and innovation cannot be proposed exclusively as an unidimensional perspective in which the only thing

²⁴ For further information on this discussion in the context of Latin-American countries see: Fabio De Castro, Barbara Hogenboom and Michiel Baud, *Environmental Governance in Latin America* (Springer 2016).

²⁵ Shane Greene, ‘Indigenous People Incorporated? Culture as Politics, Culture as Property in Pharmaceutical Bioprospecting’ (2004) 45 *Current anthropology* 211.

²⁶ See for instance: Terry Mitchell, Ken Coates and Carin Holroyd, *The Internationalization of Indigenous Rights: UNDRIP in the Canadian Context* (Centre for International Governance Innovation 2014).

that matters is to bring products and process for profit in order to protect biodiversity. In addition, it is also important to include communities in the discussion about how to create a fairer and inclusive model of innovation in the use of biodiversity in Colombia. That is why this thesis also choose the Capability Approach for its normative frame, since it is a theoretical framework that aims to conciliate economic development with the needs of vulnerable populations in order to entitle them to pursue the life they want.

Who Will Be Interested in the Research?

This analysis of Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, innovation and the contribution from local, indigenous, and Afro-Colombian communities in adding value to the use of biodiversity for the health industry and health research is significant to a broader audience in Colombia and those who are interested in understanding Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. First, the thesis has obvious implications for the constitutionality of Colombian law and practice. The 1991 Colombian Constitution brings an extensive catalogue of liberties and rights. It includes the recognition and protection of community rights, and seeks to ensure that economic development does not violate those rights. Thus, in order to be constitutionally compliant, policy makers in Colombia should implement the International Regime on Access to Genetic Resources and Benefit Sharing so as to recognise and protect the role of indigenous communities' practices and knowledge in the use of biodiversity. This thesis provides an assessment of whether the current legislation in Colombia requires amendment(s) to meet that constitutional aim.

Second, the thesis is important for the various users of genetic resources and the wide range of stakeholders within health research in Colombia and its health industry. The thesis focuses on health research and the health industry since biodiversity is an important source for treatment of human diseases. Relevant stakeholders thus include not only users – such as laboratories, research centres, universities and even pharmaceutical companies which, for

instance, synthesise genetic resources for drug production – but also other stakeholders who employ those resources to produce and distribute medicinal plants to treat human diseases (e.g. the herbal industry). Since they invest time and economic resources in bringing products and processes with human therapeutic activity into the market, it is only natural that they are concerned about the scope and the potential impact of the International Regime on Access to Genetic Resources and Benefit Sharing on their R&D and industrial activities into genetic resources. Wider still, stakeholders include everyone who falls within the Colombian health system.

As a single-country case study, the main contribution to existing knowledge that the thesis makes is its in-depth analysis of the Colombian implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, its national health industry and health research sector, the rights of local, indigenous, and Afro-Colombian communities, in the light of the use of biodiversity, and its innovation policy. However, without wanting to over-generalise, the thesis may also provide guidance to other developing countries rich in biodiversity, especially members of the Andean Community of Nations (of which Colombia is a member), to adopt policies and legal mechanisms that will lead them to take advantage of their genetic resources. The Andean Community of Nations is a regional organisation comprised of four neighbouring developing countries rich in biodiversity (Bolivia, Colombia, Ecuador, and Peru). Among its trade instruments, the Andean Community of Nations sets up general guidelines and a common policy on access to genetic resources which each member should implement at the national level, according to their country's legal system.

Further, the thesis adds to the literature mentioned above a case study from a different context. In particular, the Colombian case demonstrates the tensions between imaginaries of innovation in healthcare, the workings of research and industry at several levels (drug development and phytotherapy), and the position of local knowledge-holders. It contributes to a field of study that has demonstrated why international law has failed to seize the complexity of social relations surrounding plant and medicinal knowledge in biodiversity-rich

countries, while expanding its reach to a new local context. Finally, it contributes to existing literature by interrogating the little-explored constitutional ramifications of a debate, in which international and national jurisdictional tensions are apparent.

The Scope of the Thesis

This research centres on the use of biodiversity by the health industry and in health research. Other important industries that are based on genetic resources, such as the agricultural industry, are beyond the scope of this thesis. 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 intellectual property rights is quite different from that of genetic resources for human health, as the former have shown a different evolution. The core regulatory framework for plant genetic resources is the plant variety rights system, which is governed by the International Union for the Protection of New Varieties of Plants. Originally, this kind of protection was not intended to be introduced as an intellectual property rights system, but as a legal mechanism to encourage the sector of plant breeders.²⁷ Developing countries have also campaigned in the Food and Agriculture Organization (FAO) to create an alternative legal framework that benefits them, and especially their farmers (i.e. the International Treaty on Plant Genetic Resources for Food and Agriculture).²⁸

The International Regime on Access to Genetic Resources and Benefit Sharing focuses on genetic resources found in microorganisms, animals, and plants as defined by Article 2 of the UN Convention on Biological Diversity. Although such a definition is broad enough to include human genetic resources, the

²⁷ For further information see: Margaret Llewelyn and Mike Adcock, *European Plant Intellectual Property* (Bloomsbury Publishing 2006); Margaret Llewelyn, 'Which Rules in World Trade Law—Patents or Plant Variety Protection' [2003] *Intellectual Property: Trade, Competition and Sustainable Development* 303.; for further information on the conflict between plant breeders protection and patents in Europe see A. Andreas Hübel, Ulrich Storz and Aloys Hüttermann, *Limits of Patentability: Plant Sciences, Stem Cells and Nucleic Acids* (Springer Science & Business Media 2012).

²⁸ The International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the Food and Agriculture Organisation Conference through Resolution 3/2001

Conference of Parties of the UN Convention on Biological Diversity (the governing body of the UN Convention on Biological Diversity) has already excluded human genetic resources from the scope of Article 2.²⁹ This indicates that the International Regime on Access to Genetic Resources and Benefit Sharing does not regulate access to human genetic resources.³⁰ Therefore, the scope of the thesis includes genetic resources involving genetic material from plants, microorganisms, and animals and the information encoded in the DNA or RNA. It does not include human genetic resources.

Equally, the analysis in this thesis focuses on the practice, cultural expression, and knowledge that indigenous and local communities hold on genetic resources. This means that the personal scope of the analysis covers not only ethnic communities (i.e. indigenous communities), but also groups of people whose cosmo-vision, social, and economic practices are interrelated with biodiversity (local communities). In the particular case of Colombia, the concept of communities also includes Afro-descendants. Despite the fact they are not natives of Colombia, they have nonetheless constructed its socio-economic and spiritual heritage around Colombia's biodiversity.

In terms of its legal analysis, the thesis focuses on one particular set of international instruments: The International Regime on Access to Genetic Resources and Benefit Sharing. It includes three international agreements: The UN Convention on Biological Diversity,³¹ and the subsequent instruments that clarify the scope of access and benefit sharing of the UN Convention on Biological Diversity, notably the Bonn Guidelines³², and the Nagoya Protocol.³³ However, to understand those legal instruments in the context of

²⁹ Conference of Parties of the UN Convention on Biodiversity, n 44

³⁰ For further information on human genetic resources and the International Regime on Access to Genetic Resources and Benefit Sharing see Doris Schroeder and Carolina Lasén-Díaz, 'Sharing the Benefits of Genetic Resources: From Biodiversity to Human Genetics' (2006) 6 *Developing World Bioethics* 135; Doris Schroeder and others, 'Sharing the Benefits of Genetic Research'.

³¹ UN Convention on Biological Diversity, Rio de Janeiro, as adopted in June 1992

³² 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 UN Convention on Biological Diversity at its sixth meeting, in The Hague in April 2002

³³ 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 UN Convention on Biological Diversity at its tenth meeting, in Nagoya, Japan in October 2010

broader international law, the thesis also contemplates other instruments, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPs),³⁴ which aims to standardise patent protection among members of the World Trade Organization (WTO), including Colombia. Patents are relevant in the analysis of this thesis, since the products and processes which are considered to be innovative are protected through this intellectual property rights mechanism.

Patents protect the generation of information and knowledge that flow in the market. Although patents protect all fields of technology, patent law and practice normally does not affect forms of production which do not necessarily involve invention. More specifically, and for the interest of this thesis, those forms of production include practices and knowledge from local and indigenous communities. Patents work on the basis of documented disclosure of inventions to the relevant authorities. Where indigenous and local communities pass on their knowledge verbally, rather than in written forms of patents or in scientific journals, holders of technology have documented, collected, and synthesised inventions deriving from that indigenous knowledge and those practices in order to place products and processes onto the market. This has led to what advocates of community rights groups and governments call “biopiracy”. In general terms, the term biopiracy is deployed to relate to any practice that involves the unlawful (and unethical) appropriation (generally via patents) by holders of technology of a country’s biodiversity or indigenous people and local communities’ traditional knowledge and practices. As the discussion of biopiracy has been taken to different forums, including the World Intellectual Property Organization (WIPO) and the International Regime on Access to Genetic Resources and Benefit Sharing, there have been attempts to narrow down the concept of biopiracy to two private international law definitions: Misappropriation and misuse.³⁵ While the former refers to non-contractual disputes in which prior

³⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Annex 1C of the Marrakech Agreement Establishing the World Trade Organization, signed in Marrakech, Morocco April 15 1994

³⁵ For further information see Claudio Chiarolla, ‘Biopiracy and the Role of Private International Law under the Nagoya Protocol’ (2012) 02/12; The Conference of Parties of the UN Convention on Biological Diversity, ‘Report of the Eighth Meeting of the Ad Hoc Open-

informed consent and mutually agreed terms were not obtained, the latter refers to situations in which prior informed consent and mutually agreed terms were obtained, but there was a breach of contractual obligations. Although those concepts have not been included in the final text of any of the binding instruments of the International Regime on Access to Genetic Resources and Benefit Sharing, this thesis adopts a narrowed down term of biopiracy to refer to both misuse and misappropriation.

Since the herbal industry is within the scope of this thesis, the Colombian regulation on market approvals for pharmaceutical products, in which phytomedicines are included, is also evaluated. Market approvals for medicines consists of a risk-benefit assessment, which is carried out by a health authority, which in the case of Colombia is the *Instituto Nacional de Vigilancia de Medicamentos* (INVIMA)). In this evaluation, the pharmaceutical product has to meet certain scientific criteria on quality, safety and efficacy, which are normally corroborated by clinical trials. However, “traditional phytomedicines” are not required to carry out clinical trials, instead safety and efficacy can be corroborated through the documentation of communities’ traditional knowledge and practices. Consequently, any proposed legal solution on how to include communities’ understanding of biodiversity in the health industry demands inclusion of this regulation.

The core focus of the thesis is policies and legal mechanisms on benefit sharing. Although the research mentions different types of benefit sharing agreements (i.e. licensing and joint ownership of intellectual property rights, milestone payments, etc.), an analysis of specific provisions in mutually agreed terms (such as different types of licensing agreements related to genetic resources and intellectual property rights; or alternative mechanisms of licensing technology in the context of biodiversity and genetic resources, such

Ended Working Group on Access and Benefit Sharing’, *UNEP/CBD/COP/10/5/Add.2* (2009) <<https://www.cbd.int/doc/meetings/cop/cop-10/official/cop-10-05-add2-en.pdf>> accessed August 22 2017; IGC, ‘Glosary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions’, *WIPO/GRTKF/IC/34/INF/7* (2017) <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_34/wipo_grtkf_ic_34_inf_7.pdf> accessed August 22 2017.

as patent pools, open sources, or clearing houses) is beyond its scope. Instead, the thesis brings a modest interdisciplinary perspective to the doctrinal analysis of the International Regime on Access to Genetic Resources and Benefit Sharing.

The Thesis Road Map

Chapter Two introduces the International Regime on Access to Genetic Resources and Benefit Sharing. It identifies the main provisions of this international framework, particularly the rules on access, benefit sharing, and communities' rights over their traditional knowledge associated with genetic resources. This chapter's analysis points out that, despite efforts to include communities' rights within the scope of the regulation, the implementation of this treaty at the national level demonstrates the difficulty of capturing the complexity or "messiness" of the different actors (users of genetic resources, the industry, communities, government agencies, etc.) behind the use of communities' practices and knowledge over genetic resources for health industry and health research. In fact, the implementation of this treaty in developing countries rich in biodiversity indicates that there are difficulties in recognising and protecting communities' contributions in adding value to biodiversity for health research and the health industry, since it conflicts with the model of innovation that is primarily focused on specific sectors such as the pharmaceutical industry, and countries' interests in exploiting their biodiversity for economic development.

Chapter Three focuses on the particularities of Colombian law related to the thesis' subject matter. There are two key aspects: The Andean Community legislation on access to genetic resources and benefit sharing, in which Colombia is a member; and the constitutional provision that aims to reconcile communities' rights with economic development. This chapter also studies in particular how regulation from different governmental agencies in Colombia has eased the rules on access and benefit sharing for local researchers, which apparently contradicts the Andean Community's provisions and constitutional mandates. Also, throughout the study of the implementation of the

International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, it is also noted that the government, through different administrative decisions, has carefully exempted the herbal industry from the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, meaning it is not required to comply with this legislation. In other words, the current legislation on the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing benefits local researchers and the herbal industry, and is in apparent contradiction with the Andean Community's legislation and constitutional provisions.

Having explained the particularities of the Colombian legal system, Chapter Four analyses how Colombian law worked out in practice for health research in genetic resources as the country implements the International Regime on Access to Genetic Resources and Benefit Sharing. Drawing on data from semi-structured interviews, the chapter analyses in particular how local research has benefited from legislation that leaves aside practices and knowledge emanating from local, indigenous, and Afro-Colombian communities in adding value to biodiversity. In particular, it analyses how in health research, the current implementation of the International Regime on Access to Genetic Resources and Benefit Sharing has placed into the public domain those practices and knowledge since local researchers of genetic resources (e.g. universities) have access to them without reaching prior informed consent and signing mutually agreed terms with those communities. The chapter does so through the examples of two native plants Dividivi (*Caesalpinia spinosa*) and Anamú (*Petiveria alliacea*), in which publicly funded research realises the therapeutic value of the plant thanks to practices from local communities, yet those communities have not been acknowledged for their contribution in the research.

The evidence collected from local researchers in a Colombian university and from market traders in two locations where medicinal plants are traded also demonstrates that, in practice, there is a fragmented implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia. This involves, on one hand, the different provisions of the Andean

Community legislation and Colombian constitutional mandates that secure extensive prerogatives to communities, and, on the other hand, different Colombian authorities (ministries, state agencies, etc.) and administrative decisions that have benefited and encouraged local researchers to access those communities' knowledge without even consulting them.

Regarding the health industry, Chapter Five raises a fundamental question: To what extent should the herbal industry comply with the International Regime on Access to Genetic Resources and Benefit Sharing in the same way other industries so, such as the pharmaceutical industry, since it benefits from communities' practice and knowledge associated with genetic resources? As a result, this chapter explores the herbal industry in Colombia and how it has also benefited from Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. The chapter illustrates that this industry employed communities' practices and knowledge in the production of phytomedicines, as well as in proving safeness and effectiveness of these products, without being required to comply with the International Regime on Access to Genetic Resources and Benefit Sharing and without consulting communities.

Chapter Five also argues that this has occurred because Colombia has implemented the Access to Genetic Resources and Benefit Sharing Regime to include the use of technologies on genetic resources (e.g. chemical synthesis or biotechnology) and the use of legal mechanisms to protect inventions that derive from those resources such as patents. Those technologies and legal mechanisms of protection are common in sectors such as the pharmaceutical industry, but not in the herbal industry. As a result, again drawing on data from semi-structured interviews and observations in an important urban market in Bogotá, this chapter studies how the herbal industry operates in practice in Colombia. It explores how this industry benefits from Colombian access to genetic resources and benefit sharing regulation that does not include it within its scope.

Additionally, Chapter Five explores how the industry benefits from the efforts of scholars and authorities in documenting communities' practices and knowledge over the use of medicinal plants. Since those efforts have placed into the public domain those practices and knowledge, the herbal industry has accessed them to understand the medicinal use of plants, and to prove safeness and effectiveness of phytomedicines so as to obtain marketing approvals of those products.

As the thesis notes that Colombia has tried to reconcile economic development with other interests, particularly those who have historically suffered most from Colombia's complex history of violence, including communities, Chapter Six points out that this has not been the case with the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. Because Colombia has pursued an ambitious economic agenda and international trade in the use of genetic resources for health research and the health industry, the government has supported local researchers and the herbal industry to the detriment of communities' rights.

That is why Chapter Six points out that, despite the fact that health research and the health industry is constructed in a market-oriented perspective, it would be possible to involve other aspects, such as social concerns. Chapter Six suggests that this could be achieved by including social concerns such as communities' rights in Colombian innovation policy. As a result, this chapter includes communities in Colombian innovation policy by making a normative claim through Sen's Capability Approach.

In particular, Chapter Six correlates Sen's economic analysis of countries' development with the problems highlighted in the thesis. This thesis points out that Colombia has failed to include the valuable contribution of communities in the use of biodiversity for the health industry and health research in its market-oriented innovation policy. As a result, Chapter Six makes a normative claim, arguing for sustainable innovation in health research and the health industry, and its articulation through a list of functionings: what local communities are capable of being and doing in the

context of health research. Sen's approach allows an analysis of the steps it takes to achieve a particular capability. Therefore, thinking about sustainable innovation in terms of capabilities aims to recognise practices and knowledge over biodiversity as a fundamental aspect for health research and the health industry in Colombia.

Finally, Chapter Seven discusses and accommodates the normative claim of capability for sustainable innovation and its list of functionings so as to propose amendments to Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. Thus, Chapter Seven aims to provide both a normatively grounded and a practical solution to the thesis' main research question: How should Colombia, a developing country rich in biodiversity, implement the International Regime on Access to Genetic Resources and Benefit Sharing to recognise the contribution from local, indigenous, and Afro-Colombian communities' practices and knowledge in adding value to the use of genetic resources for the health industry and health research? It does so by proposing legal amendments grounded in a normative claim supporting a Capability Approach to sustainable innovation in health research and the health industry. This capability is, in turn, formed by a list of three functionings, and thus the legal amendments suggested are analysed according to those functionings.

Chapter Two: A Review of the International Regime on Access to Genetic Resources and Benefit Sharing

Introduction

The drafting and wording of the International Regime on Access to Genetic Resources and Benefit Sharing, and its implementation in developing countries rich in biodiversity as well as its amendments, reveal how international law that was supposed to be about conservation and sustainable use of biodiversity became a more complex tale.

This is a tale that is still evolving as interdisciplinary scholarship uncovers further aspects that add to our understandings of a continually transformative international legal regime. As matter of fact, the UN Convention on Biological Diversity, which is the core treaty of the International Regime on Access to Genetic Resources and Benefit Sharing, was designed at a time in which the loss of biodiversity was already a major preoccupation for environmental non-governmental organizations (NGOs).³⁶ Their campaigning for the UN Convention on Biological Diversity focused on that preoccupation, but as the negotiations advanced in the drafting of the UN Convention on Biological Diversity, different issues emerged which revealed that the protection of the world's biodiversity was a rather more complex matter.

Since a great deal of the world's biodiversity is mainly located in the developing world, at the time the UN Convention on Biological Diversity was negotiated there was a sense that those who would have the stewardship of the world's environment would be its poorest countries. Far from protecting their resources in the somewhat simplistic model advanced by some NGOs, these countries were relying on natural non-renewable resources such as oil and gold

³⁶ For a full account of all actors that work in the drafting of the UN Convention on Biological Diversity see David Eugene Bell, 'The 1992 Convention on Biological Diversity: The Continuing Significance of US Objections at the Earth Summit' (1992) 26 *Geo. Wash. J. Int'l L. & Econ.* 479.

for their economic growth.³⁷ For the global north to ask the global south to eschew economic development to preserve global biodiversity was an unethical extension of the forces of colonialism that created the economic disparities in the first place.

Furthermore, the question of economic disparities *within* developing countries was also an important factor. The UN Convention on Biological Diversity negotiation was also a space to advocate for groups which had been long neglected by governments in developing countries, especially indigenous and local communities which have a deeply spiritual, social, and economic “dependence” on biodiversity.³⁸ The authors of the UN Convention on Biological Diversity tried to construct a cooperative treaty in which countries would embrace the conservation and sustainable use of biodiversity as a “common concern”³⁹ of mankind, as well as addressing local and indigenous communities’ concerns in environmental issues. Both conservation and sustainable use of biodiversity became two of the three objectives of the UN Convention on Biological Diversity.

However, in practice the UN Convention on Biological Diversity, and particularly its implementation, turned into something rather different than was originally planned. Developing countries sought to secure that they would not be dictated to on what measures on conservation and sustainability they should adopt, as that could slow their path to economic prosperity. As a result, the UN Convention on Biological Diversity also centred on securing sovereignty, ownership, and control of biodiversity by developing countries

³⁷ 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 consider conservation and sustainability in the exploitation of their biodiversity. This stewardship obligation is reflected in the UN Convention on Biological Diversity 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 UN Convention on Biological Diversity) as well as identifying and monitoring components of biological diversity (Article 7 of the UN Convention on Biological Diversity). For further discussion see: William NR Lucy and Catherine Mitchell, ‘Replacing Private Property: The Case for Stewardship’ (1996) 55 *The Cambridge Law Journal* 566. and Christopher Rodgers, ‘Property Rights, Land Use and the Rural Environment: A Case for Reform’ (2009) 26 *Land Use Policy* S134.

³⁸ See Paragraph 13th of the UN Convention on Biological Diversity.

³⁹ Paragraph 4th of the UN Convention on Biological Diversity.

rich in biodiversity.⁴⁰ Further, as new technologies (e.g. biotechnology), that make use of biological material to create new products and processes, consolidated and other stakeholders such as the pharmaceutical industry raised interest in those resources as an important source for drug development, developing countries rich in biodiversity seized the sovereignty issue as an opportunity to claim also sovereign control over genetic resources; hence, they were entitled not only to be asked beforehand to grant access to genetic resources, but also to secure benefit sharing from the use of those resources. The result was the establishment of a third objective in the UN Convention on Biological Diversity: access to genetic resources and sharing of benefits that arise from their utilization.

Since its inception, the provisions on access and benefit sharing of the UN Convention on Biological Diversity have been at the centre of discussion in the Conference of Parties, the executive body of the UN Convention on Biological Diversity. Although access and benefit sharing obligations are to be implemented by country members in the context of the Convention's other two objectives (conservation and sustainable use of biodiversity), those provisions have been amplified and clarified by the Bonn Guidelines and, consequently, the Nagoya Protocol. These three international instruments make up the International Regime on Access to Genetic Resources and Benefit Sharing. As is discussed in detail in this chapter, these provisions have also evolved over

⁴⁰ This is reflected in the negotiation process of the UN Convention on Biological Diversity as it can be observed how sovereignty gained relevance over other principles. The first draft established 18 principles including principles related to sustainability and conservation of biodiversity. The principle of sovereignty was presented through the final version. It was in the seventh negotiating session that the Chairman of the Intergovernmental Negotiating Committee circulated a reduced version of Article 3 based on the fifth revised draft (which only included sovereignty as a principle) with the aim of assisting the parts of the committee to reach an agreement; see Article 3 of the following drafts and European Patent Office on the negotiation process of the UN Convention on Biological Diversity: Intergovernmental Negotiating Committee for a Convention on Biological Diversity, 'Second Informal Note by the Chairman of the INC and the Executive Director of UNEP Regarding Possible Compromise Formulations for the Fifth Revised Draft Convention on Biological Diversity', *Fourth Session, UN Environment Programme, UNEP/Bio.Div/N5-INC. 3.4*, (1991); Intergovernmental Negotiating Committee for a Convention on Biological Diversity, 'Third Revised Draft Convention on Biological Diversity', *Fifth Session, UN Environment Programme, UNEP/Bio.Div/N5-INC. 3-2* (1991); Intergovernmental Negotiating Committee for a Convention on Biological Diversity, 'Fourth Revised Draft Convention on Biological Diversity', *Sixth Session, UN Environment Programme, UNEP/Bio.Div/N5-INC. 4-2*, (1991).

the years so as to embrace further economic, technical, social and political complexities.

In brief, the International Regime on Access to Genetic Resources and Benefit Sharing seeks to provide general provisions to countries on how to establish rules on access to genetic resources and traditional knowledge associated with genetic resources, how users should share benefits from the utilisation of genetic resources, and what mechanism of compliance countries shall take into account. This has led to discussions on how to implement those provisions and the consequences for research and industry, as well as indigenous communities. Equally, the International Regime on Access to Genetic Resources and Benefit Sharing has prompted a significant body of scholarly work on different issues, ranging from the balance of power among countries and economic development⁴¹ to matters of justice, ethics⁴², and the tensions arising from the protection of technologies that employ genetic resources with intellectual property rights, including patents, and how it is claimed that patent protection on products and processes derived from biodiversity promotes biopiracy.⁴³

⁴¹ On the balance of power and dynamics between the global South and global North in the making of the International Regime on Access to Genetic Resources and Benefit Sharing see: Sabrina 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; Kal Raustiala and David G Victor, 'The Regime Complex for Plant Genetic Resources' (2004) 58 *International Organization*; Laurence Helfer, 'Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 29 *Yale Journal of International Law*; Sam F Halabi, *Intellectual Property and the New International Economic Order : Oligopoly, Regulation, and Wealth Redistribution in the Global Knowledge Economy*.

⁴² On the different perspectives on what sort of ethical principles the International Regime on Access to Genetic Resources and Benefit Sharing is constructed upon see: Doris Schroeder and Balakrishna Pisupati, *Ethics, Justice and the Convention on Biological Diversity* (United Nations Environment Program 2010); Doris Schroeder and Julie Cook Lucas, *Benefit Sharing: From Biodiversity to Human Genetics* (Springer Science & Business Media 2013).

⁴³ Chapter One introduced this discussion by analysing the difficulties to conciliate, on one hand, a market-oriented perspective of protecting inventions derived from genetic resources through patents, and, on the other hand, the interest of developing countries rich in biodiversity in maintaining access control on genetic resources, and including other forms of knowledge production over genetic resources, particularly traditionally knowledge and practices from local and indigenous communities. Further information on the conflict between intellectual Property Rights and the International Regime on Access to Genetic Resources and Benefit Sharing see: Graham Dutfield, 'Sharing the Benefits of Biodiversity: Is There a Role for the Patent System?' (2002) 5 *The journal of world intellectual property* 899; Graham Dutfield, 'Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What's Left to Discuss?' [2015] *Sage Handbook of Intellectual Property*. London: Sage 649; Michael Blakeney, 'Proposals for the Disclosure of Origin of Genetic Resources in Patent

Since the International Regime on Access to Genetic Resources and Benefit Sharing encompasses different issues, this chapter aims to locate the scope of the thesis within the analysis of the main features of the International Regime on Access to Genetic Resources and Benefit Sharing, its implementation, and the academic critique. As observed in the introduction to the thesis, this thesis argues that – at least in Colombia – the contributions from local and indigenous communities in adding value to the use of biodiversity have not been properly acknowledged and effectively protected throughout the whole R&D process, and the commercialisation of products and services based upon biodiversity. The implementation of the International Regime on Access to Genetic Resources and Benefit Sharing is unbalanced towards both a model of innovation, i.e. it only recognises and protects a market oriented-R&D, and to promoting new economic sectors, such as the herbal industry.

Overall, Chapter Two provides both a legal analysis of international texts and a literature review of academic debates on the implementation of the provisions of International Regime on Access to Genetic Resources and Benefit Sharing, particularly, those which reveal the difficulties in regulating the different complexities behind the use of genetic resources, including the contribution of communities' practices and traditional knowledge associated with genetic resources for the health industry and health research.

This chapter underlines that the International Regime on Access to Genetic Resources and Benefit Sharing and its implementation is centralising the recognition of the role of communities in adding value to the use of biodiversity and establishing mechanisms of compliance towards *downstream* stages of research and development (R&D). It also discusses how the wording of the International Regime on Access to Genetic Resources and Benefit Sharing has been constructed to include specific industries such as the pharmaceutical and biotechnological industries, leaving outside its scope other sectors such as the herbal industry, which also employ not only genetic resources to elaborate and

Applications' [2005] Study for the World Intellectual Property Organization.; Efferth T and others, 'Biopiracy versus One-World Medicine–From Colonial Relicts to Global Collaborative Concepts' [2018] Phytomedicine

commercialise medicinal plants and phytomedicines, but also the knowledge and practices of communities. This chapter also points out that since the International Regime on Access to Genetic Resources and Benefit Sharing has raised so many different issues, it is difficult for a body of international law to regulate all complexities surrounding biodiversity. The chapter concludes that, as a result, despite the fact that the International Regime on Access to Genetic Resources and Benefit Sharing aims to tackle all those issues, in practice it has favoured a market-perspective in the use of biodiversity for health research and the health industry, limiting the recognition and protection of communities' practices and knowledge.

Chapter Two proceeds as follows. It first reviews the wording of the International Regime on Access to Genetic Resources and Benefit Sharing, pointing out the main features of this international framework. It particularly clarifies, distinguishes and contextualises the three objectives of the UN Convention on Biological Diversity: conservation, sustainable use of biodiversity, access to genetic resources and benefit sharing. Second, the chapter provides an overview of the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in developed and developing countries. This has led to a range of discussions among policy makers and academics, including how to acknowledge and protect contributions of indigenous communities in adding value to biodiversity which is subsequently deployed in health research and by the health industry. The third part of the Chapter discusses in detail how the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing has focused on *downstream* users, leaving intact upstream users, revealing that communities' contributions in the use of genetic resources for health research and the health industry are not properly acknowledged. This part also identifies that the implementation of this international law has focused on specific users of genetic resources, leaving other sectors, such as the herbal industry, outside of the scope of the obligations of access and benefit sharing.

The Wording of the International Regime on Access to Genetic Resources and Benefit Sharing: From the UN Convention on Biological Diversity to the Nagoya Protocol

As noted above, the UN Convention on Biological Diversity establishes three main objectives: (i) conservation, (ii) sustainable use of biodiversity, and (iii) access to genetic resources and benefit sharing. These objectives create obligations for developing countries rich in biodiversity and also for developed countries. 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. 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. This section analyses, establishes differences between, and contextualises the three objectives of the UN Convention on Biological Diversity, and the obligations that emanate from those objectives for developing countries rich in biodiversity and for developed countries.

Conservation, Sustainable use, Sovereignty, Developing Countries Rich in Biodiversity's Stewardship Role and Developed Countries' Obligations in the UN Convention on Biological Diversity

Article 1 of the UN Convention on Biological Diversity sets out its objectives: 'the conservation of biological diversity' (objective 1), 'the sustainable use of its components' (objective 2); 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' (objective 3).

The first two objectives of the UN Convention on Biological Diversity are based on a compromise of the interests of all relevant parties. Although this means that most developing countries rich in biodiversity have a stewardship obligation of conservation of biodiversity and sustainable use of its components, the UN Convention on Biological Diversity calls on other parties, especially developed countries, to cooperate with those efforts. But these aspects of the Convention are not designed in a way that creates legally binding measures. Conversely, the third objective of the UN Convention on Biological Diversity aims to create an actual obligation on those who access genetic resources (users), to share the benefits of the utilisation of those resources. This subsection of the Chapter explains the obligations of both developing countries rich in biodiversity and of developed countries that emanate from the first two objectives of the Convention (conservation and sustainable use). The next subsection explains the third objective: access to genetic resources and benefit sharing.

First, the obligations that derive from Article 1 for developing countries rich in biodiversity depart from the express recognition that developing countries rich in biodiversity have unfettered sovereignty over their own biodiversity and its components, including genetic resources. Indeed, the UN Convention on Biological Diversity recognises in Article 3 that the only principle of the UN Convention on Biological Diversity 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.

The UN Convention on Biological Diversity imposes a stewardship obligation on developing countries rich in biodiversity. Despite the UN Convention on Biological Diversity's recognition of sovereign rights over biodiversity, this treaty also creates obligations to protect biodiversity. Indeed, under the mandate of Article 6 of the UN Convention on Biological Diversity, 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 UN Convention on Biological Diversity, 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 for environmentally sound uses (Article 15). For instance, the Andean Community 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 region (Bolivia, Colombia, Ecuador and Peru) on the implementation of the UN Convention on Biological Diversity.⁴⁴

Article 26 of the UN Convention on Biological Diversity requires the parties to the Convention to provide further information via national reports on what measures and mechanisms they have taken to implement the Convention, and how they have advanced national or regional strategies for conservation and sustainability. These national reports are submitted before the Secretary of the UN Convention on Biological Diversity, the executive body of the UN Convention on Biological Diversity. The reports also feed to the Clearing-House Mechanism,⁴⁵ which provides a platform for the exchange of information on aspects related to the implementation of the UN Convention on Biological Diversity.

Second, with the exception of Australia and the United States, developed countries do not possess most of the world's biodiversity. Through their history of activities such as deforestation, agriculture, and industrialization,

⁴⁴ Decision 523 Regional Biodiversity Strategy for the Tropical Andean Countries as signed in Lima, Peru on July 17 2002

⁴⁵ The core of the Clearing House Mechanism 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 UN Convention on Biological Diversity. 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 UN Convention on Biological Diversity; for further information see The Conference of Parties of the UN Convention on Biological Diversity, 'X/15 Scientific and Technical Cooperation and the Clearing-House Mechanism', *UNEP/CBD/COP/DEC/X/15* (2010) <<https://www.cbd.int/doc/decisions/cop-10/cop-10-dec-15-en.pdf>> accessed July 30 2017.

they have nonetheless contributed to the deterioration of global biodiversity.⁴⁶ Because developed countries have contributed to the deterioration of the world's biodiversity, the UN Convention on Biological Diversity contemplates that those countries should also contribute to the global effort of protecting biodiversity via international cooperation.

The UN Convention on Biological Diversity provides different measures of cooperation and financial assistance to support developing countries rich in biodiversity in the implementation of the UN Convention on Biological Diversity. For example, Article 5 of the UN Convention on Biological Diversity requires parties to the Convention to cooperate through international organisations in the implementation of measures of the Convention, such as those described in Articles 7 to 10 of the Convention. For instance, since 1910 the British-based organisation CABI has led taxonomy initiatives in different countries, particularly former British colonies⁴⁷, which help us to understand the potential of world biodiversity in different areas such as drug discovery, tourism, and agriculture. The UN Convention on Biological Diversity is also leading the Global Taxonomy Initiative which has the support of organisations such as national museums and botanical gardens in developed countries and developing countries rich in biodiversity.⁴⁸

⁴⁶ Biodiversity Information System for Europe (BISE), 'Species' <<http://biodiversity.europa.eu/topics/species>> accessed August 4 2017; Timothy Swanson, 'Why Is There a Biodiversity Convention? The International Interest in Centralized Development Planning' (1999) 75 *International Affairs* 307.

⁴⁷ 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 making of the UN Convention on Biological Diversity see: Brian Groombridge, *Global Biodiversity: Status of the Earth's Living Resources* (Chapman & Hall 1992). Harriet Bulkeley and others, *Transnational Climate Change Governance* (Cambridge University Press 2014).

⁴⁸ 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. ⁴⁸ The UN Convention on Biological Diversity 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 The Global Taxonomy Initiative included organisations such as the Food and Agriculture Organization, 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/>

The UN Convention on Biological Diversity calls on developed countries to support the implementation of the Convention in developing countries rich in biodiversity by providing financial assistance (Articles 20 and 21) and technical and scientific cooperation (Article 18) such as the creation and implementation of the Clearing House Mechanism. Additionally, the UN Convention on Biological Diversity creates 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 UN Convention on Biological Diversity).

The Third Objective of the UN Convention on Biological Diversity: The Cornerstone of the International Regime on Access to Genetic Resources and Benefit Sharing

Technical cooperation has not been the only mechanism through which developing countries rich in biodiversity aim to comply with the obligations of conservation of biodiversity and sustainable use of its components. The third objective of the UN Convention on Biological Diversity, i.e. the sharing of the benefits that arise from the utilisation of genetic resources, gives to developing countries rich in biodiversity an entire legal framework to obtain benefits, including access to relevant technologies such as biotechnology.

Such a legal framework is mainly designed in Articles 2, 3, 8 (j) and 15 of the UN Convention on Biological Diversity, and, subsequently, amplified and clarified by the Bonn Guidelines and the Nagoya Protocol. These two legal instruments do not derogate from or amend the UN Convention on Biological Diversity; instead both clarify the Convention's wording. The Bonn Guidelines, however, are not a legally binding instrument, rather they are an international instrument that assists states and users of genetic resources to implement and comply with the UN Convention on Biological Diversity. However, the Nagoya Protocol is a legally binding instrument that creates obligations for states in the way that the UN Convention on Biological Diversity should be implemented at the national and regional level.

As countries implement those provisions, the ways in which they understand the terms contained therein, and the legal and administrative mechanisms used, form a key part of the legal and policy context surrounding the International Regime on Access to Genetic Resources and Benefit Sharing. Consequently, it is important to provide an explanation of those terms and their scope in order to facilitate, in the next section, the analysis of how countries have implemented them into their national legislation. The next subsection of the chapter considers those matters and 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 (prior informed consent and mutually agreed terms).

The Definition of Genetic Resources

The analysis of the definition of genetic resources in the International Regime on Access to Genetic Resources and Benefit Sharing allows us to understand the difficulty in regulating the complexities behind the use of biodiversity for research and industry. For instance, depending on how the term genetic resources is implemented by Members of the UN Convention on Biological Diversity, it defines whether or not specific uses given to genetic resources (chemical synthesis, sequencing of DNA, etc.) constitutes an access activity that is required to comply with the access and benefit sharing rules. Also, the arrival of new technologies such as gene editing and synthetic biology that relies more in the intangible aspects of genetic resources rather than the actual resource present technical and scientific challenges that could disrupt the definitions of the UN Convention on Biological Diversity. For those reasons, it is important to analyse in detail Article 2 of the UN Convention which defines genetic resources, and how the Bonn Guidelines and Nagoya Protocol have aimed to clarify and update the term.

Genetic Resources in the Wording of the Article 2 of the CBD

As discussed in the previous section, Article 1 of the UN Convention on Biological Diversity establishes three principles, of which two are related to

conservation and sustainable use of biological resources, and the third is related to access to genetic resources and sharing of the benefits that arise from the utilization of those resources. A key aspect to differentiate the objectives of Article 1 is precisely to differentiate the variety of terms that the International Regime on Access to Genetic Resources and Benefit Sharing creates regarding those objectives. For instance, there is the distinction between biological resources and genetic resources which emanates from Article 2 of the UN Convention on Biological Diversity. The former entails an obligation of conservation and sustainable use of biological resources. The latter is related to appropriate access to genetic materials.

Article 2 of the UN Convention on Biological Diversity 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 contain DNA and RNA such as seeds, cuttings, individual organisms, DNA extracted from plants, animals, or microorganisms. A biochemical extract, for instance, that does not contain any functional units of heredity is not considered to be genetic material.⁴⁹ ‘Potential or actual value’ is the element of the definition of genetic resources that helps to distinguish genetic resources from genetic material. Value here refers to ‘a use that can be ascribed or is likely’.⁵⁰

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 range from animals to genes and ecosystems and that have a value for humanity.⁵¹ However, as discussed above, biological resources mainly involve an obligation to conservation and sustainable use,⁵² which means that activities related to conservation and

⁴⁹ Lyle Glowka and others, *A Guide to the Convention on Biological Diversity* (IUCN, Bonn (Alemania) Environmental Law Centre IUCN, Gland (Suiza) Biodiversity Programme 1994).

⁵⁰ *ibid.*, pp 21-21

⁵¹ *ibid.*, p 16

⁵² For instance see Preamble, Articles 6, 7, 8, 10, 12(c) of the UN Convention on Biological Diversity.

sustainability are not required to comply with the access and benefit sharing rules.

Genetic Resources in the Bonn Guidelines and the Nagoya Protocol

The Bonn Guidelines and the Nagoya Protocol have helped to clarify the content of Article 2 by employing the term ‘derivative’ and a standard of utility. The use of these terms aims 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. The Bonn Guidelines do not extend the scope of the definition of genetic resources in Article 2 of the UN Convention on Biological Diversity, but suggest that derivatives and products that arise from the utilisation of genetic resources should be part of the negotiation of mutually agreed terms under the Convention.⁵³ Furthermore, the Bonn Guidelines also focus on the term ‘utilisation of genetic resources’ from Articles 1 and 15 of the UN Convention on Biological Diversity in order to focus on a standard of utility. As it focuses on a standard of utility, it is possible to extend the definition of genetic resources to any use given to those resources within particular users such as the biotechnological and pharmaceutical industries.⁵⁴

The Nagoya Protocol establishes two terms: ‘Utilisation of genetic resources’ and ‘derivative’ in Article 2 (c) and (e) respectively. The former focuses on the different uses or utilisation given to genetic resources, for instance, in R&D for drug development processes. The Nagoya Protocol’s definition of ‘utilisation of genetic resources’ aims to clarify the definition of genetic resources so as to include not only the actual or potential value of genetic material (with functional units of heredity), but also the uses given to genetic resources. There is no list of uses or technologies, which would have helped to exemplify the

⁵³ Morten Walløe Tvedt and Olivier Rukundo, ‘Functionality of an ABS Protocol’ (2010) 9 *Journal of World Intellectual Property* 189.

⁵⁴ See for instance Guidelines 8, 16 (b)(vi), 24, 41, 44 (1); n subsection 1.3 Chapter Four; for further analysis on the term ‘utilisation of genetic resources’ see Morten Walløe Tvedt and Tomme Young, *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD* (IUCN 2007).

scope of the term utilisation, because it was agreed within the negotiations that led to the Nagoya Protocol that an open-ended term would cover new uses and technologies that were not discussed there.⁵⁵ For instance, synthetic biology, a field which aims to apply engineering principles (e.g. standardization, decoupling, etc) to generate predictable outputs for different industries, is to believe to be included within the scope of the access and benefit sharing obligations. Bagley and Rai suggest that researchers who are in the field of synthetic biology are advised to inquire into the origin of the genetic material that they employ, so as to comply with access and benefit sharing obligations. Both authors also pointed out that, regarding the information of the genetic material, developing countries rich in biodiversity could assert that such information falls within the scope of the term in Article 2 of the UN Convention and the Nagoya Protocol.⁵⁶ This means that, by focusing on the utility criteria of access to genetic resources in a binding instrument, the Nagoya Protocol covers the different technologies (e.g. genetic modification and DNA synthesis or biochemical techniques) employed within particular sectors, including the pharmaceutical and biotechnology industries.⁵⁷

On derivatives,⁵⁸ the Nagoya Protocol 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 the Nagoya Protocol). The definition of derivative is extended, therefore, to biochemical compounds such

⁵⁵ Kabir Bavikatte and Brendan Tobin, ‘Cutting the Gordian Knot: Resolving Conflicts over the Term “Utilisation.”’ (2010) 4 *Biores*. For further information on negotiations regarding the term derivatives and utilisation see IISSD Reporting Service, ‘Summary of the Ninth Meeting of the Working Group on Access and Benefit Sharing of the Convention on Biological Diversity’ (2010) 9 *Earth Negotiation Bulletin* <<http://enb.iisd.org/download/pdf/enb09503e.pdf>>.

⁵⁶ Margo A Bagley and Arti K Rai, ‘The Nagoya Protocol and Synthetic Biology Research: A Look at the Potential Impacts’ (2014) 5 *Virginia Public Law and Legal Theory Research Paper*; Carlos Augusto Conde Gutiérrez, ‘Governing Synthetic Biology in the Light of the Access and Benefit Sharing Regulation (ABS)’ (2014) 41 *Law and the Human Genome Review* 63.

⁵⁷ Thomas Griebner and others, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing* (IUCN 2012).

⁵⁸ 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); 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).

as aromas, resins and biochemicals in cells employed in, for instance, pharmaceutical products.⁵⁹

As observed, the Nagoya Protocol has actually extended the scope of genetic resources of Article 2 of the UN Convention on Biological Diversity, so as to include uses and technologies that are employed upon genetic resources to develop products and process within well-established industries such as the pharmaceutical industry. This means that the International Regime on Access to Genetic Resources and Benefit Sharing has been discussed and written to include users which heavily rely on specific technologies (i.e. chemical synthesis or biotechnology). The Nagoya Protocol does so with the aim of securing transfer of technology from those industries to developing countries rich in biodiversity.⁶⁰

However, those definitions do not necessarily reflect all aspects and complexities that emerge in the development of products and processes for industries such as pharmaceuticals, and recent technological developments. In fact, Tvedt et al. point out the difficulties in governing the different circumstances in the development of products that derive from genetic resources, particularly in the relationship between those resources and final products.⁶¹ Tvedt et al. make a comparison in the drug development process between products “harvested from one genetic resource” and other pharmaceutical products that require a more complex R&D process.⁶² Tvedt takes two examples to make this comparison: (i) the Cyclosporine A3, employed in organ transplant, which is simply harvested from the fungal culture of the *Tolypocladium inflatum* (a species native to Norway) and (ii) complex R&D initiatives on enzymes, which might require optimising well known enzymes, looking for enzymes in libraries or searching for new enzymes

⁵⁹ Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* (Brill 2014). pp 59-71

⁶⁰ *ibid.* pp 59-71

⁶¹ Morten Walløe Tvedt and Peter Schei, ‘The Term Genetic Resources’ in Sebastian Oberthür and G Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, Taylor and Francis 2014).

⁶² Morten Walløe Tvedt, ‘The Missing Link in ABS The Relationship between Resource and Product.’ (2016) 46 *Environmental Policy & Law* 227. p 228

in bioprospecting projects to find a potential compound that could eventually become a pharmaceutical product. Obviously, this R&D initiative also requires laboratory-based genetic modification of one or different enzymes to obtain a final product.⁶³

In the context of Cyclosporine A₃, the relationship between genetic resources and the final product is easy to determine since it is only one genetic resource which immediately leads to one pharmaceutical product. In the example of the enzymes, however, the different possible combinations to reach one or different potential candidates create a difficulty to define from an early stage in the drug development process whether it is a singular genetic resource (or the combination of different ones) or solely the technology employed on those enzymes which leads to the final product. For Tvedt et al., the definitions of the UN Convention on Biological Diversity and, especially, the Nagoya Protocol on the concepts of derivative and utilization of genetic resources do not reflect how in a complex R&D initiative the shared benefits of the outcome of the research will take place.⁶⁴

Examples, such as that of the enzymes, of how difficult is to fit a combination of different techniques and genetic resources to reach a specific product into the definitions of the Nagoya Protocol can prove even more difficult with the coming of new techniques of gene editing, such as CRISPR-Cas9.⁶⁵ This is because those techniques could lead researchers to transfer digitally specific sequences of DNA, entire microorganisms or even genomes, and synthesize them into living organisms without access to the actual genetic material in a

⁶³ *ibid.*, p 229

⁶⁴ *ibid.*, p 232

⁶⁵ The way that this technique operates can be summarised as follows: a specific segment of DNA which can be removed or replaced, always using the same tools: a segment-guide that is a RNA with the copy of the DNA, which has to be identified (RNA guide), and a pair of scissors that is the protein Caspase 9 (Cas9) that cuts the specific segment of DNA, and separating the double helix from DNA to open its strands so that it can be edited. Further information see Natalia Lamprea and Oscar Lizarazo-Cortés, 'Tecnología CRISPR/CAS9 Presente y Futuro En Biotecnología, y Controversias de Sus Patentes' (*Boletín Departamento Propiedad Intelectual*, 2015) <<http://propintel.uexternado.edu.co/tecnologia-crisprcas9-presente-y-futuro-en-biotecnologia-y-controversias-de-sus-patentes/>> accessed 2 September 2015.

specific territory.⁶⁶ As a result, researchers will be able to digitally access genetic resources, combine and incorporate them into products or processes; meaning that they could circumvent any access to genetic resources and benefit sharing obligation, since they will not interact with any physical aspect of the actual country that, tracing back to the beginning of the process, provides those resources.

Further, if there is indigenous and local communities' traditional community knowledge or practices associated with genetic resources, it would become increasingly difficult to accommodate them in a complex R&D situation. This is even more problematic in the light of the International Regime on Access to Genetic Resources and Benefit Sharing, since none of the instruments that are part of it define traditional knowledge, or indigenous and local communities. Regarding the definition of traditional knowledge, Morgera et al. argue that since there is not an explicit definition of traditional knowledge, it is necessary to combine different elements of the International Regime on Access to Genetic Resources and Benefit Sharing.⁶⁷ According to that line of reasoning, traditional knowledge can be understood within the definition of "utilization of genetic resources". Therefore, traditional knowledge within the definition of Article 2 of the Nagoya Protocol would serve as "lead information for the utilization of genetic resources",⁶⁸ meaning that any uses given in different industries (e.g. biotechnology or pharmaceutical) to that *lead information* would fall within the definition of genetic resources. Yet, it remains open to interpretation what traditional knowledge is, especially as countries implement the Nagoya Protocol.

On the definition of what are indigenous and local communities, since none of the instruments of the International Regime on Access to Genetic Resources and Benefit Sharing gives a definition, it is necessary to bring to bear other international instruments to provide guidance. In the case of indigenous

⁶⁶ International Civil Society Working Group On Synthetic Biology, 'Synthetic Biology and the UN Convention on Biological Diversity' [2016] *ICSWGsb* <https://www.boell.de/sites/default/files/2016-11-icswgsb_synbio_brief_cop13_.pdf>.

⁶⁷Morgera, Tsioumani and Buck (n 59)., p 74

⁶⁸ *ibid.*

communities there is the Indigenous and Tribal People Convention of the International Labour Organization (1989), which provides subjective and objective criteria. The subjective aspect is a self-assessment, meaning people who consider themselves to be indigenous or tribal people. In the case of indigenous communities, the objective aspect applies to those who are descended from people who inhabited an specific region at a time of conquest or colonization. In the case of tribal communities, the objective aspect of the definition refers to those who have social, cultural and economic conditions, as well as costumes, laws or traditions that make them different from the large majority of the country, for example, Afro-descent communities. However, when it comes to local communities, the term is rather more difficult to define objectively since local communities are group of people that do not share a set of costumes or traditions that make them different from the majority. At the same time, however, they have one or more specific characteristics that distinguish them (e.g. ancestral relation, geographical location, socio-economic activities, etc.).⁶⁹ Since it is difficult to provide a general definition, it would depend on countries to define in a case-by-case approach whether we are confronting a local community, as mentioned by the International Regime on Access to Genetic Resources and Benefit Sharing.

Although, on the one hand, this lack of definitional clarity might make it even more difficult in practice to define what is a community, what role traditional knowledge and practices play in R&D activities, how communities should participate in them, and the use of techniques such as gene editing, on the other hand, the definitional flexibilities in the international regime give the opportunity to countries to define with more clarity the scope of the definition of genetic resources and the roles and entitlements of those who participate in the development of a product or process. The significance of this national flexibility, and of the distinction between ‘ethnic’ (indigenous and Afro-Colombian) and ‘local’ (peasant) communities, will be elaborated in subsequent chapters.

⁶⁹ *ibid.* pp 38-41

To summarise, there is little clarity on the definitions of the International Regime on Access to Genetic Resources and Benefit Sharing, since they have focused on including specific technologies and industries within the scope of genetic resources. The International Regime on Access to Genetic Resources and Benefit Sharing aims to secure that users which hold technologies to transform genetic resources into processes and products are obliged to share the benefits that arise from the utilization of those genetic resources. However, as analysed, it is difficult to encompass within the regime all possible and complex scenarios that emerge from R&D activities in genetic resources. This is even more problematic in situations in which traditional knowledge and practices might be involved, since the International Regime on Access to Genetic Resources and Benefit Sharing does not even define traditional knowledge and practices, nor the communities which deploy them. Yet, as countries implement those international obligations, they can potentially narrow down those concepts, either by establishing more precise definitions, or by reaching consensus with the different actors that participate in the use of genetic resources, including industries, researchers, and communities.

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

Articles 3 and 15(1) of the UN Convention on Biological Diversity give countries 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 UN Convention on Biological Diversity should consider when they implement the Convention into their national or regional legislation. These are (1) prior informed consent, including from indigenous and local communities; and (2) how to reach an agreement with developing countries rich in biodiversity. These agreements are called ‘mutually agreed terms’. They include among other things the type 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.⁷⁰ By contrast, the Nagoya Protocol extended the ownership, access, and control of developing countries rich in biodiversity beyond their borders. Articles 15 and 16 of the Nagoya Protocol calls on countries to adopt mechanisms of compliance to ensure that genetic resources and traditional knowledge and practices utilised within their territory have been lawfully accessed according to the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries rich in biodiversity.⁷¹

Prior Informed Consent

Article 15.5 of the UN Convention on Biological Diversity establishes that access to genetic resources should be subject to prior informed consent from the country that provides the genetic resources, unless members of the Convention provide otherwise. In order to respect state sovereignty, the Convention requires users of genetic resources to secure consent from countries before they can actually have access to those resources. This necessarily means that the UN Convention on Biological Diversity leaves countries to determine the legal procedures and requirements for consent to access genetic resources located in their own territory, as well as establishing a national authority that oversees the procedure.

Indigenous and Local Communities' Prior Informed Consent

Additionally, prior informed consent not only refers to countries, but potentially to indigenous and local communities, particularly on the issue of

⁷⁰ For more information on the implementation measures of UN Convention on Biological Diversity at the national and regional level see <https://www.cbd.int/information/parties.shtml>

⁷¹ Article 6.1 of the Nagoya Protocol limits the geographical scope of ABS to genetic resources that are from countries that regulate access. This means that genetic resources that are in *ex situ* collections should not require prior informed consent, for example. On the temporal scope, the Nagoya Protocol do not make any clarification of whether access to genetic resources before the entry into force of the protocol would be into the scope of the ABS Regulation, despite the fact that developing countries rich in biodiversity want to extend the scope of the protocol at least to those resources that were accessed after the UN Convention on Biological Diversity came into force. For further discussion on whether the temporal scope of the Nagoya Protocol and possible interpretation to include genetic resources accessed before the Nagoya Protocol see: Carlos Maria Correa, 'Implications for BioTrade of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization' (2011) <<http://www.unctad.org/biotrade>> accessed February 11 2019.

traditional knowledge associated with genetic resources. Local or indigenous communities employ genetic resources for different aspects of their lives and practices, such as healing or treating diseases. The ancient knowledge that those communities have over genetic resources increases the likelihood of others using that knowledge to find therapeutic properties of plants or animals, which facilitate the discovery of new biochemical compounds for drug development. However, the UN Convention on Biological Diversity only refers to indigenous and local communities in Article 8 (j) which calls on countries to respect, preserve and maintain traditional knowledge relevant for conservation and sustainability, and to involve indigenous and local communities in benefit sharing.

The Bonn Guidelines, as a non-binding instrument, recommend that countries should require users of genetic resources to disclose all the necessary information regarding those resources, including the source of genetic resources and whether the research is commercial or not.⁷² It also calls on users to require prior informed consent from communities.

The Nagoya Protocol demands that holders of traditional knowledge and practices, especially those associated with genetic resources, are to be considered as countries which grant access to users of genetic resources. In fact, while Article 8 (j) of the UN Convention on Biological Diversity only requires countries to respect, preserve, and protect traditional knowledge, as well as to involve their holders in benefit sharing, the UN Convention on Biological Diversity and Bonn Guidelines did not require countries to regulate any particular aspects of prior informed consent from local or indigenous communities. Article 7 of the Nagoya Protocol goes a step further by calling on countries to take measures to ensure that prior informed consent of indigenous and local communities is obtained when there is access to traditional knowledge associated with genetic resources.

⁷² Guidelines 11 (j) and 16 (c) (ii)

As the Nagoya Protocol goes into detail on what countries should “take into consideration” regarding traditional knowledge associated with genetic resources, it can be observed that the protocol aims to give further guidance on relevant aspects that parties to the protocol shall observe as they implement these measures such as local communities’ customary laws, community protocols and procedures (Article 12). Also, Article 22.3 of the Nagoya Protocol calls on countries to assess capacity to develop their own endogenous research, which demands countries must recognise communities’ contribution towards innovation.⁷³

The protocol does not, however, go as far as imposing on countries specific obligations of how prior informed consent from those communities should take place,⁷⁴ leaving countries enough legal room to freely implement Article 7 and 12 of the protocol appropriately in their national contexts.

Mutually Agreed Terms and Benefit Sharing

Mutually agreed terms are agreements (or contracts) that need to be reached by users of genetic resources and the designated national authority (Article 15.4 of the UN Convention on Biological Diversity). Mutually agreed terms 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 prior informed consent from a national authority. Reaching mutually agreed terms means that the users of the genetic resources have successfully obtained prior informed consent and benefit sharing. However, mutually agreed terms 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 mutually agreed terms a

⁷³ Harry Jonas, Kabir Bavikatte and Holly Shrumm, ‘Community Protocols and Access and Benefit Sharing’ (2010) 12 Research and Information System for Developing Countries.

⁷⁴ Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity* <<http://www.brill.com/2010-nagoya-protocol-access-and-benefit-sharing-perspective>> accessed July 28 2017., pp 217-218

particularly flexible mechanism in the negotiations for benefit sharing, as they follow the contractual rules and legislation of each country.⁷⁵

Finally, Articles 15 and 16 of the Nagoya Protocol call on countries, particularly developed ones, to adopt mechanisms of compliance to ensure genetic resources and traditional knowledge utilised within their territory have been lawfully accessed according to the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries rich in biodiversity. Therefore, Article 17 of the Nagoya Protocol 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 and traditional knowledge, prior informed consent, and mutually agreed terms, 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 Nagoya Protocol also adopted the Internationally Recognized Certificate of Compliance which can also be employed by the designated checkpoint. 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 mutually agreed terms issued (Articles 6.3 (e) and 17.2 of the Nagoya Protocol). The issuance of an Internationally Recognized Certificate of Compliance should be notified to the Clearing-House Mechanism of the UN Convention on Biological Diversity via national focal points.

So far, the chapter has analysed the wording and scope of the International Regime on Access to Genetic Resources and Benefit Sharing, which includes the UN Convention on Biological Diversity, the Bonn Guidelines, and the

⁷⁵ For further information on different mutually agreed terms rules and agreements in different national jurisdiction see Shakeel Bhatti and others, *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts*, vol 4 (IUCN 2009).

Nagoya Protocol. It has shown how the UN Convention on Biological Diversity's requirements and compliance mechanisms have evolved through the Bonn Guidelines and the Nagoya Protocol. The following section of the chapter takes a step further away from the literal wording of the UN Convention on Biological Diversity. It sets out the main discussions in academic literature on the International Regime on Access to Genetic Resources and Benefit Sharing, and its implementation in both developed countries and developing countries rich in biodiversity. In particular, the next section focuses on how practices and knowledge from indigenous and local communities have been considered as the International Regime on Access to Genetic Resources and Benefit Sharing has been implemented.

The Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing

The International Regime on Access to Genetic Resources and Benefit Sharing, and more specifically the UN Convention on Biological Diversity, was originally intended to be only a treaty about conservation and sustainability, as it was the result of the efforts, during the 1980s, of environmentalist campaigners and national parks to create an international instrument to reduce the extinction of species and deforestation.⁷⁶ Whereas conservation involves the mandate to protect ecosystems and natural habits of biological diversity and components of biological diversity which are collected in, for instance, botanical gardens, zoos, and universities, 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.⁷⁷ Both commitments involve a stewardship obligation, which demands economic limitations on the use of biodiversity for developing countries rich in biodiversity.

⁷⁶ Swanson (n 46). pp 326-327

⁷⁷ Under this mandate, the Conference of Parties, the executive body of the UN Convention on Biological Diversity, and the Secretary of the UN Convention on Biological Diversity have worked on how to identify and achieve sustainability in the context of biological diversity through workshops, meetings and decisions, in order to implement principles and operational guidelines, (e.g. the Addis Ababa Principles and Guidelines of 2007) which establishes a set of 14 practical principles to accomplish sustainable use; yet these instruments are not binding

As an alternative, bioprospecting was presented as a model of doing business which did not run counter to environmental commitments. In particular, scientists such as Eisner pointed out that the importance of conservation and sustainability was not only about environmental protection and prevention of the loss of biodiversity, but also about the fact that biodiversity could permit different industries (e.g. chemical and pharmaceutical) to collect and identify new chemical and biological compounds for drug production based on genetic resources (i.e. bioprospecting).⁷⁸ In exchange, developing countries rich in biodiversity would claim a share of the benefits that arise from the commercialisation of inventions based upon genetic resources located in their territory as a mechanism of compensation.

Consequently, developing countries rich in biodiversity enthusiastically endorsed the promises of a compensatory approach, linking conservation and sustainability with access to genetic resources and benefit sharing. An earlier example of this approach was the first deal between Costa Rica's National Biodiversity Institute (INBio – Spanish acronym) and the US pharmaceutical company Merck. This agreement included that this biodiversity-rich country allowed access to their genetic resources to Merck in exchange for training, scientific infrastructure, and payment of royalties by Merck.⁷⁹ The compensatory mechanism of benefit sharing also provided reassurance to developing countries rich in biodiversity as they could effectively assert property rights over genetic resources located within their territory by granting or denying access to those resources.

⁷⁸ For further information on bioprospecting see Thomas Eisner and Elizabeth A Beiring, 'Biotic Exploration Fund: Protecting Biodiversity Through Chemical Prospecting' (1994) 44 *BioScience* 95; Thomas Eisner and Jerrold Meinwald, 'The Göteborg Resolution' (1990) 1 *CHEMOECOLOGY* 38; Thomas A Kursar and others, 'Securing Economic Benefits and Promoting Conservation through Bioprospecting' (2006) 56 *BioScience* 1005.

⁷⁹ Carmen Richerzhagen and Karin Holm-Mueller, 'The Effectiveness of Access and Benefit Sharing in Costa Rica: Implications for National and International Regimes' (2005) 53 *Ecological Economics* 445. (providing an effectiveness analysis of bioprospecting initiatives in Costa Rica and arguing that the public value of biodiversity is not assessable, although private investment is)

This approach aimed to end the discussion over the legal status of genetic resources as developed countries had campaigned to adopt “common heritage” as the legal status for genetic resources.⁸⁰ If common heritage had been adopted by the UN Convention on Biological Diversity, then genetic resources would have been freely accessible. The position of developing countries rich in biodiversity on the legal status of genetic resources was the polar opposite of common heritage: They claimed sovereignty over genetic resources. This position reflected the economic and political stand that most developing countries rich in biodiversity had already taken over the sovereignty of their natural resources such as oil, gold, etc. after the second half of the twentieth century.⁸¹

Yet, this view of compensating developing countries rich in biodiversity for the use of genetic resources for industrial application was constantly challenged for two main reasons. First, bioprospecting projects and activities, including Costa Rica’s INBio, did not deliver the promises of benefit sharing, as there had not been any significant commercial breakthrough.⁸² Second, biodiversity is not the only source for the development of new products and processes. In fact, the pharmaceutical industry has relied on synthetic products or compounds collected and deposited in their own libraries a long time ago. For instance, Telavancin (marketed under the name of Vibativ to treat infections)

⁸⁰ Common heritage has been employed in international law when has been difficult or inconvenient to allocate ownership, particularly the seabed. The use of this term was important for developed countries after the middle of the twentieth century as their economies relied on natural resources allocated outside of their jurisdiction; but, biodiversity-rich countries have watered down this term as they consider that the use of Common Heritage could dismiss ownership of natural resources (such as oil and gold) that could belong to these countries; for further information see: Christopher C Joyner, ‘Legal Implications of the Concept of the Common Heritage of Mankind’ [1986] *International and Comparative Law Quarterly* 190; Bradley Larschan and Bonnie C Brennan, ‘Common Heritage of Mankind Principle in International Law’ (1982) 21 *Colum. J. Transnat’l L.* 305.

⁸¹ Biodiversity-rich countries have been campaigning to include sovereignty before the UN Convention on Biological Diversity was enacted, but in natural resources such as oil and minerals rather than genetic resources. Indeed, the UN in 1962 decided through a General Assembly resolution that control and access to natural resources should be understood under the principle of sovereignty; individual States decided under which conditions it would be possible to have access to natural resources. Sovereignty aimed to satisfy the interests of biodiversity-rich countries (most of which had just declared independence from colonial empires at the time the resolution was issued) in the control of natural resources; See Paragraphs 4 and 5 of Preamble to the UN–General Assembly Resolution 1803 (XVII) 14 Dec 1962 *Permanent Sovereignty over natural resources*

⁸² Rex Dalton, ‘Natural Resources: Bioprospects Less than Golden’ (2004) 429 *Nature* 598.

is a derivative of Vancomycin and was launched on the US market in 2009,⁸³ yet Vancomycin was isolated for the first time in 1953.⁸⁴ Both aspects illustrate that the promises of benefit sharing throughout bioprospecting remain distant, since the use of biodiversity is not as indispensable for industries such as the pharmaceutical industry as Eisner imagined, before the UN Convention on Biological Diversity was agreed.

However, supporters of bioprospecting still campaign to make biodiversity an important source for the industry, as the development of new tools and technologies in recent years could unleash the hidden commercial potential of biodiversity. For instance, 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 1980-2010.⁸⁵ 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.⁸⁶ Indeed, 16% of those formally synthetic molecules contain ‘pharmaphores⁸⁷ 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’.⁸⁸ This means that only 36% of the 1,073 molecules were purely synthetic or free from any natural inspiration. Oldham et al.’s paper on patent activity on biodiversity also 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.⁸⁹ Nevertheless, as molecular biology tools have become faster and cheaper, research centres such as the National

⁸³ USA Food and Drug Administration, ‘FDA Approves Vibativ for Hospitalized Patients with Bacterial Pneumonia’ (FDA website, 2013) <<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358209.htm>> accessed November 23 2014

⁸⁴ Donald P Levine, ‘Vancomycin: A History’ (2006) 42 *Clinical Infectious Diseases* S5.

⁸⁵ Gordon M Cragg and others, ‘The Impact of the United Nations Convention on Biological Diversity on Natural Products Research’ (2012) 29 *Natural product reports* 1407; David J Newman and Gordon M Cragg, ‘Natural Products as Sources of New Drugs from 1981 to 2014’ (2016) 79 *Journal of Natural Products* 629.

⁸⁶ Cragg and others (n 85), p 1408

⁸⁷ Pharmaphore refers to a part of a molecular structure that is responsible for a particular biological or pharmacological interaction that it undergoes

⁸⁸ Cragg and others (n 85), p 1408

⁸⁹ Paul Oldham, Stephen Hall and Oscar Forero, ‘Biological Diversity in the Patent System’ (2013) 8 *PLOS ONE* 1.

Institute of Cancer in the US have maintained interests in carrying out bioprospecting projects in areas rich in biodiversity such as Panama (e.g. the Panama International Cooperative Biodiversity Group).⁹⁰ De Luca et al. also highlight that, despite the fact that pharmaceutical companies have lost interest in genetic resources because of 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.⁹¹ These developments could lead to the creation of new medicines or improvement of existing ones based upon developing countries' biodiversity.⁹² However, the promises of materialising the Convention on BioDiversity's benefit-sharing through bioprospecting remain elusive, as there have been no products or processes derived from genetic resources with any market yet.

Balance of Power among Countries and Intellectual Property in the International Regime on Access to Genetic Resources and Benefit Sharing

Biodiversity has not only been subscribed to the expectation of obtaining benefit sharing and market success, but has also been employed to balance the power relations between developed and developing countries in different forums. Authors such as Helfer,⁹³ Safrin,⁹⁴ Raustalia, and Victor,⁹⁵ have pointed out that the International Regime on Access to Genetic Resources and Benefit Sharing sought to offset the imbalances that have occurred in forums such as TRIPs in the WTO, in which developing countries accepted higher standards of intellectual property rights protection, including patents in inventions related to biological resources, so they could have access to developed countries' markets.

⁹⁰Kursar and others (n 78)., pp 1007-1010

⁹¹ Vincenzo De Luca and others, 'Mining the Biodiversity of Plants: A Revolution in the Making' (2012) 336 Science 1658 LP.

⁹² *ibid.*, p 1661

⁹³ Helfer (n 41).

⁹⁴ Safrin (n 41).

⁹⁵ Raustiala and Victor (n 41).

Also, the International Regime on Access to Genetic Resources and Benefit Sharing was employed as a form of recalibrating the relationship between developing and developed countries in the World Intellectual Property Organization (WIPO).⁹⁶ In fact, developing countries have managed to discuss access and benefit sharing-related provisions since Colombia, supported by the Andean Community of Nations and other developing countries, presented in 1999 a submission before the Standing Committee on Patents⁹⁷ which proposed that patent procedure for members of WIPO should guarantee protection of countries' biological and genetic resources by requiring that if a patent application was related to genetic resources, the applicant should demonstrate that those resources were acquired legally.⁹⁸ Albeit, the Colombian 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 of genetic resources and patents.⁹⁹ Colombia removed the submission on the condition that WIPO would create an international committee to discuss this issue, and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore was duly established.¹⁰⁰ In 2001, the committee began negotiations for the creation of an international instrument related to intellectual property rights and access to genetic resources.¹⁰¹ The negotiations ended in 2013 with a draft of a 'consolidated document'.¹⁰² Despite the fact that some progress was made in the consolidated document, parties have not reached any compromise in key and basic aspects, such as definition of genetic resources, biopiracy, and

⁹⁶ 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; 3

⁹⁷ 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

⁹⁸ Proposal by the Delegation of Colombia, *Protection of Biological and Genetic Resources* (WIPO, SCP/3/10, 1999)

⁹⁹ David Vivas-Eugui, 'Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)' [2012] ICTSD's Programme on Innovation, Technology and Intellectual Property (34). Geneva, Switzerland: International Centre for Trade and Sustainable Development. quino.org.

¹⁰⁰ Standing Committee of Patents, *Report of the Third Session* (WIPO SCP/3/11, 1999)

¹⁰¹ IGC, *Report of First Season* (WIPO/GRTKF/IC/1/13, 2001)

¹⁰² IGC, *Consolidated Document Relating to Intellectual Property Rights and Genetic Resources* (Facilitators' draft, WIPO, Rev 2, 2013)

misappropriation. Furthermore, the General Assembly of WIPO, the executive body of this organization, has made no substantial decision to advance in the implementation of an international treaty that counterbalances those relations of power.¹⁰³ Similarly, the World Trade Organisation (WTO) has reported no significant advance in the discussions related to the use of biodiversity by different industries.¹⁰⁴

The Problematic Aspect of Finding a Solution to the Issues of Biopiracy and Compliance of the International Regime on Access to Genetic Resources and Benefit Sharing

Although there is an apparent failure to offset the historical imbalance created by trade and intellectual property rights in other forums, the International Regime on Access to Genetic Resources and Benefit Sharing has also served as a platform to mobilise different actors which have been neglected or ignored. From farmers to non-governmental organizations and campaigners for open access, since the 1990s forums such as the International Regime on Access to Genetic Resources and Benefit Sharing have served as a platform to raise issues of injustice towards populations whose customs, tradition, or protocols do not adjust readily to the logics of markets and the balancing of international power among countries. In particular, a significant number of scholars have denounced in specific cases how the developed world has abusively appropriated knowledge and practices from local and indigenous communities because it does not fit within the model of production and appropriation of information supported by intellectual property rights. For instance, the University of Mississippi obtained a patent in 1995 for ‘Use of Turmeric in Wound Healing’, despite the fact that turmeric powder had been traditionally used for healing purposes by different generations of local communities in India.¹⁰⁵ Equally, neem or *Azadirachta indica* is a plant that has been

¹⁰³ WIPO, *Adoption of the General Report and of the Individual Report of each Governing Body* (A/54/13, 2015)

¹⁰⁴ WTO, ‘Reviews, Article 27.3b, Traditional Knowledge, Biodiversity - Background’ (WTO, 2019) <https://www.wto.org/English/tratop_e/trips_e/art27_3b_background_e.htm> accessed March 6 2019

¹⁰⁵ This is an emblematic case not only because a US research institute aimed to obtain patent exclusivity over a well-known therapeutic activity of a plant, but also because the case led to mobilise social activists, Indian authorities and communities to file oppositions in developed countries’ patent offices in order to have the patent dismissed. Such efforts led to the US Patent and Trademark Office to revoke the patent. For further information see R. Gupta and L. Balasubrahmanyam, ‘The Turmeric Effect’ (1998) 20 *World Patent Information* 185. Also, this

employed for more than 200 years by Indian local communities for different uses (pesticides, fungicides, etc.).¹⁰⁶ Yet its antimycotic agent has been patented in both the US and the Europe for the treatment of fungal infections.¹⁰⁷

These cases of biopiracy brought international condemnation and raised the question of how other forms of knowledge associated with the use of biodiversity were significantly diminished by the market-oriented perspective of intellectual property rights. For instance, authors such Shiva and Stenton put the blame for those cases upon the international standardization of intellectual property rights in the WTO-TRIPs, since it represents a new form of colonialism and biopiracy that threatens the rights of indigenous communities.¹⁰⁸ There has also been a significant amount of scholarly work on the bioethical implications of traditional knowledge for R&D in genetic resources.¹⁰⁹ As a result, there have been different proposals to avoid situations in which practices and knowledge of indigenous and local communities can be unlawfully or unethically appropriated.

More significantly, there are proposals seeking to solve the problem of compliance with intellectual property rights, in which disclosure of origin has

case added to the discussion on whether the patent system and traditional knowledge could coexist see: Claudia Finetti, 'Traditional Knowledge and the Patent System: Two Worlds Apart?' (2011) 33 World Patent Information 58; Shubha Ghosh, *The Implementation of Exhaustion Policies Lessons from National Experiences* (ICTSD Programme on Innovation, Technology and Intellectual Property 2013); Michael A Gollin, 'Biopiracy: The Legal Perspective' (2007) 2007 Policy Brief Series 1.

¹⁰⁶ Further information on the neem case see: Graham Dutfield, 'Biopiracy', *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Routledge 2010); Cormac Sheridan, 'EPO Neem Patent Revocation Revives Biopiracy Debate'; Kari Moyer-Henry, 'Patenting Neem and Hoodia: Conflicting Decisions Issued by the Opposition Board of the European Patent Office' (2008) 27 Biotechnology Law Report 1.

¹⁰⁷ EPO Patent Application, EP1945237 Use of Extracts of Myrtle and Other Mediterranean Agent Towards Yeast and Yeast-Like Microorganism; USPTO Patent, US20110091555A1, Use of a hydrophilic matrix comprising a polyacrylic acid derivative, a cellulose ether and a disintegrate in the manufacture of a medicament for treating female genital disorders

¹⁰⁸ Vandana Shiva, *Biopiracy: The Plunder of Nature and Knowledge* (South End Press 1997); Gavin Stenton, 'Biopiracy within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Prices Can Be Towards Countries of the South' (2004) 26 European Intellectual Property Review 17.

¹⁰⁹ See for instance: Schroeder and Lucas (n 42); Schroeder and Pisupati (n 42); Michiel Korthals and Bram De Jonge, 'Two Different Ethical Notions of Benefit Sharing of Genetic Resources and Their Implications for Global Development' (2009) 28 New Genetics and Society 87; Bram De Jonge and Michiel Korthals, 'Vicissitudes of Benefit Sharing of Crop Genetic Resources: Downstream and Upstream' (2006) 6 Developing World Bioethics.

been prominently analysed.¹¹⁰ 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 members of the Andean Community demands that 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 rules of the International Regime on Access to Genetic Resources and Benefit Sharing. In this way, a link between patent requirements and the regulation of access to genetic resources and benefit sharing of the International Regime on Access to Genetic Resources and Benefit Sharing could serve as a mechanism of compliance.

However, there is no international unified position on disclosure of origin, making it difficult to create a practical and effective mechanism of compliance. In fact, despite the fact 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 European Biotech Directive¹¹¹ 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’. As a result, disclosure of

¹¹⁰ 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 UN Convention on Biological Diversity in 1995; see The Conference of Parties of the UN Convention on Biological Diversity, ‘REuropean Patent Officert of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity’, *UNEP/CBD/COP/2/19, 1995* (COP 1995). For discussions carried out by the Conference of Parties of the UN Convention on Biological Diversity in this issue see: The Conference of Parties of the UN Convention on Biological Diversity, ‘The Convention on Biological Diversity and the Agreement Related Intellectual property rights (TRIPs): Relationships and Synergies’, (*UNEP/CBD/COP/3/23, 1996*) (COP 1996).; see also Frédéric Hendrickx, Veit Koester and Christian Prip, ‘Access to Genetic Resources: A Legal Analysis’ in Vicente Sánchez and Calestous Juma (eds), *Biodiplomacy: Genetic Resources and International Relations* (ACTS Press 1994); Madhav Gadgil and Preston Devasia, ‘Intellectual property rights and Biological Resources: Specifying Geographical Origins and Prior Knowledge of Uses’ (1995) 69 *Current Science* 637.; for a different analysis of different disclosure of origin proposals Blakeney (n 43); Dutfield, ‘Sharing the Benefits of Biodiversity: Is There a Role for the Patent System?’ (n 43).

¹¹¹ Directive 98/44/EC of the European Parliament and of the Council of July 6 1998 on the legal protection of biotechnological inventions

origin has triggered disagreements on how to implement the directive and whether it is effective in protecting developing countries rich in biodiversity and communities within those countries against misappropriation.¹¹² For instance, the issue has been the subject of conflict in the WTO's 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, specifically intellectual property rights of the pharmaceutical and biotechnological industries.¹¹³

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.¹¹⁴ 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 International Regime on Access to Genetic Resources and Benefit Sharing, but also a way to improve credibility and trust between developing countries rich in biodiversity and patent holders.¹¹⁵

¹¹² The controversy lies in whether Recital 27 of the Biotech Directive indicate an obligation to EU Members to adopt disclosure of origin in patents. As the European Court of Justice 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. *Netherlands v Parliament and Council Case-377/98* (1998) 1 7149.

¹¹³ 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*, (WTO 1996).; Regarding the discussion on disclosure of origin in the WIPO, it was Switzerland that proposed to include disclosure of origin in the Patent Cooperation Treaty (PCT), (1970, Washington, as in force from April 1, 2000) which is a WIPO treaty. In the PCT, a patent applicant can fill one international patent application, and simultaneously seek patent protection in one of the 152 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. However, this proposal did not materialise. See: Working Group on Reform of the PCT, 'Proposal Submitted by Switzerland. Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications' (2007).

¹¹⁴ Joseph Straus, 'How to Break the Deadlock Preventing a Fair and Rational Use of Biodiversity' (2008) 11 *The Journal of World Intellectual Property* 229.

¹¹⁵ Carlos Maria Correa, 'Establishing a Disclosure of Origin Obligation in the TRIPs Agreement' (2003) 12 *Occasional paper*; Nuno Pires De Carvalho, 'Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPs Agreement: The Problem and the Solution' (2000) 2 *Wash. UJL & Pol'y* 371; Jon Santamauro, 'Reducing the Rhetoric: Reconsidering the Relationship of the TRIPs

As a result, the disclosure of origin centred much of the discussion on biopiracy on the holders of the technology that could transform genetic resources and traditional knowledge into products and process. However, disclosure of origin is a mechanism which patent offices have not effectively used since they normally carry out patent examination with scientific and technical information, but do not cross-check patent applications against practices and knowledge from local and indigenous communities. This is because of the difficulty of documenting traditional knowledge, since indigenous and local communities have passed on this knowledge orally rather than through written forms of patents or scientific journals. The latter are the information that patent offices normally employ to examine patent requirements.

The deficiency of disclosure of origin as a compliance mechanism has led to other proposals which aim to overcome some of the difficulties in cross checking communities' practices and knowledge within patent examination processes. Such proposals aim to provide defensive measures against misappropriation within the patent system rather than imposing new requirements such as disclosure of origin. For instance, there is the Indian Traditional Knowledge Digital Library that seeks to document through internet databases traditional knowledge with the aim that patent offices and courts decline patent protection to inventions on the basis that the invention does not fulfil the patent requirement of novelty and non-obviousness.¹¹⁶ A relatively rare example of success of such approaches, the Indian Traditional Knowledge Digital Library's efforts led the patent application on neem to be withdrawn in 2012 after evidence of prior art was disclosed before the European Patent Office. But the US patent remains standing.¹¹⁷

Agreement, UN Convention on Biological Diversity and Proposed New Patent Disclosure Requirements Relating to Genetic Resources and Traditional Knowledge' (2007) 29 European Intellectual Property Review 91.

¹¹⁶ See website: <http://www.tkdil.res.in/>; for further discussion see: Jean-Paul Gaudillière, 'An Indian Path to Biocapital? The Traditional Knowledge Digital Library, Drug Patents, and the Reformulation Regime of Contemporary Ayurveda' (2014) 8 East Asian Science, Technology and Society 391.

¹¹⁷ Stefano De Luigi Brushchi and Federico Mailland, 'Use of a Hydrophilic Matrix Comprising a Polyacrylic Acid Derivative, a Cellulose Ether and a Disintegrant in the Manufacture of a Medicament for Treating Female Genital Disorders.' <<https://patents.google.com/patent/US20110091555/en>> accessed July 11 2018.

A clear problem with such an approach is that would automatically place knowledge and practices from indigenous communities into the public domain, limiting the practical ability of communities to prevent their knowledge from being appropriated. Yet, there are systems which seek to address those concerns by entitling communities to have a more profound role in deciding the fate of their knowledge. For instance, the Peruvian Collective Knowledge Protection Regime creates a national database for traditional knowledge associated with genetic resources, in which local and indigenous communities decide whether to include their knowledge in the database, how much they want to share, and with who they want to share it.¹¹⁸ The Peruvian approach secures that communities decides whether their practices and knowledge would go into the public domain so as to be employed, for instance, as a defensive mechanism in patent prosecution, or shared with users to develop new products and process. Furthermore, this protection regime also establishes “licenses” for users who want to access those resources.

However, the implementation of databases such as the Peruvian Collective Knowledge Protection Regime to protect communities’ practices and knowledge could clash with the interests of populations in need. For instance, at least hypothetically, if a community does not want to share a potentially life-saving medicinal plant, it would deny patients, for instance, in developing countries to access those medicines. Although such an eventuality has not emerged yet, the Nagoya Protocol, Article 8 calls on parties to pay due consideration to situations such as lack of access to medicines as they enforce access and benefit sharing rules. This obligation could include easing the rules of secrecy in databases. Nonetheless, it would depend on each country to decide the way that they will pay due consideration to those situations.

In a similar line of enquiry, Dutfield has also indicated that courts and patent offices in developed countries have already taken into account traditional

¹¹⁸ Ley que Establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos (Ley 27811 de 2012)

knowledge to deny or revoke patent protection on genetic resources.¹¹⁹ For instance, Dutfield points out that Lord Hoffman, from the then¹²⁰ 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’.¹²¹ Another important example that Dutfield 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.¹²² Both examples indicate that there are patent examiners and courts in developed countries that consider relevant traditional knowledge associated with genetic resources in order to dismiss the novelty or non-obviousness of a patent, regardless of such information not having been presented in scientific or technical terms.

But those defensive mechanisms rather seek to fit traditional knowledge within the patent system, which, as mentioned above, is intrinsically a form of protection that follows a market-oriented perspective. Drahos and Frankel also find that difficulties in accommodating this knowledge in patent systems are not exclusively connected with the difficulty of documenting the relevant practices and knowledge, but that there are substantial aspects of the innovation process in communities that are different from what patents protect.¹²³ The authors find that innovations in those communities are intrinsically interconnected with the land that those communities inhabit, their cosmology, and the diffusion of such information does not depend on the expiration of a patent term. This can be reflected in cases such as the San

¹¹⁹ Graham Dutfield, ‘A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy’ (2011) 33 EIPR.

¹²⁰ Now the Supreme Court of the UK.

¹²¹ *Merrell Dow Pharmaceuticals Inc v. HN Norton & Co Ltd* [1996] R.P.C. 76 (HL)

¹²² Dutfield, ‘A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy’ (n 119). see also *Board of Patent Appeals and Interferences of USPTO, Ex Parte Pfizer, Inc.*

¹²³ Peter Drahos and Susy Frankel, ‘Indigenous Peoples’ Innovation and Intellectual Property: The Issues’ in Peter Drahos and Susy Frankel (eds), *Indigenous Peoples’ Innovation* (ANU Press 2012).

people and Hoodia plant. This case involves the Council for Scientific and Industrial Research (CSIR), a South African research institute, which carried out research on hoodia, a medicinal plant employed by the San people in staving off hunger. The CSIR obtained a patent for the hoodia and eventually reached an agreement with Pfizer for the possible commercialisation of the patented product. 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.¹²⁴ After intensive pressure and negotiations, the CSIR agreed to recompense the San people with monetary benefits. Although the deal was deemed an important breakthrough, as it was the first of its kind, authors such as Wynberg consider that the final agreement did not provide appropriate benefits to the San people because the CSIR exclusively owned the patent and the indigenous communities would receive only a percentage of the royalties.¹²⁵

The Complexities and “Messiness” behind the Use of Biodiversity

Another important concern in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing is the sociological impact of using western values to pay off local communities for the use of their genetic resources, as they might have a more communal and non-economic interest in the use of those genetic resources.

¹²⁴ 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. See also: Evanson Chege Kamau, ‘Common Pools of Traditional Knowledge and Related Genetic Resources: A Case Study of San-Hoodia’ in Evanson Chege Kamau and Gerd Winter (eds), *Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law*. (Taylor and Francis 2013).

¹²⁵ Rachel Wynberg, ‘Rhetoric, Realism and Benefit-sharing’ (2004) 7 *The Journal of World Intellectual Property* 851.

Since there are so many different concerns regarding communities' practices and knowledge associated with genetic resources, there has also been interdisciplinary scholarship that aims to identify what is missing in the International Regime on Access to Genetic Resources and Benefit Sharing. This is extensively reflected in the work of Hayden, who finds that there is a prominent market-oriented perspective in the way that the International Regime on Access to Genetic Resources and Benefit Sharing has been underpinned by bioprospecting. As Hayden takes as a case study the partnership between the International Cooperative Biodiversity Project (ICGB), an US-based initiative, and the *Universidad Nacional Autonoma de Mexico* (UNAM), a local user of Mexican genetic resources, she discloses that the role of local researchers in R&D is to establish the plausible "leads" of pharmaceutical activity in medicinal plants. In turn, those users secure mutually agreed terms with holders of knowledge associated with the use of those medicinal plants. As soon as those leads are established, and mutually agreed terms are signed up, the UNAM send what they have collected to US partners of the ICGB to carry out R&D in labs upon those "leads" with the aim to transform them into products and processes for the pharmaceutical industry. Through this R&D process, as genetic resource went towards upstream stages, what holders of knowledge contributed to R&D is blurred through different aspects in the drug development process which include issues such as use of different techniques on those genetic resources, confidentiality in the information collected, filing of patents, and potentiality to transform those genetic resources into products and processes.

As a result, Hayden concludes that benefit sharing in bioprospecting leaves intact the upstream stages of R&D, because it singularises the role of holders of knowledge by making local researchers such as the UNAM establish "leads" and negotiating mutually agreed terms in order to separate the contribution of holders of knowledge as medicinal plants make their way through bioprospecting partnerships. That is why Hayden considers that the role of local researchers is that of brokers between upstream users of genetic

resources and local and indigenous communities.¹²⁶ Furthermore, the author employs an ethnographic approach to claim that local and indigenous communities' knowledge and practices on medicinal plants is not the only aspect that should be considered in bioprospecting.

Through her ethnographic methodology, which includes interviews, history, and socio-economic analysis, Hayden provides an inclusive and critical scrutiny that identifies who else is behind those "leads", i.e. a complex network of actors that goes from indigenous communities, road travellers, mine workers, wholesalers of plants, peasants or *campesinos*, urban markets which create, acquire, develop, sell, and share the knowledge on medicinal plants.¹²⁷ Such analysis led Hayden to criticise how the International Regime on Access to Genetic Resources and Benefit Sharing and its implementation in developing countries rich in biodiversity do not explain all those complexities behind bioprospecting. In fact, Hayden's analysis permits us to point out that those who are in downstream stages are centralising the compliance of the International Regime on Access to Genetic Resources and Benefit Sharing so as to benefit upstream stakeholders such as ICGB. With a similar perspective, Osseo-Asare highlights how six African medicinal plants reveal intricate stories of power-relations, colonisation, patent protection, and fairness, in which R&D activities such as bioprospecting in genetic resources just tell a part of the story.¹²⁸

From a socio-legal scholarship perspective, Cloatre also asserts a similar discourse as she considers that the International Regime on Access to Genetic Resources and Benefit Sharing reflects a simplistic view of bioprospecting, in which it is only important to identify a single compound from biodiversity to obtain patent protection and, eventually, negotiate and place them towards upstream industries, hence, benefit sharing can take place.¹²⁹ For Cloatre, access and benefit sharing regulation and its implementation in developing countries rich in biodiversity are unable to comprehend and regulate the

¹²⁶ Hayden (n 19). p 105

¹²⁷ *ibid.*

¹²⁸ Osseo-Asare (n 20).

¹²⁹ Cloatre (n 21).

“messiness” of the different dynamics of communities’ knowledge and practices, leading to incomplete solutions, which at the end of the day exclude and affect the more vulnerable. Clearly the work of Hayden, Osseo-Asaren, and Cloatre testifies significant numbers of actors and conditions behind biodiversity, which have not fitted into the scope of the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing.

Improving Compliance in the Implementation of the Nagoya Protocol: Lessons from the EU

Although the use of biodiversity involves different complexities and “messiness”, which it is difficult to encapsulate within a body of law, it provides opportunities to improve the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. Since the Nagoya Protocol established guidelines on acknowledging the role of communities in the utilization of genetic resources and on how to create mechanisms of compliance, the Nagoya Protocol helps amplify the discussion on how to protect communities’ knowledge and practices. For instance, since the EU has not established disclosure of origin in patents as a mechanism of compliance for EU members,¹³⁰ the EU has implemented the Nagoya Protocol in a way that not only holders of technology that employ genetic resources are obliged to comply with this international body of law, but also other users.

Indeed, the EU has included within the scope of its regulation a variety of industries which range from cosmetics to herbal medicines. This can be reflected in the EU’s mechanisms of compliance established by the EU Regulation 511/2014.¹³¹ This Regulation has created two important elements to comply with the International Regime on Access to Genetic Resources and Benefit Sharing within EU territory. These are (1) users and due diligence; and (2) measures of monitoring users’ compliance. 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 regime on access to

¹³⁰ *Netherlands v. Parliament and Council Case-377/98* (n 112).

¹³¹ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

genetic resources and benefit sharing and traditional knowledge associated with genetic resources. Due diligence is a mechanism to demonstrate that users of genetic resources have made the necessary efforts to comply with the regulation of 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 the International Regime on Access to Genetic Resources and Benefit Sharing, 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 Bioprospecting¹³² (Article 8). But it is not only members of the biotechnology industry, such as BIO, who are discussing what are best practices in bioprospecting to comply with the EU Regulation. In addition, the Association of the European Self-Medication Industry (AESGP), the organisation that represents the interest of the herbal industry in Europe, has begun a dialogue with the EU Commission on how to establish specific guidelines to comply with the EU Regulation 511/2014 in the form of best practices.¹³³ However, in 2019 the EU Commission reported that there has been no significant progress in establishing best practices with the different industries across the EU.¹³⁴

Article 5 of the EU Regulation also states that member states 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. standardised procedures for verification and collection of information on genetic resources. Collections should request EU member states to include a register of the collection in the EU ('the register'), which is established and maintained by the EU Commission (Article 5.1). Yet,

¹³² BIO, 'Guidelines for BIO Members Engaging in Bioprospecting – BIO' <<https://www.bio.org/articles/guidelines-bio-members-engaging-bioprospecting>> accessed July 31 2017.

¹³³ AESGP, 'Communication of the AESGP to the EU Commission on the EU ABS Regulation 511/2014' <<http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/AESGP.pdf>> accessed January 29 2019.

¹³⁴ Report From The Commission to the European Parliament and the Council Regulation (EU) No 511/2014 of the European Parliament and of the Council of April 16 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union COM/2019/13 final

to date there is only one registered collection in the register.¹³⁵ The importance of registered collections is the role these will play in R&D. By acquiring genetic resources through a registered collection, users operating towards upstream research (e.g. applied research, clinical trials, or manufacturing) can prove their due diligence (Article 4.7). This entire approach indicates that the EU is centralising compliance with the International Regime on Access to Genetic Resources and Benefit Sharing on users that interact directly with developing countries rich in biodiversity and communities. Hence, users operating at the downstream stages (e.g. users that carry out bioprospection, collections, botanical gardens etc.) will be complying with prior informed consent and mutually agreed terms.

Articles 6, 7 and 9 of the EU Regulation establish measures to monitor users' compliance. Each member state of the EU should establish a competent authority to oversee that users of genetic resources comply with the Regulation and the Nagoya Protocol (Article 6.1.). Moreover, each member state should create a national focal point that provides information on prior informed consent and mutually agreed terms. In order to monitor user compliance, the EU Regulation suggests two mechanisms: (1) Article 7.1 requires member states and the European Commission to request publicly funded research to comply with due diligence as established by Article 4 of the EU Regulation; and (2) Article 7.2 demands users should declare to the competent authorities their compliance with due diligence 'at the stage of final development'.

On the definition of what is the stage of the final development, Article 7.6 delegates to the EU Commission to 'determine the stage of final development of a product to identify the final stage of utilisation in different sectors' such as the pharmaceutical industry. The EU Commission in the Implementing Regulation 2015/1866 defines this concept with different events: When a product developed via utilisation of genetic resources needs market approval

¹³⁵ See: EU Commission, 'Register of Collection-EU ABS Regulation' <http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register_of_Collections.pdf> accessed January 29 2019.

or authorisation or when a notification is required before the product is placed in the market; or, if there is no need for notification or marketing authorisation, when it is placed in the EU market for the first time; or when the result of the utilisation is sold or transferred; or when the utilisation in the EU has ended and is then transferred outside of the EU. As observed, the EU has established a comprehensive catalogue of activities that fall within “the stage of final development”, which is not only directed to holders of technology, but also to other industries. In the case of the European herbal industry, the AESGP has pointed out that this Regulation will not only affect their market approved products (e.g. phytomedicines), but also other activities such as providing plant starting material to upstream users (e.g. the pharmaceutical industry).¹³⁶ As a result, this industry, which did not have to follow access and benefit sharing rules, will now be obliged to comply with the International Regime on Access to Genetic Resources and Benefit Sharing in the EU.¹³⁷

The EU Regulation also 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 provider’s country (developing countries rich in biodiversity) ‘special consideration shall be given’ to that information (Article 9.3 (b)). Finally, despite the fact the EU Regulation indicates that states should accept the IRCC as proof of compliance of national legislation, it does not make it compulsory.

¹³⁶ AESGP (n 133).

¹³⁷ Yet, the herbal industry had already acquired compromises of conservation and sustainability in the growing and harvesting of plant material as required by the European Medicine Agency in the Guidelines of Good Agricultural and Collection Practice of EMA (EMA/HMPC/246816/2005)

Although the effects of the implementation of the EU Regulation remain to be seen,¹³⁸ there are already authors that are at least sceptical about the effect of this Regulation in, for instance, R&D on genetic resources. Burton et al. and Kang et al. point out that this legal framework will place the responsibility of complying with the UN Convention on Biological Diversity and the Nagoya Protocol on users at the beginning of the R&D process.¹³⁹ In fact, the creation of registered collections indicates that other potential users will comply with due diligence by accessing genetic resources through those collections. In other words, since this Regulation will centralise user measures in the EU, it indicates that it will be at downstream stages (i.e. basic and applied research) where compliance will have more impact. Also, the EU Regulation has included sectors such as the herbal industry to comply with access and benefit sharing regulation. These are businesses that were in a “blind spot” as they did not have to comply with any of the access and benefit sharing rules such as prior informed consent and mutual agreed terms despite the fact that they actually benefit from the commercialisation of medicinal plants.

The EU’s implementation of the Nagoya Protocol in Europe has brought two important lessons. First, it indicates that developed countries are focusing on users that are in downstream stages of the research (e.g. universities and small and medium size companies) to comply with the International Regime on Access to Genetic Resources and Benefit Sharing’s requirements.¹⁴⁰ Second, there are new actors who have been included within the scope of the International Regime on Access to Genetic Resources and Benefit Sharing, particularly the herbal industry.

The approach of the EU to implementation of these aspects of the International Regime on Access to Genetic Resources and Benefit Sharing gives important insights for the particular case of Colombia, the country on

¹³⁸ The EU Commission has already pointed out that the regulation is at its early days as EU Members have just began to make institutional changes to comply with it see: Report From The Commission to the European Parliament (COM/2019/13 final).

¹³⁹ Geoff Burton and Elizabeth A Evans-Illidge, ‘Emerging R and D Law: The Nagoya Protocol and Its Implications for Researchers’ (2014) 9 ACS Chemical Biology 588; Kyung-Nam Kang, Chan-Sik Jung and Tae-Kyu Ryu, ‘The Nagoya Protocol and the Biotechnology Industry’ (2015) 4 International Journal of Pharma Medicine and Biological Sciences 209.

¹⁴⁰ Burton and Evans-Illidge (n 139)., p 590

which this thesis focuses. As we will see in subsequent chapters, in the Colombian context, local researchers such as universities and research centres are also playing an intermediary role between the industry and communities, as they are the first to access genetic resources or obtain lead information on practices and knowledge from local communities on the industrial application of genetic resources. Also, the Colombian herbal industry is in a “blind spot” as it is not required to comply with the access and benefit sharing rules in the country, even though the industry benefits from communities’ practices and knowledge associated with genetic resources.

All in all, the recognition, protection and establishing of mechanisms of compliance to protect the role of traditional knowledge associated with genetic resources has been placed in downstream stages, which means that countries’ implementation of the International Regime on Access to Genetic Resources is centralising compliance at the beginning of the R&D process, in which mainly universities, local researchers, and small and medium size companies are located, so as to benefit upstream stakeholders such as large industries. The consequence is that local and indigenous communities’ participation in R&D is limited and restricted so as to leave the rest of the innovation process intact. This means it is not only difficult to accommodate communities’ rights into patent regulation, but also in the International Regime on Access to Genetic Resources and Benefit Sharing. Indeed, the implementation of these instruments has resulted in placing the role of communities in adding value to biodiversity for industrial application almost exclusively in downstream stages of R&D. A critical problem with this approach, as observed in the following chapters, is that knowledge and practice which goes on in upstream stages (applied research, clinical trials, production, and distribution) tends to become less relevant because users and other stakeholders focus exclusively on the biochemical description of genetic resources, rather than what has led them to find the therapeutic activity of that resource. This situation has become even more complex in the context of new technologies such as synthetic biology and gene editing which aim to rely less on the actual genetic resource and communities’ practices and knowledge to develop products and process. As a result, communities are relegated to be mere “leads” in the

discovery of therapeutic activity. Equally, other industries which are not considered innovative, such as the herbal industry, openly employ the knowledge and practices from indigenous communities in the production of phytomedicines, as well as in proving safety and effectiveness of those products, without even recognising the role of those communities in the industrial application of their practices and knowledge.

This thesis shows how Colombia is a perfect illustration of this point, found in the broader literature. Regulation of R&D in genetic resources for the health industry and in health research aims to make technological innovation and market interest prevail over other forms of knowledge and information production, particularly those from local, indigenous, and Afro-Colombian communities. In the case of Colombia, this is evident not only in the way that Colombia has implemented the International Regime on Access to Genetic Resources and Benefit Sharing, but also in the forms in which the country's laws, policies, and practices approach innovation and the commercialisation of medicinal plants in the herbal industry.

Conclusions

A legal analysis of the evolution of the International Regime on Access to Genetic Resources and Benefit Sharing, its implementation in developing countries rich in biodiversity, and its academic critique, reveals a range of discussions. These include questions pertaining to the geopolitical and economic balancing of power *among* countries with historically very different relations to biodiversity. They also concern questions about issues from different communities *within* countries, and the balancing of their various interests. In the particular case of the practices and knowledge of local and indigenous communities in adding value to biodiversity for industrial application and research, what can be observed is a narrative of a constant search for recognising and protecting them as the International Regime on Access to Genetic Resources and Benefit Sharing has evolved from the UN Convention on Biological Diversity to the Nagoya Protocol. However, that

progression has centred the discussion of recognition and protection (through mechanisms of compliance) in downstream stages of R&D, leaving untouched upstream stages, where that contribution can potentially fade away as users employ technology to isolate and synthesize genetic resources for industrial production, not considering the knowledge and practices from those communities.

Therefore, the problem for countries such as Colombia is that the discussion of how to implement the International Regime on Access to Genetic Resources and Benefit Sharing in order to protect communities' participation in R&D and industrial process needs to be addressed. An effective response would be to create a more inclusive approach to innovation and the commercialisation of medicinal plants, which considers the complexities and actors behind the use of biodiversity throughout the entire R&D process, and in the distribution and production of medicinal plants (e.g. phytomedicines). These aspects are discussed in the chapters that follow.

Chapter Three: The Particularities of the Colombian Legal System

Introduction

The International Regime on Access to Genetic Resources and Benefit Sharing sets up an ambitious agenda aiming to secure benefit sharing arising from the use of biodiversity and the practice and knowledge related to genetic resources. It is up to each member of the UN Convention on Biodiversity to implement this legal framework, by adopting the access and benefit sharing provisions into their national legislation. However, such an implementation is not exclusively a question of creation of legal mechanisms or administrative provisions, for instance through creation of a national authority or procedures to obtain prior informed consent and mutually agreed terms. It is also a question of whether, and if so how, countries make those provisions enforceable, meaning how they implement the International Regime on Access to Genetic Resources and Benefit Sharing, so as to make users comply and obey this international treaty. In fact, the previous chapter points out that one of the key problems in the International Regime on Access to Genetic Resources and Benefit Sharing is that its implementation does not effectively impose an obligation on users of genetic resources to comply with its provisions. For example, as already noted, a publicly funded research centre in South Africa originally failed to include an indigenous community into a set of mutually agreed terms, even though this user aimed to commercialise that community's knowledge in the medicinal use of a plant.¹⁴¹ This is despite the fact that South Africa had implemented the UN Convention on Biological Diversity, including provisions regarding respect for, and acknowledgment of, communities' knowledge and practices.

¹⁴¹ Eventually, the research centre included those communities in mutually agreed terms after the pressure from NGOs and academics. In Chapter One, Section 2. Kamau (n 124). Wynberg (n 125).

This thesis focuses on the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia. It discusses whether Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing recognises contributions from local, indigenous, and Afro-Colombian communities' practices and knowledge in adding value to the use of genetic resources for the health industry and health research. To that end, this chapter centres on the particularities of Colombia's legal system and how it works. The next chapter assesses whether – in practice – Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing recognises communities' contribution and practices, in compliance with Colombia's international obligations.

The analysis here of the Colombian legal system is not exhaustive.¹⁴² Its core focus is the particularities of Colombian law that are related to the subject matter of the thesis. There are two key facets of Colombian law: Its obligations as a member of the Andean Community of Nations, and its constitutional provisions that reconcile cultural rights with economic development.

Since Colombia is a member of the Andean Community, and Andean Community membership entails obligations relevant to access to genetic resources and industrial property, it is necessary to analyse the relevant measures of Andean Community law. In particular, these are Decision 391 of 1996 on the Common Regime on Access to Genetic Resources and Decision 486 of 2000 on the Common Industrial Property Regime of the Andean Community. Andean decisions are of direct application, which means they automatically become part of Andean countries' legislation without further requirements (e.g. passing through the congress). Those Andean decisions also demand that each member regulates them through legal and administrative dispositions, and these are analysed below.

¹⁴² Colombia legal system is mainly influenced by the Civil or Continental Law tradition, in which principles and rules are in Statutes or *Codex*. For instance, the Civil Codex, which is inspired in the Napoleon Civil Codex, sets up all rules for equity, trust and contract law. There is also the Commerce Codex, influenced mainly by the Italian and Spanish Codex of Commerce. For a general introduction of Colombia law see: Arturo Valencia Zea and Álvaro Ortiz Monsalve, *Derecho Civil. Tomo I: Parte General y Personas* (18th edn, Temis 2016).

The Colombian Constitution 1991 is “the primary source” of the Colombian legal system. It includes a comprehensive catalogue of fundamental rights. In the event of an incompatibility between the constitution and any law or regulation, the former must prevail and be applied.¹⁴³

The constitution creates the Constitutional Court of Colombia, the highest constitutional tribunal in the country. The constitutional court has two judicial mechanisms that aim to secure the supremacy of the Colombian constitution and make enforceable fundamental rights such as freedom of speech. The constitutional court can carry out judicial review of specific situations via the writ of protection of fundamental rights (*acción de tutela*). In addition, the constitutional court is entitled to order the government and parliament to create effective mechanisms of protection or to either amend or reject any legislation that goes against the constitution (*acción de inconstitucionalidad*). The relevance of those aspects of the constitutional court’s jurisdiction to this thesis is that they have served to solve social, political and economic conflicts effectively. In other circumstances, such conflicts would either have taken years of endless judicial procedures, or would have unjustifiably benefited ruling elites against the interests of the most vulnerable, including local, indigenous, and Afro-Colombian communities.¹⁴⁴

One example of the conflicts that the constitutional court has helped to solve is the protection of local, indigenous, and Afro-Colombian communities’ rights. Indeed, those communities have been victims of the long cycle of exclusion and violence in Colombia, involving state agents, businesses, multinational companies, landlords, far-left and far-right armies, drug barons, and so on. The constitution establishes as a fundamental right the “recognition and protection of ethnic and cultural diversity”. The constitutional court has exercised its jurisdiction under *acciones de tutela* and *acciones de inconstitucionalidad* to interpret this constitutional provision. In doing so, it

¹⁴³ Article 4 of the 1991 Constitution

¹⁴⁴ Because of such a judicial activism, the court has been accused of stepping into the role of other high tribunals such as the Supreme Court and the Council of State, and even into the role of other branches of government; for further discussion see Manuel José Cepeda-Espinosa, ‘Judicial Activism in a Violent Context: The Origin, Role, and Impact of the Colombian Constitutional Court’ (2004) 3 U. Global Stud. L. Rev.

has recognised and developed a set of rights of local, indigenous and Afro-Colombian communities. These constitutionally-protected rights include a right of subsistence (as an aspect of the right to life), a right of cultural integrity, right to be publicly consulted, and a right to communitarian land.

The 1991 Colombian Constitution prevails over the entire Colombian legal system. The constitutional court gives practical effect to its provisions through the *acción de tutela* and *acción de inconstitucionalidad*. In so doing, the constitutional court gives effect to the purposes of the Colombian Constitution. The following section of this chapter therefore explores some of the reasons behind the particular rules in the 1991 Colombian Constitution. It argues that the 1991 Colombian Constitution was constructed with the idea of reconciling, on the one hand, economic development and international trade, and, on the other hand, other social and cultural concerns, including the rights of local, indigenous, and Afro-Colombian communities. The final part of the chapter turns to analyse the International Regime on Access to Genetic Resources and Benefit Sharing in the Andean Community, and how Colombia has integrated relevant Andean legislation within the Colombian system, including within the 1991 Colombian Constitution.

The focus of this chapter is a textual analysis of the relevant legal provisions. In the following chapters, the focus is on the law in practice. It is not enough to understand what the legal texts envisage. We also need to understand how the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing has worked out in practice for the health industry and health research, and whether communities' practices and knowledge have been recognised by local authorities and users according to the requirements of the Andean decisions and Colombia's constitution.

The Colombian Constitution 1991: Reconciling Economic Development and International Trade with Communities' Rights

As discussed in the introduction to this thesis, to carry out any analysis of Colombian law, it is essential to understand the context of Colombia's long

history of favouring the economic interests of ruling elites (businesses, landlords, politicians, etc.), over other sectors such as its rural population and minorities, including local, indigenous, and Afro-Colombian communities. For instance, it was very common in Colombia during the 19th century and a good part of the 20th century for policy decisions to be taken with regard to family and business links, rather than, for instance, rational economic interests. These practices led to the creation of strong and close elites that continue to enjoy considerable power even nowadays. Indeed, two of the three last presidents of Colombia (i.e. Juan Manuel Santos and Andres Pastrana) belong to families that for a long time have politically, economically, and culturally dominated the country.¹⁴⁵ As those elites have benefited from Colombian development, their influence has led to cultural, economic and social tensions, which is one of the reasons for Colombia's civil conflict. Among the different accounts of why Colombia has such a long history of violence since its independence in the 19th century, there is one explanation that relates the conflict to the economic prevalence of ruling elites. Colombia has a geographical situation that makes it difficult to access remote areas. Those remote areas are where local, indigenous, and Afro-Colombian communities live. This distance and difficulty of access make it hard to reconcile the economic interests of educated ruling elites in the capitals with those of rural elites. At the same time, rural elites have embraced power through violence. The conflict between those elites has ended up affecting minorities and communities.¹⁴⁶

However, since the 1990s, Colombia has aimed to reconcile economic development and international trade with those social circumstances, so as to

¹⁴⁵ Further information see Mario Aguilera Peña, *Insurgencia Urbana En Bogotá: Motín, Conspiración y Guerra Civil* (Instituto Colombiano de Cultura 1997); Sergio Paolo Solano and Roicer Alberto Flórez Bolívar, 'Historia Social y Literatura En Colombia a Comienzos Del Siglo XX. Los Sectores Sociales Medios En La Novela Cosme de José Félix Fuenmayor' (2011) 71 *Revista de Indias* 601.

¹⁴⁶ For instance, the political parties dispute between Liberals and Conservatives during the second half of twenty century led to an unprecedented scale of violence in rural areas; further information see: Safford and Palacios (n 8), p 159. For a review of different accounts of history of Colombia's violence see John H Coatsworth, 'Root of Violence in Colombia' (2003) 11 *ReVista -Harvard Review of Latin America*. For an explanation of the different dynamics of Colombia diversity and violence see James D Henderson, *When Colombia Bled: A History of the Violence in Tolima* (University of Alabama Press 1985).

have a more inclusive state that safeguards and protects the most vulnerable. As a result, Colombia enacted a constitution in 1991 which sets up the principles for an open economy,¹⁴⁷ but also brings a comprehensive set of fundamental rights to safeguard and protect all Colombians, regardless of status. The constitution thus includes civil and political rights such as freedom of speech, but also economic and social rights, such as union rights, gender rights, and the right to health.¹⁴⁸ In an effort to make both types of rights enforceable, the constitutional court has pointed out that those rights are constitutional principles, meaning that three branches of government must give them material effect through legislation, administrative procedures, and rules, as well as judicial decisions.¹⁴⁹ Hence, it is under those constitutional principles that the state is designed. In other words, the Colombian legal and administrative system is underpinned by the 1991 Constitution's catalogue of fundamental rights. As a matter of legal principle, the enforceability of fundamental rights in Colombia cannot be deterred or defined by contingent circumstances, such as changes in government, judicial interpretation, contractual dispositions among citizens, or economic circumstances.¹⁵⁰

The 1991 Colombian Constitution and the Rights of indigenous, Afro-Colombia, and local communities

The rights of indigenous, Afro-Colombian, and local communities enjoy the status of prevalence of fundamental rights in Colombian constitutional law. Indeed, the constitution has established the “recognition and protection of ethnic and cultural diversity” (Article 7 of 1991 Constitution) as a fundamental

¹⁴⁷ This is known in Colombia as the *Apertura*. The *Apertura* was an economic plan by President Cesar Gaviria to open Colombia economy as to include Colombia in the economy to international trade (selling public companies and softening taxes on Foreign Direct Investment (FDI) further information see WTO, ‘Trade Policy Review-Colombia’, *WT/TPR/S/18* (WTO 1996). For further information in the history of Colombia's economy see: José Antonio Ocampo Gaviria, *Historia Económica de Colombia*. (FCE - Fondo de Cultura Económica 2017).

¹⁴⁸ For more information on Colombia's constitutional reforms see Manuel Fernando Quinche Ramírez, *Derecho Constitucional Colombiano de La Carta de 1991 y Sus Reformas: Tercera Edición* (Editorial Universidad del Rosario 2009).

¹⁴⁹ T- 406 of 1992., Constitutional Court; see also T-881 of 2002, Constitutional Court and C-143 of 2015, Constitutional Court

¹⁵⁰ T-426 of 1992, Constitutional Court

principle. This legal status leads to the recognition of a set of rights that derive from this fundamental principle. Those rights include: (i) a right of subsistence, which involves protecting communities' form of life (e.g. values, beliefs, knowledge, and so on),¹⁵¹ (ii) rights of self-determination and self-governance, which derive from the right of integrity,¹⁵² and (iii) the right to possess their own communitarian land, where they can exercise their cultural, social and economic activities.¹⁵³ In a series of landmark rulings, the constitutional court has prevented Colombian authorities from applying specific duties under the law in contexts where to do so would threaten the cosmo-vision and cultural practices of certain Colombian communities. For instance, military service is compulsory for all Colombian males when they reach their legal capacity (i.e. 18 years old). Notwithstanding, the constitutional court, in an *acción de constitucionalidad*, found that members of indigenous communities should not be obliged to serve in the military as such a situation could threaten the very existence of those communities.¹⁵⁴ Further, the constitutional court has stated that communities are entitled to create their own form of governments and justice, regardless of whether to do so contradicts Colombian law.¹⁵⁵

Furthermore, the constitutional court has not only focused on aspects of self-government and self-determination, but also on how to strike a balance between economic development, and communities' cultural, economic, and social relations with the environment. Through a number of rulings on *acciones de tutela*, the constitutional court has pointed out that, even though natural resources such as oil and gold are the property of the state, if their

¹⁵¹ T-380 of 1993, Constitutional Court

¹⁵² C-882 of 2011, Constitutional Court

¹⁵³ Frank Semper, 'Los Derechos de Los Pueblos Indígenas de Colombia En La Jurisprudencia de La Corte Constitucional' (2006) 2 Anuario de derecho constitucional latinoamericano 761.

¹⁵⁴ C-058 of 1994, Constitutional Court. Indigenous communities have been particularly victimized by all sides of Colombian conflict as their territories are unfortunately located in the most conflicted areas in the country; further information see William Villa and Juan Houghton, *Violencia Política Contra Los Pueblos Indígenas En Colombia 1974-2004* (Grupo Internacional de Trabajo sobre Asuntos Indígenas 2005).

¹⁵⁵ The right to those communities to decide their own form of government and justice is expressly protected by the Constitution in Article 246 and 287, which is a materialisation of the principle of cultural and ethnic diversity protected in Article 7 of the Constitution. However, if the indigenous form of justice and government go against other constitutional principles such as human dignity, the latter should be prevailed and protected. See T-496 of 1996, Constitutional Court

economic exploitation affects the rights of communities (such as the right of subsistence or cultural integrity), those communities have the right to decide whether such activity can take place, by means of a public consultation.¹⁵⁶

Indeed, the Colombian Constitutional Court has suspended exploitation of those resources until communities are involved or publicly consulted before the economic activity of extraction of those resources takes place. For instance, in 2015, the constitutional court ordered suspension of the activities of extraction of oil until the Awa community, a native population located in the south-west of the country, was consulted on how to protect their territories.¹⁵⁷ Similarly, in 2017, the constitutional court ordered the government to suspend the exploitation of gold by Gran Colombia Gold until the different indigenous, Afro-Colombian, and local communities located in *Marmato (Caldas)* were included in public consultations. Despite the fact the government had granted to the company the right (*Titulo*) to exploit gold, the court found in favour of those communities because they have environmental, cultural, and economic links with the region (including the practice of artisanal mining). As a result, the government was obliged to include those communities in the decision-making process through public consultations. In particular, the court ordered the government to consult with the communities on how the exploitation of natural resources should respect communities' environment and culture. The government was also ordered to include those communities in the exploitation of the non-renewable resource. In particular, the court requested the government to help them to technically improve and formalise their artisanal mining.¹⁵⁸ The ruling in this case has led different communities across the country to demand public consultations whenever there are plans from the government to perform activities of oil and mining exploitation in those

¹⁵⁶ According to Article 332 of the 1991 Constitution, natural non-renewable resources such as gold are property of the State. Since those resources are owned by the State, it is the President through its Ministers and Agencies who decide how to exploit those resources. Such an exploitation is normally granted to private owned companies such as Gran Colombian Gold company. This also reflects what developing countries, more specifically former colonies, campaigned in the UN as to establish that natural non-renewable resources belong to States rather than being considered common heritage, see Paragraphs 4 and 5 of Preamble to the UN-General Assembly Resolution 1803 (XVII) Dec 14 1962 Permanent Sovereignty over natural resources

¹⁵⁷ T-539 of 2015, Constitutional Court

¹⁵⁸ SU-133 of 2017, Constitutional Court

territories.¹⁵⁹ As a result, communities have the fundamental right to be publicly consulted about the exploitation of resources in their land before the action of the state or any other agent takes place.¹⁶⁰

However, there is a legal distinction between ethnic communities, indigenous and Afro-Colombian communities, and non-ethnic communities or local communities. While any project that involves ethnic communities needs to obtain prior informed consent from those communities, projects in territories of local communities do not necessarily have to obtain prior informed consent. Rather, local communities should be included in the decision-making process if the activity affects their environment and socio-economic activities.

Regarding ethnic communities, there are two separate pieces of legislation.¹⁶¹ On one hand, there is the Decree 2164 of 1995, which regulates indigenous communities. This decree defines these communities as a group of people, who are of *Amerindian* descent, are aware of their identity, and share values, uses or customs, as well as having their own form of government and law. All of these aspects distinguish them from other communities. In order to have representation before Colombian authorities and have recognition over their territories, Decree 2164 creates *Cabildos Indigenas* (Indigenous Councils). This legal entity is created not to establish a form of government or rule in those communities, but to adjust whatever form of government, political organization, law and customs those communities possess, which entitles them to specific rights, including communal land rights (*Resguardo Indigena*), self-governance (e.g. how they make their own decisions regarding use of their soil or traditional knowledge). Since indigenous communities vary

¹⁵⁹ There are approximately 8 public consultation in course, 5 which have been suspended and there are nine *acción tutela* demanding to carry out a public consultation; further information see Juana Marina Hofman-Quintero, 'El Falso Dilema de Las Consultas Populares' (*La Silla Vacía*, 2018) <<http://lasillavacia.com/silla-llena/red-verde/historia/el-falso-dilema-de-las-consultas-populares-64228>> accessed July 2 2018.

¹⁶⁰ The Constitutional Court has included as part of Colombia constitution the Indigenous and Tribal Peoples Convention, 1989, of the International Labour Organization, which calls countries to public consulted those communities when their rights and guarantees might be affected. As this treaty is part of Colombia constitution, its provision including public consultation should be guarantee and protected in the same way that any fundamental rights. See SU-510 of 1998, Constitutional Court

¹⁶¹ Both regulations implement the Indigenous and Tribal People Convention of the International Labour Organization (1989), which is discussed in Chapter Two

in the way that they govern themselves, each community establishes how its decision-making process takes place and how they want to be represented before national authorities or other agents that, for instance, want to access to their ancestral land, knowledge and practices. On the other hand, for Afro-Colombians, there is the Decree 1745 of 1995. This regulation states that Afro-descendent communities can create *Consejos Comunitarios*, which are the main administrative authorities within these communities' land (*Tierras de las Comunidades Negras*). However, since they are not considered to have an ancestral origin as in the case of indigenous communities, the wording of Decree 1745 establishes basic guidelines on how those *Consejos Comunitarios* are organized and managed, as well as how they can make decisions that affect communities' rights. For instance, the main body of *Consejos* is the General Assembly, whose decisions should have a majority of 50 plus 1. Both indigenous and Afro-Colombian communities have the right to be previously consulted in order to grant their consent if any activity is carried out in their lands.

However, by contrast, local communities do not have a specific law that recognizes the right to be consulted beforehand. There is no even a legal definition of what a local community is. Yet, this does not mean that local communities are not constitutionally protected. As there is an absence of a legal definition, there has been a case-by-case approach from the Constitutional Court to protect local communities, for instance, of peasants that are affected by infrastructure and exploitation of non-renewable resources projects.¹⁶² For instance, the construction of the hydroelectric station *Urrá I* in the north of the country was delayed until local and national authorities assessed the potential socio-economic damages and consulted rural and fisherman communities (*Pesqueros*), whose main socio-economic activities were affected by the infrastructure project. As a result, although there is not a legal text that grant rights to local communities such as communal land, the Constitutional Court has imposed an obligation on authorities and other agents interested in carrying out infrastructure projects

¹⁶² T-194 of 1999, Constitutional Court

(e.g. bridges, dams, etc.) or mining and oil activities, which could have a potential impact in local communities' socio-economic activities, to identify those communities and include them in decision making process. In particular, agents should assess any potential negative impact of carrying out their projects for local communities' socio-economic activities, and should agree with local communities' mechanisms to overcome those difficulties.¹⁶³

Additionally, even if there is a legal distinction between ethnic and non-ethnic communities regarding prior informed consent, in practice, the Constitutional Court's rulings illustrates that, since infrastructure or extractive projects affect considerable extension of territory, there is no single and specific community involved, but rather indigenous, Afro-Colombian and local communities are joined in one territory as occurred in the case of *Marmato* (Caldas).

Furthermore, the fundamental principle of "recognition and protection of ethnic and cultural diversity" of indigenous and Afro-Colombian communities, as well as the constitutional protection of local communities' socio-economic relationship with their environment has not only been relied upon to require authorities involved in the exploitation of non-renewable resources in Colombia to carry out public consultations. The Constitutional Court has also drawn on the principle to request the government and parliament to consider communities' concerns on international intellectual property rights-trade related compromises. This is exemplified in the government's efforts to give greater protection on plant variety for agriculture to plant breeders and multinational companies by implementing the 1991 International Convention for the Protection of New Varieties of Plants (UPOV 1991). Colombia acquired the obligation of implementing the Convention 1991 in two separate Free Trade Agreements: the US-Colombia Free Trade Agreement¹⁶⁴ and the EU-Colombia and Peru Free Trade Agreement.¹⁶⁵

¹⁶³ T-348 of 2014, Constitutional Court, and T-135 of 2013, Constitutional Court

¹⁶⁴ See Article 16.1.3 (c) of the US-Colombia Free Trade Agreement

¹⁶⁵ See Article 232 of the Trade Agreement Between the European Union and its Member States, of the one part, and Colombia and Peru, of the other part (EU/CO/PE/en 1)

The Constitutional Court held that the legislative effort to implement the International Convention for the Protection of New Varieties of Plants in Colombia was unconstitutional. The main reasoning of the Court was to the effect that unconstitutionality arose because indigenous and local (peasants) communities did not participate in the implementation of the 1991 Convention. That lack of participation in the implementation of the Convention rendered it constitutionally deficient. For the Constitutional Court, the government was ignoring both “the practices and traditional knowledge of ethnic people and peasants, communities” and “the rights that such communities may have over traditional or native varieties, particularly those that do not circulate within commercial and technological channels”.¹⁶⁶ Furthermore, although there is an apparent legal distinction between ethnic and non-ethnic communities regarding prior informed consent for infrastructure projects and extractive activities (mining or oil), this constitutional ruling on the implementation of the UPOV 1991 shows that such a distinction does not even operate when local and indigenous communities’ practices and traditional knowledge associated with genetic resources for agriculture are at stake.¹⁶⁷ In other words, prior informed consent is mandatory equally for all communities if their practices and traditional knowledge can be potentially affected by an industrial activity such as plant variety protection.

To summarise, the Colombian legal system, through the *acción de tutela* and *acción de inconstitucional*, has elevated communities’ rights to the level of fundamental rights. It seeks to provide an effective mechanism of protection

¹⁶⁶ C-1051 of 2012, Constitutional Court; for further information in this case see: Jhonny Antonio Pabón Cadavid, ‘Indigenous and Traditional Communities Must Be Consulted before Approval of Intellectual Property Treaties’ (2015) 10 *Journal of Intellectual Property Law & Practice* 11.; the supremacy of the Constitutional Court rulings on communities’ rights regarding the implementation of international treaties has also been reflected in other governmental non-binding actions. This is the case of the Consultant Body of the Council of State, which is the techno-legal adviser of the government. It recently recommended the government to consult communities before it officially implements the Nagoya Protocol in the country. This recommendation was based completely upon the Constitutional Court rulings, see: Recommendation 2017-00057-00 of the Consultant Body of the Council of State

¹⁶⁷ This is also reflected in the Constitutional Court’ ruling on the constitutionality of a bilateral environmental agreement between Colombia and Canada, in which the terms indigenous and local communities were used indistinctively to demand prior informed consent from both local and indigenous communities in any State decision that affect them. See C-915 of 2010, Constitutional Court

to those communities. In the case of exploitation of non-renewable resources, the Constitutional Court highlights that, since the economic use of those resources affects the cultural and socio-economic link that exists between communities and their environment, the rights of subsistence and cultural integrity are at risk. As a result, those communities have the right to be publicly consulted. It is also important to notice that, despite the fact that the Colombian legislation makes a distinction between ethnic communities, and local communities, regarding the obligation to obtain prior informed consent, the Constitutional Court has extended that right to local communities too when their socio-economic activities are affected by State and different agents' actions or inactions.

Furthermore, the Court rulings are not only limited to an obligation on the government to reconcile economic development and communities' rights, but also to reconcile those rights with international trade agreements. The constitution and the rulings of the Constitutional Court have been used as instruments to ensure that the action – or inaction – of different stakeholders does not transgress the fundamental rights of local, indigenous, and Afro-Colombian communities. This means that the three branches of government must observe those communities' rights if any policy, ruling, or legislation (including in economic development and international trade) affects their right of cultural integrity, right of communitarian land, etc.

The next section analyses how the legislation that implements the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, including the Andean Decisions, is articulated within those principles of the Colombian Constitution and constitutional court decisions.

[The Access and Benefit Sharing Regime in the Andean Community and Colombia](#)

Although Colombia has comprehensive legislation on the protection of its biodiversity, including the rights of communities, the legal and administrative implementation of the Access and Benefit Sharing Regime in Colombia has not

been carried out exclusively within the country's legislative processes. Colombia has geographical, historical, cultural, and economic links with its neighbouring countries.¹⁶⁸ The Andean countries have worked together in specific areas of common interest. As a result, Bolivia, Colombia, Ecuador, and Peru have addressed the interests of biodiversity protection, and communities' rights, through the Andean Community.¹⁶⁹ The Andean Community 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. Therefore, the following section explains how the Andean Community of Nations legislation works and is implemented within its members, and how it fits within the Colombian constitutional regime. As an example of such an organizational relation with its members, it also explains how the International Regime on Access to Genetic Resources and Benefit Sharing has been implemented through the Decision 391 in the Andean sub-region and Colombia.

The Andean Community of Nations, the Colombian Constitutional Regime and ABS Implementation

The Andean Community is composed of the state members and the Andean System of Integration or SAI (Spanish acronym).¹⁷⁰ 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.).¹⁷¹ For the specific interest of this thesis, the institutions of the SAI that

¹⁶⁸ For instance, all the Andean countries have the same official language (Spanish), were Spanish colonies and were freed by Simon Bolivar (*El Libertador*), have the same main religion (Catholicism), follow the Civil law tradition, belong to the same international and regional organizations (e.g. Organization of American States (OAS)) and so on).

¹⁶⁹ Chile was a country founder member of the Andean Community of Nations but renounced its membership on 30 October 1976; whereas Venezuela was added to the Andean Subregional Integration Agreement (Cartagena Agreement) on October 30 1973, but renounced its membership on April 22 2006.

¹⁷⁰ Article 5-6 of the Cartagena Agreement

¹⁷¹ There are three sets of institution in the Andean Community of Nations: (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 Andean Community of Nations, the Latin American Development Bank, the Latin American Fund, the

define policies and legislation on access to genetic resources are: (i) the Andean Presidential Council (led by the presidents of each state member), the top decision making body of the Andean Community which sets up the policies of integration;¹⁷² (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;¹⁷³ (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;¹⁷⁴ and (iv) the Andean Tribunal of Justice (v) which interprets Andean legislation to ensure it is applied uniformly by member states. The Andean Tribunal of Justice does so 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.¹⁷⁵

The Andean Community's legislation (acts and decisions) is legally and automatically binding on state members and does not require further local legal procedures to be enforceable. At the same time, Andean Community Acts and Decisions might need to be harmonized with national legal systems by state member authorities (e.g. the president or local parliament) through regulations.¹⁷⁶

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

¹⁷² Articles 11-14 of the Cartagena Agreement

¹⁷³ Articles 15-22 *ibid.*

¹⁷⁴ Articles 21-28 *ibid.*

¹⁷⁵ Articles 40-41 *ibid.* and Treaty which creates the Tribunal of Justice of the Andean Community of Nations as subscribed on May 28 1979 as modified by the Trujillo Protocol

¹⁷⁶ See Article 1-4 of the Treaty which creates the Tribunal of Justice of the Andean Community of Nations as subscribed on May 28 1979 as modified by the Trujillo Protocol of 1996; for further information on the Andean legal system see: Galo Pico Mantilla, 'Temas Jurídicos de La Comunidad Andina' [2009] Editorial Académica Española; Galo Pico Mantilla, *Derecho Andino* (1992); Luis Carlos Plata López and Donna Yepes Ceballos, 'Naturaleza Jurídica de Las Normas Comunitarias Andinas' [2009] *Revista de Derecho* 196.

As mentioned above, the acts and decisions of the Andean Community are binding for its members; yet, it also requires that Andean countries regulate in detail the obligations that emanate from the sub-regional organisation. For instance, Decision 391 is a law that is part of the Colombian legislation, despite the fact this regulation did not go through the normal law-making process. Normally, the implementation of any international treaty in Colombia involves the three branches of government. The Colombian Constitutional Court has stated that Andean legislation does not contradict the Colombian Constitution as Andean decisions are of direct application to all state members. According to the constitutional court, Andean legislation is “mandatory from the moment of its promulgation”, prevailing over local laws.¹⁷⁷ In this regard, the constitutional court has pointed out that, since Andean law is constructed with the main purpose of securing Andean integration, its content is not limited to creating general compromises through treaties, protocols, or conventions. Rather, state members have delegated to the Andean Community’s institutions the attributed power of generating binding legal norms.¹⁷⁸

The Constitutionality of the Andean Community’s Legislation in Colombia

To explain how the Andean Community’s structure and legislation fits within the Colombian Constitution and legal system, the Constitutional Court highlights that there are two types of Andean Community laws: Primary and secondary law. Primary law takes the form of international treaties in which the Andean Community acts as a representative of all state members. Primary Andean law is not directly binding.¹⁷⁹ For instance, the Andean Community acted on behalf of state members in the negotiation of the Patent Cooperation Treaty of the World Intellectual Property Organisation (WIPO), yet it is up to each state member to adopt that treaty locally.¹⁸⁰ Secondary law are acts of the

¹⁷⁷ C-231 of 1997, Constitutional Court

¹⁷⁸ Ibid., Paragraph 6

¹⁷⁹ Ibid, Paragraph 8

¹⁸⁰ Ecuador, Colombia and Peru have already joined the Patent Cooperation Treaty, while Bolivia has not done so yet, further information see WIPO, ‘The PCT Now Has 152 Contracting

Andean Community's institutions which make possible the integration of the Andean Community in different areas. One such area is the International Regime on Access to Genetic Resources and Benefit Sharing. Secondary law, as mentioned above, is mandatory from the moment of its promulgation and prevails over local regulations.¹⁸¹ This means that the Andean Community structure and its legislation do not contradict the Colombian legal system, including its Constitution. Rather, it develops specific areas of common interest in the process of integration of the Andean countries.

The implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in the region is an example of how primary and secondary law operate in the Andean Community and Colombia. The Andean Community has negotiated on behalf of its state members the different international instruments that are part of the regime (i.e. the Convention on Biodiversity, the Bonn Guidelines and the Nagoya Protocol). Yet each Andean Community state member has separately ratified and included those instruments in their domestic legislation. For instance, Colombia adopted the Convention on Biodiversity through a piece of national legislation, Act 165 of 1994. Act 165 merely replicates the exact content of the convention. It did not create any specific guidance or obligations for the country. To achieve this, and as part of a regional strategy in the use of biodiversity, Colombia delegated to the Andean Community the power or competence to implement the Convention on Biodiversity through Andean Community secondary law. This was done through the Andean Community's Decision 391.¹⁸² This decision, as the constitutional court has ruled,¹⁸³ is directly applicable in Colombia, as it regulates an area of common interest: The use of genetic resources and traditional knowledge in the Andean region.

States' (WIPO, 2018) <http://www.wipo.int/pct/en/pct_contracting_states.html> accessed September 8 2018.

¹⁸¹ C-231 of 1997, Paragraph 8

¹⁸² The latest regional strategy in conservation and the sustainable use of biodiversity was set up in the Decision 523 Regional Biodiversity Strategy for the Tropical Andean Countries as signed in Lima, Peru on 17th of July 2002; Achim Seiler and Graham Dutfield, 'Regulating Access and Benefit Sharing Basic Issues, Legal Instruments, Policy Proposals' (2001) <<https://www.bfn.de/fileadmin/MDB/documents/access.pdf>> accessed September 19 2018.

¹⁸³ C-231 of 1997, Paragraph 8

In addition to primary and secondary Andean Community law, each member of the Andean Community may accommodate its binding provisions into their legal system through administrative mechanisms and regulations. For instance, since Decision 391 is based on the concept of sovereignty over genetic resources (Article 5),¹⁸⁴ the property regime over those genetic resources is determined by each state member. In fact, Article 6 of Decision 391 mentions that genetic resources are property that belongs to the Andean state members according to their own legislation. These resources are inalienable. In other words, the Andean Community law on access to genetic resources is subject to the sovereignty of states (Article 5). As a result, Article 6 of Decision 391 establishes that genetic resources are subject to a property regime in which Andean state members could ensure that those resources are not transferable. Additionally, Decision 391 establishes that each country decides its own policies on biological resources.

As analysed in Chapter Two, biological resources are all living and non-living entities that have any value for humanity. Biological resources include animals, ecosystems, genetic resources and so on. However, in law, the distinction between biological resources and genetic resources emanates from the Convention on Biodiversity. This legal distinction creates two different legal obligations, pertaining to biological resources and genetic resources respectively. The former entails an obligation of conservation and sustainable use of biological resources. The latter is related to appropriate access to genetic materials. As a result, a single biological component may fall under two regimes, as one and as the other. This can be clearly exemplified in the case of Colombia.

¹⁸⁴ It follows what Articles 3 and 15 of the UN Convention on Biological Diversity establishes (see Chapter Two)

On one hand, biological resources are regulated by the 1974 Colombian National Codex of Renewable Resources and Protection of the Environment. This is the national regulation that establishes rules for conservation and sustainable use of biodiversity.¹⁸⁵ Although, in principle, renewable resources are also public property, the Colombian legislation allows private property over those resources, but imposes a stewardship obligation on those who own land where renewable resources are located.¹⁸⁶ For instance, if an owner of a farm is located in an area certified as protected in which there are renewable resources such as water or forest, the owner cannot exploit their land in a way affecting the enjoyment of those resources. Furthermore, according to the administrative Decree 309 of 2000, which regulates research activities in biological resources and complements the National Codex of Renewable Resources, research activities on biological resources are not subject to the rules of Decision 391. The objective of administrative Decree 309 is to encourage the conservation and sustainability of biological resources. It does not seek to control access to genetic resources or benefit sharing.¹⁸⁷ As Decree 309 regulates the activities of conservation and sustainability, it is more flexible than the access and benefit sharing rules. For instance, publicly funded research institutions may carry out research activities (e.g. collection and classification of biological species) without governmental authorisation.¹⁸⁸

On the other hand, genetic resources as found in nature are considered public property. In fact, the Council of State, one of the highest tribunals in the country, held that genetic resources as found in nature are public property, inalienable, and not subject to prescription or seizure.¹⁸⁹ In line with the public status of genetic resources as found in nature, Decision 391 regulates how to

¹⁸⁵ 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 L Villar and others, 'Evaluación y Perspectivas Del Código Nacional de Recursos Naturales En Colombia En Sus 30 Años de Vigencia' [2004] Bogotá: Universidad Externado de Colombia.

¹⁸⁶ 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; C-126 of 1998, Constitutional Court

¹⁸⁷ Articles 1 and 2 of Decree 391

¹⁸⁸ Paragraphs 1 and 2 of Article 2 of Decision 391

¹⁸⁹ Sentence No 997 of 1997, Council of State

access them. According to Decision 391 and the Council of State, there cannot be private property in genetic resources as found in nature as they are public property, inalienable, and not subject to prescription or seizure. As a result, the state requires users who seek to access to those resources to obtain prior informed consent and reach mutually agreed terms. Furthermore, Decision 391 establishes the primacy of regulation on access to genetic resources over regulation of biological resources. It does so by establishing that biological resources are subject to Decision 391 if there is any activity that involves access to genetic resources. This is the case regardless of the property regime applicable to the biological resources concerned.¹⁹⁰

Decision 391 is thus a critical element of the Colombian regulatory regime on access and benefit sharing, and its scope is therefore important. The decision defines genetic resources as including both genetic resources themselves, and also derivatives and by-products, which do not include functional units of heredity. Decision 391 embraces most of the wording of Article 2 of the Convention on Biodiversity on the definition of genetic resources. The Convention defines genetic resources as ‘genetic material of actual or potential value’, that contain functional units of heredity such as DNA and RNA from plants, animals, or microorganisms. However, Decision 391 goes further, by including elements that do not contain functional units of heredity, such as by-products. According to Article 2 of Decision 391, by-products includes any 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.

However, Decision 391 does not include any definition regarding traditional knowledge associated with genetic resources. Nonetheless, Article 1 of the Decision 391 brings a broad definition of communities, which includes indigenous, Afro-American and local communities in one concept, as a group whose own socio-economic and cultural conditions makes different from the “national collectively” and which are governed by its own costumes, laws and

¹⁹⁰ See Articles 2 (c), 4 (b), 6, 14, 23 and 26 (b) of Decision 391

traditions. This means that Decision 391, in an ample way, creates a definition that is not limited by ethnic considerations alone, but it rather focusses on communities' conditions and own governance.¹⁹¹ This is a definition that is even adopted by the Constitutional Court in a decision related to the ratification of an environmental bilateral agreement between Canada and Colombia.¹⁹² This means that Decision 391 does not conflict with the Colombian legislation and constitutional rulings on ethnic communities (indigenous and Afro-Colombian) and local communities, which were explained above.

The Procedure

The obligations imposed by Decision 391 also include important procedural obligations. Each Andean Community member must create a procedure under which users of genetic resources seeking to access those resources (which are broadly defined) must obtain prior informed consent, and secure mutually agreed terms. State members must appoint a local authority in charge of that procedure. In the case of Colombia, the local authority that is legally authorised to oversee this procedure and sign up to mutually agreed terms on behalf of the state is the Ministry of the Environment.¹⁹³ In particular, the Ministry of the Environment has created within its administrative structure a specific agency in charge of centralising, carrying out and negotiating mutually agreed terms. The agency is known as the *Dirección de Bosques Biodiversidad y Servicios Ecosistémicos-Grupo de Recursos Genéticos*.

Colombia has also regulated the administrative procedure according to which a body seeking to use genetic resources may obtain prior informed consent and

¹⁹¹ This definition is even broader than the one provided by the Indigenous and Tribal People Convention of the International Labour Organization (1989), which establishes conceptual difference between tribal and indigenous communities, and does not include local communities; See Chapter Two.

¹⁹² C-915 of 2010, Constitutional Court

¹⁹³ 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

reach mutually agreed terms, as required by Decision 391, through the Ministry of Environment Resolution 620 of 1997.¹⁹⁴ Articles 16 and 17 of Decision 391 establish three steps in this procedure: (1) admission and formal review of the user's application; (2) publication and public registration of the user's application; and (3) technical and legal evaluation, and negotiation of mutually agreed terms.¹⁹⁵ The procedure is to operate as follows.

First, the local authority should examine whether the applicant fulfils formal requirements. Formal requirements include a description of the access activities, a template of mutually agreed terms, identification of the user, and identification of the specific local area in which the access will take place.¹⁹⁶ Once the first step has been reviewed and formally approved, the application should be registered in a public registration office. The registration should also be published in a national newspaper of the Andean Community.¹⁹⁷ These steps involve transparency. Consequently, the application is technically and legally evaluated by the local authority to define its viability. For instance, the local authority should analyse whether there is an activity that involves access to genetic resources or whether users have disclosed all relevant information to determine the origin of the resource. Once the evaluation has been carried out and there are no objections, the local authority will begin the process of negotiating the mutually agreed terms. Those negotiations include what benefit sharing mechanisms should take place. However, Decision 391 does not define what these mechanisms are.¹⁹⁸

Decision 391 imposes some temporal obligations on the process. Admission and formal review must be completed within a deadline of 15 days. The publication and public registration of the user's application has a deadline of 90 days, but this may be extended indefinitely by the agency in charge in the Ministry of the Environment. This means that the ministry can delay any

¹⁹⁴ Resolution 620 of 1997 by which is Implemented the Andean Community of Nations Decision 391 of 1996

¹⁹⁵ Articles 29-31 of Decision 391 and Articles 11-20 of Resolution 620

¹⁹⁶ See Articles 26 and 27 of Decision 391

¹⁹⁷ Article 28 of Decision 391 and Articles 9-12 of Resolution 620

¹⁹⁸ Articles 31-37 of Decision 391

evaluation and negotiation of mutually agreed terms for as long as it considers convenient.

Mechanisms of Compliance: From Administrative and Criminal Sanctions to Disclosure of Origin in Patents

Decision 391 also calls on parties to create mechanisms to enforce access requirements (Articles 46 and 47). As a result, Colombia has established within its environmental sanctioning legislation different sanctions for those who access genetic resources without complying with access and benefit sharing rules before any access activity takes place. Those sanctions include fines, confiscation of genetic resources, disciplinary sanctions for public servants who participate in illegal access activities, and criminal prosecution.¹⁹⁹

Furthermore, the Andean legislation on patents also establishes a mechanism to enforce Decision 391. In fact, Decision 391 is linked to the Andean legislation on patents. Since intellectual property, including patents, is a matter of common interest for all state members of the Andean Community, they have established a common regime in Decision 486. As analysed in Chapters 1 and 2, inventions are protected through patents, giving patent holders the opportunity to exclusively exploit those inventions. This is the case even though the inventions at issue are based upon natural resources, including genetic resources. Countries rich in biodiversity therefore aim to secure the position that users of genetic resources share benefits from the exploitation of the relevant intellectual property rights when genetic resources belonging to that country are involved in those inventions. To achieve this, the Andean Community has established a mechanism within its patent regulation that seeks to ensure that the filing and granting of patents should be carried out in accordance with Decision 391. The Andean Community's Decision 486 requires its state members' patent office to observe and favour the Andean regulation on access to genetic resources (Decision 391), when they grant

¹⁹⁹ Act 1333 of 2009, Colombian Environmental Sanctioning Procedure

exclusivity rights on inventions.²⁰⁰ In the case of Colombia, the relevant national authority is the *Superintendencia de Industria y Comercio* (SIC)).

The legal bridge between Decision 486 and Decision 391 is found in the obligation of origin disclosure. Disclosing origin plays a fundamental role in the regulation of genetic resources in Colombia, and access to and sharing of the benefits of those genetic resources. Disclosure obligations are very strict because those who do not comply with these obligations not only face Colombian environmental sanctioning legislation, but also legal consequences within patent law. Articles 22 and 25 of Decision 391 make it mandatory for users of genetic resources to disclose any information that involves genetic resources in patent application. A similar wording is found in Article 26 (h) of Decision 486 as it requires that any patent application that involves genetic resources must include mutually agreed terms. 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).²⁰¹

On these aspects of the link between patents and regulation of access to genetic resources, it is also important to mention that Colombia's Free Trade Agreements with the US and the EU include aspects related to disclosure of origin of Decision 391. In fact, although the US is not part of the Convention on Biodiversity, it reached an agreement with Colombia in a side letter to the main text of the US-Colombia Free Trade Agreement that both parties would "endeavour" to share information relating to genetic resources, including traditional knowledge, via public databases.²⁰² Although scholars are still discussing whether the side letters of the US are binding,²⁰³ it proves how

²⁰⁰ See paragraph 4 Article 3 of Decision 486

²⁰¹ As explained in Chapter One, the conditions for access to genetic resources and benefit sharing are included in mutually agreed terms (Article 15.7 of the UN Convention on Biological Diversity); this agreement is reached by users of genetic resources and a governmental authority

²⁰² 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 September 17 2018

²⁰³ For further information on the nature of side letters in Free Trade Agreements with the US see Rodolfo Cruz Miramontes, "The North American Free Trade Agreement and the So-Called

important it is for Colombia to include at least some provisions into the Free Trade Agreement that link patent legislation with access and benefit sharing regulation. As for disclosure of origin in patents in the EU-Colombia and Peru Free Trade Agreement, this treaty does not require the adoption of the legal mechanism of disclosure of origin. The free trade agreement does acknowledge its ‘usefulness’ in creating a more transparent mechanism of protection of countries’ genetic resources. That said, there is nothing in the text of the treaty to suggest that the EU will create further patent requirements, such as disclosure of origin, in the Union.²⁰⁴

Disclosure of origin is an important element of Colombian regulation on access to genetic resources, linking Colombian patent law (Decision 486) with access to genetic resources (Decision 391). However, in Colombia disclosure of origin operates *only* for patent applications. It does not extend to other administrative procedures, such as market approvals of medicines. Market approval/authorisation or market notification are mechanisms that require certain manufacturers, producers, or distributors to obtain permission from health and safety authorities to place certain products into a market, as those products could have potential risks for the general population. Market authorisation applies to products such as food, chemicals, and medicines. For instance, the EU’s Regulation on the International Regime on Access to Genetic Resources and Benefit Sharing requires that, when such mechanisms are required, users of genetic resources should disclose how they obtained those genetic resources (see Chapter Two). Even if those mechanisms are not required, users should disclose such information when a product is placed in the EU’s market for the first time, if that product is developed via utilisation of genetic resources, or the result of the utilisation is sold or transferred, or the utilisation in the EU has ended and then transferred outside of the EU (see Chapter Two). Although Colombia has a health agency, the *Instituto Nacional*

“Parallel Letters” [2005] Anuario mexicano de Derecho Internacional; Pedro Roffe and Christoph Spennemann, ‘The Impact of FTAs on Public Health Policies and TRIPS Flexibilities’ (2006) 1 International Journal of Intellectual Property Management 75; Carsten Fink and Patrick Reichenmiller, ‘Tightening TRIPS: Intellectual Property Provisions of US Free Trade Agreements’ in Richard S Newfarmer (ed), *Trade, Doha, and development: A window into the issues* (World Bank 2006).

²⁰⁴ Article 201, 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).

de Vigilancia de Medicamentos y Alimentos (INVIMA), which grants market approvals (*Registros Sanitarios*) for the production and distribution of chemical, biological, and natural/herbal medicines, it does not require them to disclose any information related to genetic resources.²⁰⁵

The Andean and Constitutional Protection of Communities' Practices and Knowledge
Associated with Genetic Resources

Decision 391 stresses that genetic resources, as well as communities' practices and knowledge related to those resources, have a "strategic value" in the international context of the region biodiversity, since they are "a primary source of products and processes for industry".²⁰⁶ Decision 391 thus regulates the contribution that local, indigenous, and Afro-American communities give to the understanding of the Andean countries' biodiversity. Consequently, the wording of Decision 391 seeks to protect the knowledge and practices that indigenous, Afro-American, and local communities possess over genetic resources. It does so by calling on Andean Community state members to recognise that they have the right to decide on the use of their knowledge and practices if someone is interested in accessing traditional knowledge associated with genetic resources (Article 7).²⁰⁷

Article 7 of Decision 391 also found echoes in the Constitutional Court's rulings. The Constitutional Court aims to strike a balance between the state's economic interest in the use of biodiversity and the rights of its indigenous communities. In fact, with similar reasoning to that in Decision 391, the court emphasises that Colombia has the exclusive "faculty to use [genetic resources] and take advantage of them economically according to their own interests",²⁰⁸ while it should recognise and respect the rights of communities over their practices and knowledge. In other words, according to the Constitutional

²⁰⁵ For further information on INVIMA see: Decree 677 of 1995

²⁰⁶ See Paragraphs 4 and 8 of the Preface of the Decision 391 on the Common Regime on Access to Genetic Resources of 1996.

²⁰⁷ Also, the Preamble of the Decision 391 "recognises the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution"

²⁰⁸ C-519 of 1994, Constitutional Court

Court, since genetic resources are valuable for economic development, they are property of the state. At the same time, Colombia should consider it of vital importance to include local, indigenous, and Afro-Colombian communities in any decision that involves the use of their practices and knowledge related to Colombia's genetic resources.

As a result of all of the legal provisions discussed above, Colombia has extended the mechanism of public consultation in the exploitation of non-renewable resources to the use of ethnic communities' (i.e. indigenous, and Afro-Colombian) practices and knowledge associated with genetic resources. This means if any user wants to access genetic resources associated with traditional knowledge, it is necessary for that user to publicly consult those ethnic communities beforehand. For instance, the Minister of Environment's Decree 1375 points out that the collection of samples such as medicinal plants for research and non-commercial activities in ethnic communities' lands (i.e. *Resguardos Indigenas* or *Territorios de Comunidades Negras*) requires obtaining prior informed consent according to the Ministry of State's regulation. This procedure requires three steps. First, users of genetic resources must request from the Ministry of State a permit to contact ethnic communities. Once the Ministry of State grants the permission, users should carry out a public consultation with the community. The aim of the consultation is to obtain that particular community's prior informed consent. Finally, in that public consultation, users should also negotiate what benefits will be shared with the community.

In this way, Colombia seems to give effect to Decision 391's disposition on traditional knowledge and practices associated with genetic resources. Colombian legislation grants property control over all its natural resources, including genetic resources, exclusively to the state. At the same time, the legal system aims to grant the right to be publicly consulted to communities when their knowledge and practices associated with genetic resources is at stake.²⁰⁹

²⁰⁹ See Article 7 of Decision 391 and Decree 1320 of 1998 of the Ministry of State Colombia, further information see PNUD, 'Política Pública Pluricultural Para La Protección de Los Sistemas de Conocimiento Tradicional | El PNUD En Colombia' (PNUD, 2014) <<http://www.co.undp.org/content/colombia/>

However, the Ministry of State and Ministry of Environment regulations also indicate that it is only ethnic communities (Afro-Colombian and indigenous) which are entitled to be publicly consulted before the access activity takes place (prior informed consent), meaning that local communities, whose practices and knowledge are at stake, such as peasants, are not to be considered to have a right to be consulted. This is in clear contradiction with Decision 391 and the Constitutional Court's jurisprudence on ethnic and local communities' right to be consulted a priori when their traditional knowledge and practices can be affected by industrial applications and research.

[The Difficulties in Protecting Communities Rights in the Light of Colombian Government Administrative Decisions](#)

Although communities benefit from an important set of constitutional rights and the recognition of their role in the use of biodiversity by Decision 391, the administrative design of the public consultation was originally created for the activities of extraction of minerals and oil, as well as infrastructure projects, in territories in which those communities are located. This means that the legal structure of public consultation responds to the exploitation of natural non-renewable resources, rather than genetic resources. For instance, the national authority that oversees the public consultation is the Ministry of State, a political orientated ministry, rather than the Ministry of the Environment, which actually has a specialized and technical dependency on genetic resources (i.e. *Dirección de Bosques Biodiversidad y Servicios Ecosistémicos-Grupo de Recursos Genéticos*).

Furthermore, recent administrative regulations on access to genetic resources do not seem to provide sufficient clarity on how the contribution from communities is adequately protected according to the mandates of Decision 391 and the Constitutional Court, nor on a clear definition of what traditional knowledge and practices are. For instance, through Ministerial Decrees 1375 and 1376 of 2013, Colombia does not demand local researchers such as public

[es/home/presscenter/articles/2014/12/16/pol-tica-p-blica-pluricultural-para-la-protecci-n-de-los-sistemas-de-conocimiento-tradicional-.html](#)> accessed April 7 2018. p 32

universities and research centres to obtain prior informed consent and reach mutually agreed terms with local (or non-ethnic) communities when they carry out non-commercial activities, specifically the collection and sampling of genetic resources. Also, the Ministry of Environment in 2014 enacted Resolution 1348, which establishes that only two activities require prior informed consent and mutually agreed terms. These are: (i) activities on native species *in situ* or *ex situ*, including virus and viroids, which involve either the isolation of functional and non-functional units of DNA and RNA, as found in nature; and (ii) the isolation of one or more molecules, including micro and macromolecules, produced by the metabolism of an organism. In other words, users of genetic resources' activities that do not fit within these two activities do not need to require prior informed consent and reach mutually agreed terms. However, Resolution 1348 does not make any mention of what occurs if users of genetic resources access traditional knowledge and practices, but their activities do not fit within the content of this regulation. This means for instance that if local researchers carry out research activities on traditional knowledge associated with non-native species, users might not be required to obtain prior informed consent from holders of that knowledge such as local communities.

Similarly, the effect of Resolution 1348 is also to exempt *de facto* the herbal industry in Colombia from obtaining communities' prior informed consent. The herbal industry produces and distributes phytomedicines, pharmaceutical preparations which are based upon medicinal plants. Since phytomedicines are not products whose therapeutic activity is accredited to isolated and purified molecules, or combination thereof, as occurs with chemical synthesized products or biological medicines, they fall outside the scope of Resolution 1348. That means those products do not require prior informed consent and mutually agreed terms, even if that knowledge belongs to ethnic communities. There are two reasons why the herbal industry enjoys such a legal treatment: First, throughout the wording of Decision 391, the Andean Community and its members have focused primarily on industries which transformed genetic resources into products by means of specific technologies such as biotechnology and chemical synthesis (see Chapter Three). In fact,

Article 2 of Decision 391 defines terms such as biotechnology²¹⁰ and synthesised products²¹¹ as to include the biotechnology and pharmaceutical industry within its legislation.²¹² Second, as the nature of phytomedicines do not fit within the definitions of genetic resources and by-products in the Colombian access and benefit sharing rules, there is a “blind spot” for phytomedicines, which clearly benefits this growing industry in the country.

Additionally, herbal producers and distributors are only required to file for market approval before *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA), according to the Ministry of Health’s Decree 2266 of 2004. Furthermore, the regulation of INVIMA has created a subcategory within the regulation of phytotherapeutic medicines that allows the herbal industry to prove safety and efficacy of a phytotherapeutic product with traditional knowledge and practices. In brief, Decree 2266 regulates the marketing approval of phytomedicines in Colombia. Producers and distributors of phytotherapeutic products are required to prove therapeutic activity through clinical studies. However, Decree 2266 has created a subcategory called “traditional phytotherapeutic product”, which exempts the herbal industry from proving therapeutic activity through clinical trials, if two conditions are demonstrated: (i) the medicinal plant, either native or introduced, is locally produced; and (ii) there is either documentary proof that the plant has been employed for medical uses by three or more generations in Colombia,²¹³ or, in the case there is no documentary proof, it can be proved by a “competent professional” or the knowledge from “indigenous or Afro

²¹⁰ Article 2 defines biotechnology as follows: 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.

²¹¹ Article 2 defines synthesised product as follows: 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)

²¹² Alejandro Grajal, ‘Biodiversity and the Nation State: Regulating Access to Genetic Resources Limits Biodiversity Research in Developing Countries’ (1999) 13 *Conservation Biology* 6.

²¹³ Decree 2266 requires that the documentary proof is included within the *Vademécum colombiano de plantas medicinales*, which is the Colombia pharmacopeia for medicinal plants. This document is elaborated by the Specialised Working Group of Natural Products of the Health Minister; for further information of the *Vademécum* see Sala Especializada de Productos Naturales, *Vademécum Colombiano de Plantas Medicinales* (Ministerio de Salud 2007) <[https://www.minsalud.gov.co/sites/rid/1/Vademecum Colombiano de Plantas Medicinales.PDF](https://www.minsalud.gov.co/sites/rid/1/Vademecum%20Colombiano%20de%20Plantas%20Medicinales.PDF)> accessed June 6 2018.

Colombian groups”.²¹⁴ Yet, even though it relies on traditional knowledge of genetic resources, this law does not impose any obligation on the herbal industry to carry out public consultation when it employs communities’ practices and knowledge in the granting process of marketing approvals.

All in all, it is fundamental to notice that the wording of Andean Community laws, the Colombian Constitution and the rulings of the Constitutional Court suggest that Colombia seems to provide a balance between economic development, including international trade, and the interests of all communities in the exploitation of both natural non-renewable resources and genetic resources. In particular, Colombia aims to secure such a balance through the right of public consultation. However, the objective of finding a balance does not seem to be clear enough in the different administrative mechanisms and regulations that Colombia employs in the use of genetic resources and communities’ practices and knowledge associated with genetic resources.

In fact, Colombia is not enforcing communities’ rights against local researchers of genetic resources and the herbal industry. Different administrative decrees have already exempted those actors from meeting Decision 391’s requirements, including the due recognition of indigenous, local, and Afro-Colombian contributions. This means that Colombia has benefited local researchers and the herbal industry despite the fact that there are constitutional rules and legislation which seek to make communities’ rights enforceable. In other words, those administrative mechanisms and regulatory exceptions clearly depart from the aims of Decision 391 and the Constitutional Court mandates regarding the rights of those communities.

It is therefore important to analyse whether, in practice, local authorities are acting contrary to those Andean and constitutional principles. The next chapters consider that question in more depth. They do so through the analysis of two particular cases: (i) the *Dividivi* and the *Anamú* plant cases, which

²¹⁴ Articles, 2, 31 to 36 Decree 2266; Although traditional phytotherapeutic products can be produced in any conventional pharmaceutical form, except injectables and ophthalmic forms.

involve the commercial exploitation of a traditional medicinal plant employed by a local community of peasants, and (ii) how the herbal industry have been employing communities' practices and knowledge to get marketing approval of traditional phytomedicines without obtaining those prior informed consent from those communities. This analysis of the law in practice will help us understand whether Colombia is effectively protecting indigenous, local, and Afro-Colombian practices and knowledge associated with genetic resources.

Conclusions

The 1991 Colombian Constitution and the Constitutional Court have designed an extensive catalogue of fundamental rights that should serve as a platform for the construction of any law, policy decision, and administrative structure of the Colombian state. This means that each action or inaction of the three branches of government should observe and safeguard those fundamental rights. Among those rights, there is the fundamental principle of “recognition and protection of ethnic and cultural diversity” of Colombia, which has led the Constitutional Court to create a set of rights for communities that derive from this fundamental principle. Rights of communities in Colombian constitutional law include a right of subsistence, which flows from the right to life, a right of cultural integrity, and rights to communitarian land.

Furthermore, the Constitutional Court has relied upon this principle to generate a balance between the exploitation of natural non-renewable resources and the rights of indigenous, local, and Afro-Colombian communities when their cultural, social, and economic environment is affected by such an economic activity. As a result, the Constitutional Court points out that although the state is the sole owner of non-renewable resources, it is required to publicly consult those communities before any activity takes place.

Equally, the wording of the Decision 391 and the Constitutional Court's jurisprudence on communities' traditional knowledge and practices associated with genetic resources have pointed out the importance of striking a balance

between the strategic value of genetic resources, which are also the property of the state, and the recognition of the contribution of those communities in adding value in the use of biodiversity for the industry. In principle, such a balance is possible through public consultation, as occurred with exploitation of natural non-renewable resources. However, administrative decisions and regulations from different ministries (environment, state, and health) seem to favour the interests of local researchers and the herbal industry as some of their access activities are not required to comply with the requirements of Decision 391, including the obligations to recognise those communities' contributions in health research and the health industry. Therefore, those administrative mechanisms and regulations appear to contradict Decision 391 and the Constitutional Court's mandate. To explore whether local authorities are contradicting those obligations, the next chapter will carry out an analysis of two specific cases in which indigenous, local, and Afro-Colombian practices and knowledge associated with genetic resources are in the balance.

Chapter Four: Making Genetic Resources and Traditional Knowledge Public: A Tale of Innovation and Access in Colombia

Introduction

Chapter Three introduced the central elements of the Colombian legal system pertaining to genetic resources and to communities' practices and knowledge related to those resources. The chapter highlighted the extensive catalogue of fundamental rights that are the foundation for any law, policy, and administrative mechanism in the country. In particular, the 1991 Constitution established as a fundamental right the "recognition and protection of ethnic and cultural diversity" of Colombia. Also, the Constitutional Court of Colombia has expanded the scope of this provision to establish a set of rights for communities, which includes a right of subsistence, which flows from the right to life; a right of cultural integrity; and rights to communitarian land. As a result, the Court has intervened in the country's economic development policy and trade, with the aim of generating a balance between the exploitation of genetic resources, and the rights of indigenous, local, and Afro-Colombian communities. For the Court, the balance between the use of genetic resources and communities' rights should be reached through public consultation.²¹⁵ The Constitutional Court's reasoning is also reflected in the Andean Community's Decision 391 regarding communities' traditional knowledge and practices associated with genetic resources.

Yet, as Chapter Three also points out, the Ministry of the Environment's recent administrative decisions and regulations have focused on protecting the interests of local researchers, rather than enforcing the fundamental rights to which those communities are entitled over their knowledge on Colombian biodiversity for health research and health industry. This means that

²¹⁵As explained in Chapter Two, Colombia has rather employed the same public consultation procedure for access to other natural resources such as oil and minerals.

Colombian government practice appears to depart from the aims of Decision 391 and the Constitutional Court's mandates.

This chapter explores that claim more fully. It investigates why those recent administrative decisions and regulations have, in effect, placed communities' practices and knowledge into the public domain, in a way they can be employed or appropriated by local researchers without the protections envisaged by Decision 391 and the Constitutional Court rulings. Such a position would be a violation of Decision 391 and the Constitutional Court rulings.

To summarise the chapter's conclusion: this is indeed the case. Through an analysis of litigation, administrative decisions, policy papers, and drawing on semi-structured interviews with seven relevant and representative actors, the chapter shows that the apparent protections of Decision 391 and the Constitutional Court rulings are a de facto sham. Further, the chapter offers a possible explanation of why this is the case. It argues that the reason Colombia placed communities' understanding of Colombia's biodiversity into the public domain is because of the way Colombia has framed innovation in its aims to become a more competitive country. In brief, 'innovation' is seen as encompassed within research and development (R&D) activities for specific industries, such as biotechnology or information technology. In contrast, traditional knowledge and practices of local communities do not fit within the scope of 'innovation' as conceived in Colombian law and practice. As a result, communities' understanding is considered to be mere 'leads' to scientific innovation for local researchers, not an asset or value in itself, to be protected through fundamental rights norms.

This approach to 'innovation' is particularly reflected in the role of the Colombian Scientific and Research Department, known as Colciencias, the national science and technological authority. Colciencias is charged with addressing resources for universities and research centres, including local researchers. It is responsible for measuring what can be considered 'innovative'. In this regard, Colciencias does not act in a vacuum, or by

reference only to internal considerations. Rather, Colciencias follows international standards of innovations set up by the OECD's Oslo Manual.²¹⁶ These standards echo research and development activities in different industries to define and measure innovation. The Oslo Manual standards involve industrial applications from sectors well placed in international markets, such as internet companies, biotechnology, or the pharmaceutical industry.

Those standards do not reflect other forms of knowledge or information, such as those from local, indigenous, and Afro-Colombian communities. Since innovation is only defined and measured by reference to research and development activities from the biotechnology industry, the strategic value of genetic resources and traditional knowledge means that, in practice, genetic resources and traditional knowledge are placed in the public domain, so as to benefit the country's economy in the international trade arena.

Although such an approach has the potential of bringing benefits for Colombian capabilities in R&D, and Colombian global competitiveness in sectors such as health, the effect of the approach is in contradiction of the fundamental right of local communities to be recognised as actors that also contribute to innovation with their understanding and use of Colombia's biodiversity. As such, Colombia's innovation policy is biased towards holders of technology, as it is considered that only the use of those technologies in biodiversity contributes to the industrial application of biodiversity.

There are at least three different governmental authorities which have different approaches on traditional knowledge and practices: the Ministry of the Environment; the Ministry of State; and Colciencias. The Ministry of the Environment oversees the International Regime on Access to Genetic Resources and Benefit Sharing, and has taken recent decisions to facilitate

²¹⁶ OECD and Eurostat, *Oslo Manual-Guidelines for Collecting and Interpreting Innovation Data* (4th edn, OECD Publishing 2018) <<https://www.oecd-ilibrary.org/docserver/9789264304604-en.pdf?expires=1541951164&id=id&accname=guest&checksum=F1A8012F0687F122BA16F5D31ABF15CF>> accessed 8 November 2018.

access to genetic resources to local researchers without due consideration of holders of traditional knowledge and practices, particularly local communities. This has occurred since the Ministry of Environment only requires users of genetic resources, including local researchers, to obtain prior informed consent from indigenous and Afro-Colombian (i.e. ethnic) communities, without due consideration to local communities such as peasants. The latter, as explained in Chapter Three, have been recognised as a subject of constitutional protection when their socio-economic activities and their relationship with the environment are affected, including their practices and traditional knowledge. The Ministry of State should enforce communities' rights, particularly public consultation, but it has not carried out any public consultation yet. Colciencias, the science bureau, defines what research activities, including those over genetic resources, are innovative, in order to allocate resources into those activities. However, this governmental authority does not deem communities' practices and knowledge as innovative, placing these cultural assets into the public domain.

This means that it is Colombian central authorities who do not comply with Decision 391 and constitutional mandates to conciliate communities' rights with other economic interests. Although in theory, states such as Colombia should work as a unified entity, in practice, governance acts in different directions as it pursues different interests, which potentially run against each other. This is the particular case when economic interests clash with fundamental rights.²¹⁷ This has occurred because, as observed throughout this chapter, Colombian authorities are pursuing an economic agenda to meet

²¹⁷ Different authors have argued that international trade has led to the fragmentation of States. For instance, rules of international organizations such as the International Monetary Fund and the World Bank, and economic interests of multinational companies have set countries' economic agendas despite the fact that could go against other interests such as protection of human rights or the environment. For further information see Sol Picciotto, 'Networks in International Economic Integration: Fragmented States and the Dilemmas of Neo-Liberalism' (1996) 17 *Northwestern Journal of International Law & Business*; Sol Picciotto, 'Fragmented States and International Rules of Law' (1997) 6 *Social & Legal Studies* 259; Mahmood Monshipouri and others, *Constructing Human Rights in the Age of Globalization* (Routledge 2015). There is also in Colombia a study by Gomez-Lee who analyses the different interests (farmers, communities, agro and chemical industries, plant breeders, etc.) in the use of biodiversity in Colombia: Martha Isabel Gómez Lee, *Biodiversidad y Políticas Públicas: Coaliciones de Causa En Las Políticas de Acceso a Los Recursos Genéticos En Colombia* (Universidad Externado de Colombia 2017).

global markets' interests regardless of international commitments and local constitutional obligations to enforce communities' fundamental rights.

Consequently, a problematic aspect of Colombia's current implementation of International Regime on Access to Genetic Resources and Benefit Sharing is that the Colombian government, in practice, does not observe, and even ignores, communities' rights. This means that Colombia is constructing a policy over the exploitation of genetic resources which considers that only technical and scientific contributions are worth encouraging and protecting. A more appropriate approach would be to strike a balance between Colombia's interest in constructing and supporting its scientific and technical capacity, which encompasses local researchers, and in safeguarding communities' rights. To adopt such an approach would mean that the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia and its innovation policy would be inclusive. The policy would reflect the fact that products that derive from biodiversity are not exclusively the result of research and development, defined in a techno-scientific way, but rather are also the outcome of dynamics that involve knowledge and practices from local, Afro Colombian and indigenous communities.

Having introduced the main features of Colombian access and benefit sharing regulation in the previous chapter, this chapter first carries out an analysis of Colombia's political and economic considerations in implementing the International Regime on Access to Genetic Resources and Benefit Sharing in the 1990s, and how it has tried to overcome, since the 2010s, some of the difficulties of implementing this international regime, particularly responding to concerns among local researchers (e.g. public universities and publicly funded research groups). Second, this chapter analyses in some detail how Colombia's innovation policy has also been a key aspect in benefiting and encouraging local researchers to access genetic resources, without recognising communities' contribution. Finally, this chapter studies two practical cases in which it can be observed how the recent legal and administrative changes, and the innovation policy, have led to genetic resources and communities' practices and knowledge being placed into the public domain to be freely

employed by local researchers. This part also provides insightful evidence from interviews with a local research group on how these users operate in practice within the complexities of carrying out research and development in medicinal plants, dealing with legal requirements and meeting the economic expectations of Colombian authorities. The chapter concludes by explaining why it is important to recognise and protect practices and knowledge that comes from local and indigenous communities in Colombia.

The Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing and Holders of Technology

As explained in Chapter Three, the evolution of the access and benefit sharing regulation in Colombia indicates that the country moved from a very strict and comprehensive legislation in the 1990s towards a less restrictive regulatory approach in the first two decades of the twenty-first century. The less restrictive approach facilitates access to local researchers. However, despite such a change in the tone of the legislation, there has always been an implicit assumption in the implementation of the International Regime in Colombia; that assumption is that holders of technology are only those who are capable of employing genetic resources in contributing to the processes of innovation in the country. This has occurred because Colombia has approached genetic resources and communities' practices and knowledge as a key aspect of its economic development, rather than focusing on recognising those communities' contribution in the understanding of Colombia's biodiversity for industrial applications.

At first, in the 1990s as Colombia implemented the International Regime on Access to Genetic Resources and Benefit Sharing along with other members of the Andean Community, Colombia sought to counterbalance technological disparity in sectors such as the pharmaceutical industry through the trade-off of natural resources with technology. In fact, the Andean Tribunal of Justice, in a prejudicial interpretation, points out that these policy aspects were already considered by state members, such as Colombia, even before the Andean Community discussed and enacted Decision 391, as follows:

Lack of sufficient resources for an autonomous development of the chemical and pharmaceutical industry, since, among other things, [developing countries] should import raw materials that incorporate a high technological level, these [developing] countries cannot cope with an open competition in the world market with likely possibilities to succeed. This situation 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). (Translation by the author)²¹⁸

That reasoning became a key aspect leading Colombia and other Andean countries to create a comprehensive and strict access and benefit sharing legislation in Decision 391. The Decision was expected to create a framework in which holders of technology, particularly multinational companies, and activities in R&D would be regulated with the purpose of securing benefits from the utilization of the Andean Community's biodiversity. This approach reflected the international environment at that time, in which developing countries rich in biodiversity expected that large multinational companies would turn to these countries' biodiversity to extract and synthesize single chemical compounds which would become market valuable products.²¹⁹

However, the expectations of obtaining valuable products or transfer of technology from multinational companies through the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing were not delivered. Instead the actual application of the access and benefit sharing rules brought a different panorama, which the country's legislative and institutional architecture did not anticipate. Particularly, these circumstances include: Colombian government expectations that overseas users (e.g. multinational companies) would be eager to access to genetic resources and

²¹⁸ *Prejudicial Interpretation of Articles 5 (c) and 22 of Decision 85 of the Commission of the Andean Community of Nations (1989) 7-IP-89.*

²¹⁹ For instance, the case of INBio in Costa Rica; see Richerzhagen and Holm-Mueller (n 79). For a critical perspective to this approach see: Dalton (n 82).

share benefits were not met; those who were actually interested in accessing genetic resources were local and publicly funded researchers, specifically universities and research centres; and those local researchers experienced difficulties in complying with access and benefit sharing rules.

This meant that, even though Colombia's expectation, lying behind its strict implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, was that overseas users such as multinationals would access genetic resources, official records of the Ministry of the Environment point out that those who actually accessed genetic resources were local researchers, particularly universities and research centres, which were mainly publicly funded.²²⁰ Those local researchers had neither the experience nor the resources to carry out R&D in the way that large business operates.²²¹ Since the access and benefit sharing rules in Colombia were comprehensive and strict, local researchers also lacked resources necessary to comply with the law. For instance, the National University of Colombia, the largest publicly funded university, was involved in tortuous administrative procedures that took around 12 years to obtain prior informed consent and mutually agreed terms. These aspects also demonstrate that the lack of understanding was not only the main reason why publicly funded institutions were in breach of the access and benefit sharing regulation, but also demonstrate a fragmented State in enforcing a particular regulation.²²² In fact, on one hand, the Colombian government was trying to implement and enforce the International Regime on Access to Genetic Resources and Benefit Sharing with a precarious infrastructure as the Ministry of the Environment was handling all mutually

²²⁰ Dirección de Bosques Servicios Ecosistémicos y Biodiversidad-Ministerio de Medio Ambiente, 'Seguimientos a Los Contratos de Acceso a Recurso Genéticos Marzo 2018' (2018) <http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Recursos_Genéticos_/seguimiento_EXp_CARG_Mar_2018.pdf> accessed April 7 2018.

²²¹ In fact, research and development transforms constantly to meet different stakeholders' interests. For instance, in recent time, the drug development has gone from in-house research, in which large companies cover the whole de drug development process, to a more diversified model that includes different players. In the new models, large pharmaceutical companies rely more in acquisitions, merges or licensing, rather than investing from the very beginning of the drug development process; for further information see WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade* (WTO 2013), pp 102-114

²²² Gabriel Ricardo Nemogá Soto and Dali Alexandra Rojas Díaz, 'Desencuentros Institucionales Sobre La Investigación En Diversidad Genética' (2010) 12 *Revista Colombiana de Biotecnología* 4.

agreed terms obligations through only two public servants,²²³ and, on the other hand, other actors who officially belong to the state (e.g. publicly funded universities) were in breach of the law.²²⁴

Further, this was not the only case in which public institutions clashed over the enforceability of the access and benefit sharing rules. For instance, the Technological University of Pereira filed 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.²²⁵ Although the plant species is native to the Choco/Darrien region, the university did not disclose all information related to the genetic resources employed in the invention. In fact, the Colombian patent office requested the university to comply with Decision 486 of 2000 (the Andean Patent legislation), as it requires inventions from genetic resources to disclose any information of their origin. Therefore, the university should have ensured that it obtained prior informed consent and reached mutually agreed terms with the Ministry of the Environment.²²⁶ The university responded that it had been carrying out the process of obtaining mutually agreed terms for more than three years with the Ministry of the Environment, but nothing had been decided.²²⁷ As a result of the non-compliance with Decision 486, the patent was not granted.²²⁸

Along with this difficulty of compliance and a fragmented structure of the state, local researchers such as research centres accessed genetic resources without requesting prior informed consent or negotiating mutually agreed

²²³ Ministerio de Ambiente, 'Política Nacional Para La Gestión Integral de La Biodiversidad y Sus Servicios Ecosistémicos' (2012) <http://www.humboldt.org.co/images/pdf/PNGIBSE_español_web.pdf> accessed May 4 2018.

²²⁴ Although Colombia granted to public and private universities the right of self-governance, public universities are public institutions which are subject to fiscal and disciplinary rules as any other public institution. Public university staff are also selected and evaluated by the rules of the civil servant service. Further, the directive boards of all public universities are formed by members of either central and regional governments, see Act 115 of 1994

²²⁵ Superintendencia de Industria y Comercio (SIC), *Resolution Number 3654 of June 2012* which upholds SIC, *Resolution 60646 of October 2011*

²²⁶ *Ibid.*, p 1

²²⁷ *Ibid.*, pp 2-3

²²⁸ *Ibid.*, p 6

terms. In fact, there were only 45 sets of mutually agreed terms from 1996 (the year in which Colombia implemented the International Regime on Access to Genetic Resources and Benefit Sharing) to 2012, despite the fact that during this time there was significant research activity involving those resources from local researchers.²²⁹ For instance, Chaparro et al.'s study into the research activities involving biological resources of 957 research groups registered in Colciencias in 2010 found that almost half of them involved access to genetic resources. These investigations did not comply with Colombia's access and benefit sharing rules.²³⁰

The lack of understanding of access and benefit sharing rules, and the dysfunctionality in applying those rules among public institutions, led local researchers to mobilise the demand that the government amend the law in order to facilitate access.²³¹ In response, from 2011, the government set up a different policy in White Papers such as the *Plan Nacional de Desarrollo*²³² and the 2011 *Política Nacional para la Gestión Integral de la Biodiversidad y sus Servicios Ecosistémicos*.²³³ These papers aimed to conciliate the interests of local researchers, including public institutions, and the government interest in employing genetic resources as a strategic value for economic development. As observed in Chapter Three, these reforms involved excluding local researchers from prior informed consent and mutually agreed terms

²²⁹Dirección de Censos y Demografía, 'Colombia Una Nación Multicultural' (2007) <https://www.dane.gov.co/files/censo2005/etnia/sys/colombia_nacion.pdf> accessed April 4 2018.

²³⁰ Gabriel Ricardo Nemogá Soto and Alejandro Chaparro, 'Regímenes de Propiedad Sobre Recursos Biológicos, Genéticos y Conocimiento Tradicional' (2005) 1 Series Plebio; Florelia Vallejo Trujillo, Gabriel Ricardo Nemogá Soto and Dalí Alejandra Rojas Díaz, *Guía Práctica Para El Acceso a Los Recursos Biológicos, Los Recursos Genéticos y/o Sus Productos Derivados, y El Componente Intangible* (Grupo PLEBIO-U Nacional 2009); Villar and others (n 185).

²³¹ See Gómez Lee (n 217)., pp

²³² *Plan Nacional de Desarrollo* is the political and economic guidelines of the President in Colombia; in content it is similar to Party Manifestos in the UK, but due to Colombian civil law and constitutional tradition it is treated as a binding law. See Title XII, Chapter Two of the 1991 Colombian Constitution and the 1994 Colombian Act of the National Development Plan (Ley 152 de 1994 or Ley Organica del Plan de Desarrollo); see also, Departamento Nacional de Planeación Plan Nacional de Desarrollo 2014-2018 (n 11). and Consejo Nacional de Política Económica y Social, 'Documento Conpes 3527 Política Nacional de Productividad y Competitividad' (2008) <http://www.mincit.gov.co/publicaciones/14894/politica_nacional_de_productividad_y_competitividad> accessed October 10 2017.

²³³ Ministerio de Ambiente (n 223).

obligations when such local researchers were carrying out non-commercial activities on genetic resources. Additionally, the Ministry of the Environment adjusted its administrative structure, so as to create a specific agency within the ministry charged with centralising, negotiating, and implementing mutually agreed terms in order to overcome the lack of adequate infrastructure to enforce access and benefit sharing rules. This agency is the *Dirección de Bosques Biodiversidad y Servicios Ecosistémicos-Grupo de Recursos Genéticos*. The new agency was also in charge of diffusing and providing training in access and benefit sharing rules across the country, to encourage universities and research centres to comply with the law, and build their capacity to do so.²³⁴ Also, the Ministry of the Environment set a goal of increasing capacity in the process of granting mutually agreed terms, through measures such as reducing evaluation and negotiation periods.²³⁵

Those governmental administrative measures resulted in the ministry subscribing to 37 sets of mutually agreed terms in 2013 and 20 in 2014. This indicates that the number of mutually agreed terms negotiations increased dramatically compared with the period 1996-2011, which involved only 45 sets of mutually agreed terms. Furthermore, in 2013, the ministry, in a performance and accountability report, highlighted that the average time to reach mutually agreed terms with users of genetic resources was seven months.²³⁶

Furthermore, the National Government and the Ministry of the Environment enacted Decrees 1375 and 1376 of 2013,²³⁷ and Resolution 1348 of 2014²³⁸ to clarify that non-commercial research such as collecting and sampling of genetic resources, which were the main activities carried out by local

²³⁴ Dirección de Bosques Servicios Ecosistémicos y Biodiversidad-Ministerio de Medio Ambiente, 'Acceso a Recursos Genéticos y Sus Productos Derivados En Colombia-Grupo de Recursos Genéticos' <http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Recursos_Geneticos_/Presentacion_ARG_y_sus_productos_derivados.pdf> accessed May 5 2018.

²³⁵ *ibid.*

²³⁶ Ministerio de Ambiente (n 223).

²³⁷ Further information on the content of both Decrees see Chapter Two

²³⁸ Further information on the content of this regulation see Chapter Two

researchers, require neither permission to access, nor mutually agreed terms. This regulation also states that prior informed consent is only required when both commercial and non-commercial activities access to “ethnic” (i.e. Afro-Colombian or Indigenous)’ plants. Finally, the regulation points out that if the research moved towards commercialisation, users should immediately notify the Ministry of the Environment as to reach newly mutually agreed terms.

Following these policy and legal developments, as well as the mobilisation of local researchers to demand changes in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, in 2015, Colombia gave a grace period of 2 years to local researchers who previously accessed genetic resources without prior informed consent or mutually agreed terms to be in a good standing by submitting a new application before the ministry. This amnesty was well received by users who were in breach of Colombian legislation. 170 applications were submitted during those two years, which added to the 150 sets of mutually agreed terms already signed.²³⁹

The Colombian legislation and infrastructure designed to implement the International Regime on Access to Genetic Resources and Benefit Sharing was reconfigured to meet demands of local research, including public ones. This approach indicates how open the national authorities were in responding to the concerns of local researchers, who were facing significant challenges in engaging with strict rules and in navigating a dysfunctional system within the state. However, it was not only the concerns from local researchers which led to Colombia making significant legal and administrative changes: Colombia’s innovation policy has been constructed as seeking to make the country more competitive in terms of R&D at the international level. As a result, Colombia adapted its innovation policy to comply with international standards.

Yet, those standards do not include practices and knowledge associated with

²³⁹ Those mutually agreed terms were mainly reached with universities. For instance, the National University of Colombia accounts for 87 of the 245 applications and mutually agreed terms granted in Colombia, Andes University 12 and the Antioquia University 7. Dirección de Bosques Servicios Ecosistémicos y Biodiversidad-Ministerio de Medio Ambiente (n 220).

genetic resources, which are placed into the public domain. As a result, Colombian authorities are not enforcing communities' fundamental rights, including public consultation, as mandated by Decision 391 and the Colombian constitutional system. The next sections analyse how Colombia's current innovation policy has led local researchers to actively appropriate communities' practices and knowledge without even consulting them. This part of the chapter argues that this is a violation of communities' fundamental rights.

Innovation Policy behind the Exploitation of Genetic Resources

An essential aspect to be considered in this story of Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing is how Colombian economic policies have underlined legislative and administrative transformations. When Colombia began the process of implementing the regime, the country had just embarked upon a process of profound economic reforms. These were part of what was called *Liberation* of the economy to international trade. In brief, structural reforms in the economy and trade sought to make Colombia a more competitive country. Among those structural reforms, science and technology began to have a more prominent role in the Colombian economic environment.

Economic and technological development also came along with political reforms that sought to reach populations that were previously alienated. Although Colombia has always been a culturally diverse country, its recognition as such was only given by the law as late as 1991, when a new constitution secured rights for such a diverse population, including local, indigenous, and Afro-Colombian communities. However, through its process of *Liberation*, which continues to the present day, economic development became more prominent, compared to other aspects such as social inclusion of those communities, particularly in the case of the knowledge associated with genetic resources.

Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing through the Andean Community in the 1990s took place in the context of Colombia finding a place in international trade and becoming a more socially inclusive country. As explained above,²⁴⁰ the Andean Community's approach to biodiversity is as a resource of strategic value for member countries. In that context, Colombia tried to balance the interest in employing its biodiversity for its economic and technological ambitions, and at the same time protecting traditional knowledge. However, as explained above, at first, the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing did not meet the government's expectation that overseas companies would share benefits such as transfer of technology, and thus would contribute to economic development. Nor did overseas companies engage with local, indigenous, and Afro-Colombian communities. Instead, it was local researchers who began to engage in access activities.

The interests of local researchers in accessing genetic resources and understanding communities' practices and knowledge converged with Colombia's interest in becoming a more prominent actor in international trade. Since the country signed up to free trade agreements with the US and the EU and revealed its intention to become part of other organizations such as the OECD, Colombia's scientific and technological infrastructure, including its legal and administrative infrastructure, was built in terms of becoming a key aspect of the economic development of the country as well. As Colombia initiated important investment in its scientific and technological capability, it decided to adopt a model of innovation which was related to international standards, particularly to those set up by the OECD.

Since 1992, the OECD, a club of countries (mainly developed ones) which share common policies to evaluate economic development, has published guidelines for collecting and interpreting innovation data. Known as the Oslo Manual, these guidelines mainly focus on data collected from the government,

²⁴⁰ *Prejudicial Interpretation of Articles 5 (c) and 22 of Decision 85 of the Commission of the Andean Community of Nations* (n 203).

sectors, and industries that create new products, processes, and services in a variety of areas such as information technology and biotechnology.²⁴¹ The data in the Oslo Manual primarily focuses on how the production of knowledge and information is carried out by industries. The Oslo Manual does not consider other forms of production of innovation, including traditional knowledge associated with genetic resources and local practices.

This problematic issue of what can be innovative in the light of international trade and how this approach falls short of including communities' practices and knowledge is another ramification of the complex discussion behind bioprospecting. Although a discussion on bioprospecting in general is found in Chapter Two, it needs to be contextualised in the light of Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing and its innovation policy.

Colombian Innovation Policy and Bioprospecting

Bioprospecting involves the activities of scanning and scoping of biodiversity for the collection of biological material for potential industrial application (see Chapter Two). Some actors have defended it as a way to promote sustainable use of developing countries' biodiversity on the verge of the discussions that led to the enactment of the Convention on Biological Diversity.²⁴² However, it has also been criticised as potentially disregarding the social, cultural, and economic value of both biodiversity and traditional knowledge associated with genetic resources. While supporters of bioprospecting claim that it brings benefits for those who participate in those initiatives (e.g. increasing local capability and transfer of technology),²⁴³ scholars and social activists point out

²⁴¹ OECD and Eurostat (n 216)., pp 32-41

²⁴² For further information on how researchers campaigned for bioprospecting as model of transfer of technology between global north and global south on the verge of the discussions that led to Convention on Biological Diversity see Eisner and Meinwald (n 78)., and Richerzhagen and Holm-Mueller (n 79).

²⁴³ A leading organisation in bioprospecting developing countries' biodiversity is the International Cooperative Biodiversity Groups (ICBG) (a US programme funding), which have developed bioprospecting programs in different countries including Mexico and Panama. Regarding the latter, ICBG-Panama launched a program with the aim of screening the Panamanian ecosystem and supporting the transfer of technology and knowledge. It is claimed that the project has encouraged capacity with the intention of providing Panama with

its pitfalls.²⁴⁴ In brief, it is claimed that bioprospecting is a neo-colonial phenomenon that enables the theft of biodiversity and traditional knowledge (biopiracy) (see Chapter Two).

Although the International Regime on Access to Genetic Resources and Benefit Sharing aims to address those concerns, there are other aspects, which are allegedly not being taken into account. For instance, it is claimed that the complexity of research activities leaves almost intact upstream users, who are large multinational companies (see Chapter Two).²⁴⁵ For instance, the researchers who collect genetic material or interact with communities for leads are those who comply with and follow the International Regime on Access to Genetic Resources and Benefit Sharing. Once they have collected the material or information, they hand it over to laboratories which might even be located in developed countries. In turn, laboratories might license upstream users in

high quality training and equipment to exploit its own genetic resources, but this project has not delivered a commercially new biochemical compound yet. However, since the ICBG is carrying out different projects in Panama in association with universities, museums and research centres in the US, scientists have identified within a microorganism, *Leptolyngbya*, a promising anticancer compound named Coibamide A, which is currently in preclinical trials. However, this research has not been considered yet to be a commercial research as Panama has not reported any change of intent, including on Coibamide A. Further information on the benefits of bioprospecting see: Anthony Artuso, 'Bioprospecting, Benefit Sharing, and Biotechnological Capacity Building' (2002) 30 *World Development* 1355; Kursar and others (n 78); Newman and Cragg (n 85). For the particular case of Colombia see Oscar Duarte Torres and Lea Velho, 'La Bioprospección Como Un Mecanismo de Cooperación Internacional Para Fortalecimiento de Capacidades En Ciencia y Tecnología En Colombia' (2010) 38 *Ciência da Informação*. For further information of the ICBG and Panama program see C Benjamin Naman, Christopher A Leber and William H Gerwick, 'Modern Natural Products Drug Discovery and Its Relevance to Biodiversity Conservation' in Ipeck Kurtböke (ed), *Microbial Resources: From Functional Existence in Nature to Applications* (Academic Press 2017); Jeffrey D Serrill and others, 'Coibamide A, a Natural Lariat Depsipeptide, Inhibits VEGFA/VEGFR2 Expression and Suppresses Tumor Growth in Glioblastoma Xenografts' (2016) 34 *Investigational New Drugs* 24; CBD, 'Panama: Country Profile' (*Access and Benefit-Sharing Clearing-House*, 2018) <<https://absch.cbd.int/countries/PA>> accessed February 20 2018.

²⁴⁴ Among those scholars and organization, some of the most outspoken are Vandana Shiva and the ETC Group, formerly Rural Advancement Foundation International (RAFI), see Shiva (n 108). and ETC Group, 'From Global Enclosure to Self Enclosure: Ten Years After-A Critique of the CBD and the "Bonn Guidelines" on Access and Benefit Sharing (ABS)' (2004) <www.etcgroup.org>. See also Stenton (n 100); Rachel Wynberg, 'Access and Benefit-Sharing Agreements in the Commercial Development of Hoodia' in Rachel Wynberg and Sarah Laird (eds), *Access and Benefit-Sharing in Practice: Trends in Partnerships Across Sectors* (Secretariat of the CBD Technical Series No 38 2008) <http://mddb.apec.org/Documents/2008/IPEG/SEM2/08_ipeg_sem2_015.pdf> accessed July 31 2017. For a recent analysis on discussion about biopiracy and bioprospecting see: Benjamin D Neimark, 'Bioprospecting and Biopiracy' [2017] *The International Encyclopedia of Geography: People, the Earth, Environment and Technology*.

²⁴⁵ Cloatre (n 21).

the research and development pipeline. As those who comply with the access and benefit sharing rules are the researchers who appear in the first stages, it leaves intact upstream users.²⁴⁶ However, upstream users claim that there is still lack of clarity in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries, which has led them to move away from bioprospecting.²⁴⁷

Yet, developing countries such as Colombia are increasingly interested in being competitive in terms of innovation in international markets and are reconfiguring their policy, legal, and administrative mechanisms behind the use of biodiversity. A key aspect of such an approach to innovation in developing countries is that the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, as argued in the previous section, has been reconfigured to facilitate access to local researchers and publicly funded projects. This means that, particularly in Colombia, the adoption of international standards of innovation to measure research and development is leaving unscathed local researchers in complying with the International Regime on Access to Genetic Resources and Benefit Sharing. That is why it is important to highlight the impact of Colombia's innovation policy in the bioprospecting debate.

As mentioned above, Colombia has adopted the innovation standards of the OECD. The agency in charge of implementing those guidelines is Colciencias, which embraced, in its entirety, the Oslo Manual for the approach adopted for evaluation and collection of data related to innovation in Colombia. Since Colciencias is the national organization that supervises and allocates resources to publicly funded universities and research centres, it becomes critical to local researchers to meet those OSLO Manual standards.

²⁴⁶ There are even sectorial reports that illustrates this point as they blame that the implementation of the Nagoya Protocol, which is part of the International Regime on Access to Genetic Resources and Benefit Sharing, has imposed the economic and logistic burden of the ABS Regulation in downstream users see Kang, Jung and Ryu (n 139); Bart Van Vooren, 'Impact on the Food Industry of New EU Rules Implementing the Nagoya Protocol' (2016) 3 European Food and Feed Law Review (EFFL) 220.

²⁴⁷ It is reported that large pharmaceutical companies have closed their natural products research division because of the International Regime on Access to Genetic Resources and Benefit Sharing, see for instance: Cragg and others (n 85); Neimark (n 244).

As a result, the government addresses resources to universities and research centres who carry out R&D activities according to the Oslo Manual. Since Colciencias is the leading scientific agency in the government, its primary focus is on increasing innovation in sectors and industries that are considered to be innovative, such as biotechnology. This has resulted in an agency that supports, for example, PhD and Masters students in science-related fields, as well as providing economic resources directly to universities. This administrative department also created different programmes and established 'lines of action' in areas related to biotechnology through the National Biotechnology Program. At present, the Colciencias' ScienTI Network has identified approximately 108 research groups registered, most of them based within universities, which cover different areas including human health. Likewise, Colciencias prompted the creation of the Centre for Bioinformatics and Computational Biology and the National Centre for Genomic Sequencing (CNSG) which serves to increase the country's scientific and technological capability. Similarly, Colciencias promoted the creation of technology parks where different actors (such as guilds, universities, and local and national authorities) come together to encourage the use of biotechnology in different sectors. Examples of these are Ruta N in Medellín, BioPacífico in Valle del Cauca and the National Research Centre for Agroindustrialization of Tropical Medicinal Aromatic Plant Species in Santander (CENIVAM).²⁴⁸

Turning this discussion to the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, the national government sought to ease the implementation of the regime in respect of local researchers such as publicly funded universities and research centres, so they could employ genetic resources in the improvement of Colombian scientific and technological capacities according to Colciencias' policies. In addition, in a 2011 White Paper, the Colombian government highlighted the importance of incentivising bioprospecting among local researchers as part of its strategy to

²⁴⁸Colciencias, 'History of Colciencias' (2018) <<http://www.colciencias.gov.co/node/94>> accessed 5 May 2018. Colciencias, 'Programa Nacional En Biotecnología' <<http://www.colciencias.gov.co/node/1133>> accessed October 31 2017. BIOS, 'Centro de Bioinformática y Biología Computacional' <<http://www.bios.co/>> accessed October 31 2017.

increase its national R&D capacity.²⁴⁹ The government also requested the National Planning Department (NDP), which is the national agency that elaborates the economic plan for the state, to assess the technical viability of establishing the first national bioprospecting company (*Empresa Nacional de Bioprospección*).²⁵⁰ Although at this time the NDP has not assessed whether it is recommended to create such a publicly funded entity, Colciencias has already addressed around USD 165 million to create scientific and technological infrastructure in Bogotá for bioprospecting Colombian natural products for health research and health industry, known as PhairiLab.²⁵¹ The economic resources are just beginning to be spent in the construction of facilities and laboratories in the capital of the country, which means that access to genetic resources activities have not begun yet. However, during the whole process to date, there has not been a single mention of whether communities are to be publicly consulted when access to medicinal plants takes place. This aspect of the International Regime on Access to Genetic Resources and Benefit Sharing is absent from Colombian governmental policy.

The increasing public expenditure in R&D capacity in the country, the policy papers that sought to place biodiversity as a key aspect of increasing Colombian research and development capacity, and the different measures that facilitate access, all demonstrate the focus of Colombian policies. These policies make genetic resources of “strategic value” to health research and health industry. This framing has led the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing towards an unbalanced legislation that only considers the contribution of holders of technology, either local or overseas users, where that contribution adds value to the use of biodiversity innovation.

²⁴⁹ Consejo Nacional de Política Económica y Social, ‘Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad’ (n 14). p 28

²⁵⁰ *ibid.*

²⁵¹ Secretaría de Planeación de Bogotá, ‘Implementación de La Plataforma Científica y Tecnológica Para La Obtención de Fitomedicamentos Antitumorales Con Estándares Internacionales Bogotá D.C. | Regalías Bogotá’ (*Regalía Bogotá Región e Innovación*, 2018) <<http://regaliasbogota.sdp.gov.co:8080/regalias/portfolio/implementación-de-la-plataforma-científica-y-tecnológica-para-la-obtención-de>> accessed November 11 2018.

Although this approach could have a noble intention of encouraging local researchers to access genetic resources and increase the country's scientific capacity, in practice this innovation policy has placed into the public domain the knowledge and practices of those who provide "leads" in the understanding of biodiversity for the health industry. As a result, Colombia's innovation policy goes against those constitutional and regional mandates that demand inclusion of communities in the decision-making process when their practices and knowledge have been or will be employed by users. This situation can be exemplified in the cases of the native plants Dividivi (*Caesalpinia spinosa*) and the Anamú (*Petiveria alliacea*). Both cases are studied in detail in the next section.

[From Public to Private: The Cases of the Dividivi and Anamú in Colombia](#)

Since Colombia opened its economy, it has built an important scientific and technological infrastructure which follows international standards of innovation, particularly those established by the OECD's Oslo Manual. An important aspect for Colombia in terms of innovations has been R&D activities from local researchers.

The government has recently enacted regulations that have eased the strict rules of Decision 391 with the aim of encouraging local researchers to access genetic resources. However, as has been discussed throughout this chapter, these governmental efforts are in contradiction with the Andean legislation and the Constitutional Court mandates on protecting communities' practices and knowledge. This situation can be characterized with two cases involving two different plants (Dividivi and Anamú), and an immunobiology research group based at the Javeriana University of Colombia, who have worked for more than two decades with Colombia's medicinal plants to treat cancer. This section brings the testimony of the members of the research group through a series of interviews which evidence how research on two medicinal plants involves different legal, scientific, technological and, even, personal complexities, which are very challenging to encapsulate in a particular legal,

administrative or policy framework. Yet, the evidence collected in the interviews also demonstrates how important it is to consider researchers' own experiences with medicinal plants in the construction of any framework that implements the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia.

That is the case, for instance, of the lead researcher of the Javeriana Group, Professor Susana Fiorentino, who has experienced a long professional relationship with both medicinal plants. As will be observed, Fiorentino's work has led her to travel around the country experiencing different dynamics concerning medicinal plants. Her research has also allowed her to build an accomplished scientific career over two decades,²⁵² as well as to navigate the changing legal, administrative and policy landscape of the International Regime on Access to Genetic Resources and Benefit Sharing Regulation and innovation policy in Colombia over the years.

In addition, Fiorentino's work has had a profound impact in her own *personal* life. In particular, her husband, Javier Barnier, who is in the business of producing, promoting, exporting and importing agricultural products, has closely accompanied and advised Fiorentino's personal and professional journey in the field of natural products for medicinal applications. The professional and personal aspects of Fiorentino's story are difficult (or perhaps impossible) to disentangle.

Furthermore, Professor Fiorentino's influence and significance extends beyond her own career. In particular, Fiorentino's approach in Colombia to medicinal plants is a constant inspiration for other members of her research group, such as Claudia Urueña and Wilmar Olaya. These are the senior researchers of the future in Colombia. All those dynamics and complexities, and more, are studied in detail in the following sections.

²⁵² Professor Fiorentino has published a large amount of scientific papers, obtained different awards and recognition, from a great deal of PhD and Master students. See Fiorentino's CV at https://scienti.colciencias.gov.co/cvlac/visualizador/generarCurriculoCv.do?cod_rh=0000267732

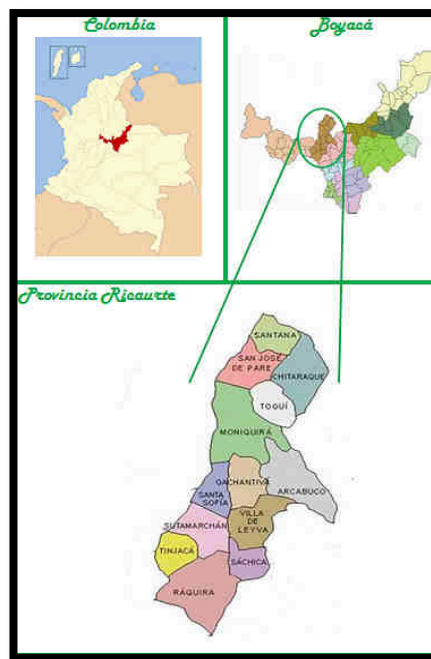
Researchers Wilmar Olaya (left) and Claudia Urueña (right) at the Immunology lab in the Javeriana University. Picture taken by the author.



Spouses Javier Barnier (Left) and Professor Susana Fiorentino (Right) at their home. Picture taken by the author.

The Dividivi

The Dividivi (*Caesalpinia spinosa*) has had a long-standing close relationship with the inhabitants of the *Ricuarite* in the region of Boyacá (see Map 1). The plant has not only been employed by local communities of peasants (*campesinos*) in the region to treat tonsillitis, sinusitis, and bronchitis, among other conditions, because of its qualities as anti-inflammatory, astringent, and disinfectant,²⁵³ but it was also a significant source of revenue for the region as the seed of the plant was employed for leatherworking in countries such as the United States. Mr. Wilmar Olaya highlights that such activity is something that the local community in the region hardly remember



Map 1. Source: <http://www.boyacacultural.com/>

“as an useful products for leatherworking” (Translation by the author).²⁵⁴ This is because the plant was substituted by a laboratory-made component known as Chromo VII, which eventually led the leather industry to abandon the crop production of the Dividivi.²⁵⁵

However, the plant’s usefulness for inhabitants of *Ricuarite* did not disappear because of the lost interest from the leather industry. The community of *campesinos* continued employing Dividivi as a medicinal plant. Before the plant was collected and identified by ethnobotany researchers in 2007, records illustrate that the Dividivi had been employed as a medicinal plant by those

²⁵³ Vanessa Molina Medina, ‘La Revolución de Los Fitomedicamentos’ (*Pequisa Javeriana*, 2010) December <<http://www.javeriana.edu.co/pesquisa/la-revolucion-de-los-fitomedicamentos/>> accessed May 3 2018.

²⁵⁴ Original transcription in Spanish: “como productos útiles para la peletería”. Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

²⁵⁵ For further information on the economic and ecologic impact of the *Dividivi* as plant employed by the leather industry see Joaquín Molano Barrero, ‘Villa de Leiva: Ensayo de Interpretación Social de Una Catástrofe Ecológica’ (Fondo FEN Colombia 1990).

communities before Spanish colonization.²⁵⁶ Through those ethnobotanical studies of the plant, in 2012, the Javeriana research group noticed that the uses of the biochemical properties of the plant could have other potential uses in medicine.²⁵⁷

In particular, the anti-inflammatory quality of the plant was of great interest for the Javeriana research group because of its potential use in the treatment of cancer. Consequently, this research group, which had received public funding from Colciencias for carrying out the research, reached mutually agreed terms with the Ministry of the Environment for non-commercial research, and, consequently, published several scientific papers including one that identified that the plant possessed acid gallic, one of the bioactive components responsible for its therapeutic activity.²⁵⁸ The research group did not focus on the specific *uses* given by the communities, but on the biochemical *qualities* of the plant itself. Those qualities led the research group to identify and extract a natural fraction from the plant, which in combination with conventional chemotherapy and other natural products, increases therapeutic effectiveness in the treatment of cancer.²⁵⁹

Thus, the information collected from the communities from *Ricaurte* did not include knowledge that the plant had a potential use *in the treatment of cancer*. Rather, the community's practices and knowledge associated with the plant – for treating other illnesses – led the Javeriana research group to identify specific qualities of the plant to treat cancer. Dr Claudia Ureaña, a researcher in this group, explains how communities' uses of the plant is a lead to find the potential biochemical qualities for the treatment of cancer:

[C]learly communities do not say 'we have used [the plants] for cancer', [...] they have been used [by communities] because they have

²⁵⁶ Diana M Castañeda and others, 'A Gallotannin-Rich Fraction from *Caesalpinia Spinosa* (Molina) Kuntze Displays Cytotoxic Activity and Raises Sensitivity to Doxorubicin in a Leukemia Cell Line.' (2012) 12 BMC complementary and alternative medicine 38., p 2

²⁵⁷ *ibid.*, p 2

²⁵⁸ Tito A Sandoval and others, 'Standardized Extract from *Caesalpinia Spinosa* Is Cytotoxic Over Cancer Stem Cells and Enhance Anticancer Activity of Doxorubicin' (2016) 44 The American Journal of Chinese Medicine 1693., pp 1702-1708

²⁵⁹ Dirección de Bosques Servicios Ecosistémicos y Biodiversidad-Ministerio de Medio Ambiente (n 220).

*microbial or anti-inflammatory activity, others because they have hypoglycemic activity [...] knowing that cancer is a chronic inflammation process, if I have a possible plant that people use as an anti-inflammatory, why not think that this plant can have an effect on a chronic inflammatory disease like cancer, [...], or the fact that [the plant] has a hypoglycemic activity, [we have] the knowledge that tumor cells consume a lot of glucose so I have something that decreases the uptake of that glucose, that could have an effect on the tumor area.*²⁶⁰ (Translation by the author)

This view is an aspect of the Javeriana research group's approach that is shared by the other members of the research group. For instance, Mr. Olaya highlights that communities “do not refer [the research group] directly to cancer treatment [...] but that [anti-inflammatory] characteristic powerfully drew the attention of the research group and, from there, it was developed everything that we have discovered” (Translation by the author).²⁶¹ In a similar perspective, Professor Fiorentino explains that the dissimilarities of communities' practice and knowledge, and research and development in her field is not something that she has experienced exclusively with the *Dividivi*. She exemplifies this point by recounting her experience with the *Cogui* community, an indigenous community located in la *Sierra Nevada de Santa Marta* (North of Colombia) (see Map 2), and communities in the region of Amazon. First, Florentino mentions visiting the *Sierra Nevada*, where she had the opportunity to inquire of the *Cogui* community about medicinal plants

²⁶⁰ Original transcription in Spanish: “claramente no dicen las comunidades ‘nosotros lo hemos utilizado para cáncer’, [...], unas sea han utilizado [por parte de las comunidades] porque tienen actividad microbiana o antiinflamatoria, otras porque tienen actividad hipoglucemiante” [...] sabiendo que el cáncer es un proceso de inflamación crónica, si tengo una posible planta que la gente utiliza como un antiinflamatorio porque no pensar que esta planta pueda tener efecto en una enfermedad inflamatoria crónica como lo que es el cáncer, entonces digamos, o el hecho que [la planta] tiene una actividad hipoglucemiante, [nosotros tenemos] el conocimiento que las células tumorales consumen mucha glucosa entonces yo tengo algo que disminuya la captación de esa glucosa, podría tener efecto sobre la zona tumoral” Interview with Claudia Urueña, Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

²⁶¹ Original transcription in Spanish: “no hacen alusión directa al tratamiento del cáncer” “pero esa característica [antiinflamatoria] llamó poderosamente la atención del grupo de investigación y desde ahí se desarrolló todo lo que hemos venido descubriendo” Interview with Claudia Urueña, Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

used for the treatment of cancer. She points out that this community consider some plants such as the *Anamu* as “a magical plant that cures everything. But specifically, cancer, [the community] did not have much knowledge, because they have no idea what cancer is”.²⁶² Second, the Professor confirms her empirical evidence in the Amazon when visiting “a guy who knew a *jurgo*²⁶³ of plants” as this person explained to her in general terms what the medicinal plants



Map 2: Sierra Nevada de Santa Marta.
Source: Google Maps

were for, including the ‘woman’s disease’, which might be a reference to cancer. However, according to Florentino, “the guy” never mentioned that the plant was used for cancer because he does not “know what cancer is”.²⁶⁴

These testimonies are evidence of the difficulties in a legal approach that includes protecting practices and knowledge from communities that are used in any research and development process. Communities’ practices and knowledge are considered to be mere “leads”, and only “useful” (hence, valuable in an economic sense, and to be protected) in the context of the knowledge (here, about cancer) of the researcher. The researchers’ views suggest no sense of improper exploitation or breach of communities’ rights: to them, the value-added is the knowledge of the researchers, which is incommensurable with the type of knowledge held in local communities. To underline this insight, on being questioned whether communities’ uses of medicinal could be considered innovative or be understood as involved in, or part of, research and development activities, all three researchers (Florentino, Olaya and Urueña) and Javier Barnier answered: No. Mr. Olaya, in particular,

²⁶² Original transcript in Spanish: “para ellos [los Cogui] el Anamú es una planta mágica que cura todo, pero pues específicamente el cáncer no tenían mucho conocimiento, porque no tienen ni idea que es el cáncer” Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

²⁶³ A colloquial term to say a lot. Ibid.

²⁶⁴ Ibid.

was emphatic in explaining that, in his view, innovation in health research could not dwell in communities' practices and knowledge, because it was "science" which actually transforms those uses into products. As he explains: "the innovation lies in the possibility of taking all these resources [Colombia's biodiversity and communities' practices and knowledge] and making them useful for society" (Translation by the author).²⁶⁵ This interpretation of knowledge and usefulness shows that the Colombian policy on innovation, which recognizes and benefits well-established sectors in the market (e.g. the Internet, biotechnology or services), has also an echo in the views and understandings of researchers who work with medicinal plants in Colombia. This interpretation could potentially involve a clash with Constitutional Court rulings, international and regional agreements regarding the rights of communities over their practices associated with medicinal plants (see Chapters 2 and 3).

However, the interviews with the Javeriana research group's members also indicated that their approach to health research in medicinal plants is lawful and compliant with the relevant Constitutional Court rulings and regional/international agreements. As Mr. Olaya was questioned about how the research group obtained the information related to the medicinal characteristics of the *Dividivi*, he was consistent in stressing that the group works on "public knowledge" rather than traditional knowledge or practices. According to Mr. Olaya, the group acquired the information on the anti-inflammatory characteristic of the *Dividivi* from different sources which are in line with Colombia's legislation:

[D]igging into a plant, about its presence in the territories and knowing not only from the communities; but we also use other sources of information for example: patients in hospitals, surveys, in which patients are consulted on what plants have been suggested to them, how the information has come to them: if by voice-to-voice, consulted

²⁶⁵ Original transcript in Spanish "la innovación esta en poder en tomar todos estos recursos [biodiversidad colombiana, y practicas y conocimiento de las comunidades] y convertirlo en algo útil para la sociedad" Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

a website, or by the experience of a case in the family. (Translation by the author) ²⁶⁶

At first glance, this statement could indicate that the research group might be in direct conflict with the Decision 391 of the Andean Community, and the rulings of the Constitutional Court (see Chapters 2 and 3). The research group, according to Mr. Olaya ‘digs into’ information about the plant ‘from the communities’. But the information search does not stop there: it includes asking patients about their experiences, including interacting with non-traditional, non-indigenous information sources, such as the internet. The Javeriana group’s approach is more complex than mere exploitation and obvious breach of the law suggest. Rather, the interview data indicates that local researchers face a more difficult legal landscape, as the Colombian authorities are pursuing different agendas that clash with each other.

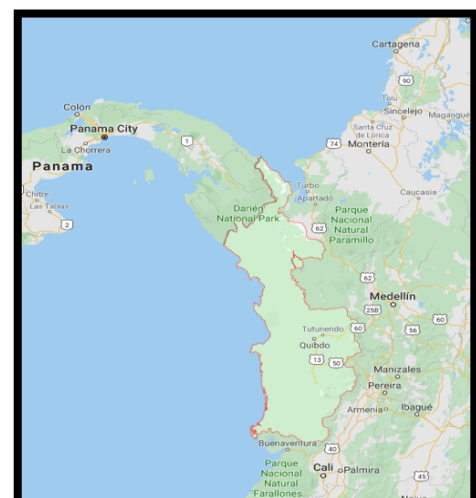
As explained above, the economic agenda to meet global markets’ interests pulls in direct confrontation with international commitments and local constitutional obligations to respect communities’ fundamental rights. In fact, although Decision 391 and constitutional precedents regarding local communities’ right to be consulted appear to be breached by the Javeriana research group, the research group is not in breach of the Resolution 1348 of 2014 of the Ministry of Environment (see Chapter Three). This is, it will be recalled, the Resolution that implements the Andean Decision in Colombia. This administrative regulation establishes that prior informed consent is required when there is presence of ethnic groups, meaning communities that are distinguished by their ethnicity and race such as indigenous or Afro-Colombian people. In the particular case of the Dividivi, there is no presence of ethnic communities in the *Ricaurte*, nor relationship between indigenous or Afro-Colombian people and the plant; it is rather the local community of *Campesinos* which have interacted with the plant in different ways, from the

²⁶⁶ Original transcript in Spanish: “indagar sobre una planta, sobre su presencia en los territorios conocer no solo de mano de las comunidades” sino que echamos mano de otras fuentes de información, por ejemplo: pacientes en los hospitales” “encuestas donde se consultan a los pacientes que plantas les han sugerido “como ha llegado la información a ellos si por el voz a voz, consultado una pagina de internet, o por la experiencia de un caso en la familia”.Ibid.

use as a material for leatherworking to medicinal uses. As noted above, it was the latter that led the Javeriana research group to the anti-inflammatory characteristics of the plant.

The issue of different local researchers' approach to different communities depending on their ethnic background was also mentioned in the interview with Professor Fiorentino. She was emphatic in declaring that her research group worked only in plants, including the *Dividivi*, "that are not anywhere near where there are indigenous communities; a thing that doesn't seem very *chevere*,²⁶⁷ but we did it even on the recommendation of the Ministry [of Environment]" (Translation by the Author). As can be observed, it is the very administrative authority which oversees the enforceability of the access and benefit sharing regulation in Colombia which recommends local researchers not to include indigenous and Afro-Colombian communities in innovative processes. This can, of course, be seen as securing compliance with the law: if the research group does not include indigenous and Afro-Colombian communities, then it does not breach their fundamental rights.

To explore this further, it was appropriate to ask Professor Fiorentino in the course of the interview why her research group finds it difficult to work with indigenous and Afro-Colombian communities, but not so with local communities. In response, she brought two examples from her experience. First, her research group "wanted to approach for the first time the fair and equitable distribution of resources [i.e. benefit sharing] with [ethnic] communities" as they found "plants that interested [them] in the Choco, and



Map 3 Department of Choco. Source: Google Maps

²⁶⁷ A local expression that means "cool" or nice. Original transcript in Spanish: "no se encuentran en ningún sitio donde haya comunidades indígenas; cosa que no parece muy *chévere*, pero lo hicimos incluso por recomendación del ministerio" Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

[they] had to make public consultation" (Translation by the author).²⁶⁸ Choco is a department in the east part of Colombia (see Map 3) where Afro-Colombians are the majority, in contrast with the rest of the country.²⁶⁹ The department is one of the most biodiverse regions of Colombia, but it is also one of the poorest and more violence-affected regions in the country.²⁷⁰ As the research group tried to carry out the required prior consultation, it found that the process was like "the one who wants to sell a house" (Translation by the author),²⁷¹ meaning that from the point of view of Professor Fiorentino, communities tend to bargain for access to their plants in merely economic terms without considering technical and scientific complexities. Despite the fact that the research group found it difficult to reach out to the community, the group still wanted to pursue access to those plants. Consequently, they decided to outsource the process of prior consultation to a specialized company; but, it turned out that the price asked was 400 million pesos, approximately 125,000 USD. As a result, Professor Fiorentino declined the offer, or in her own words: "I told them, go to the *Cuerno*".²⁷²

Second, Professor Fiorentino also pursued the use of medicinal plants from indigenous communities, the *Kamëntsa*, *Ingas* and *Quillacingas*,²⁷³ in the *Valle del Sibundoy*, located in the department of Putumayo in the region of the

²⁶⁸ Original transcript in Spanish "nos quisimos aproximar por primera vez a la distribución justa y equitativa de los recursos [con comunidades]" "Había una de las plantas que nos interesaba en el Choco, y nos tocaba hacer consulta previa". Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

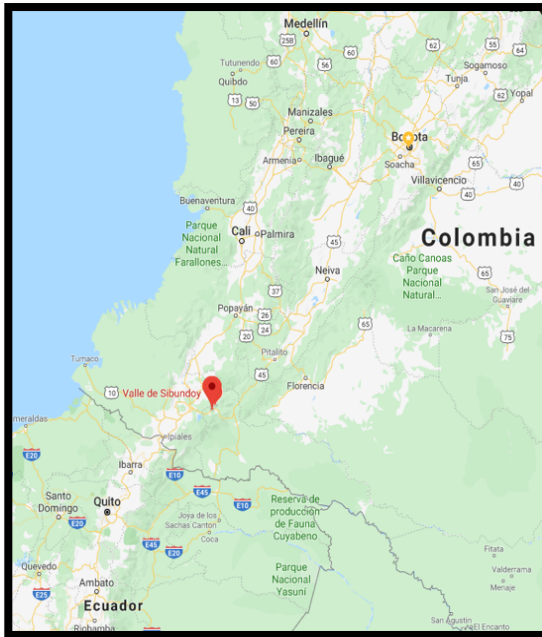
²⁶⁹ According to the national department of statistics (DANE, Spanish acronym), the 85.94% of the general Colombian population is not ethnic related, while 10.62% is Afro-Colombian. In contrast, in Choco, the Afro-Colombian population is 82.12 %. This indicates a clear geographical segregation of Afro-decedents in the country. This is more prominent in Bogotá, where the main structure of power (central government), wealth (e.g. companies) and education such as universities are located, whose general population is 98.27 %, and Afro-Colombians are only 1.49 %. Dirección de Censos y Demografía (n 229)., p 38

²⁷⁰ Luis Armando Galvis-Aponte and others, 'La Persistencia de La Pobreza En El Pacífico Colombiano y Sus Factores Asociados' [2016] Documentos de Trabajo Sobre Economía Regional y Urbana; No. 238.

²⁷¹ Original transcript in Spanish: "el que quiere vender una casa". Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

²⁷² It is a Colloquial expression which its English equivalent would be "go to hell". Ibid.

²⁷³ For further information on indigenous communities in the *Valle del Sibundoy* and medicinal plants see John James Rodríguez-Echeverry, 'Uso y Manejo Tradicional de Plantas Medicinales y Mágicas En El Valle de Sibundoy, Alto Putumayo, y Su Relación Con Procesos Locales de Construcción Ambiental' (2010) 34 Rev. Acad. Colomb. Cienc 309.



Map 4: Valle del Sibundoy (Putumayo): Source Google Maps

Amazon (See Map 4). Putumayo, like Choco, is a very distant territory from the main urban centers of the country (e.g. Bogotá, Medellín, Cali and Barranquilla). It is also an underdeveloped area with a long history of violence.²⁷⁴ Professor Fiorentino explains how the research group found out about those communities and their relationship with the plants:

I had a student from the Valle del Sibundoy, her dad was a Mamo²⁷⁵ of the Putumayo, and we were going to work with the plants there [Valle del Sibundoy]. When we started talking to him [the Mamo], he came to college in featherdress one day, and asking me to pay him for the information, and I said no, because we're going to build a project where you're going to win. (Translation by the author)²⁷⁶

Professor Fiorentino's expressions and words such as *go to the Cuerno* and *featherdress*, the latter used by Colombian to singularize indigenous people typical dress, denote a clear frustration on her part concerning the difficulties in even establishing a dialogue with ethnic and racial communities on the use

²⁷⁴ In the history of violence and poverty of Putumayo converged different actors and phenomes of the Colombian armed conflict, including paramilitary groups, guerrilla, drug trafficking and border tensions with the Ecuador. Further information see: Salomón Cuesta Zapata and Patricio Trujillo Montalvo, 'La Frontera de Fronteras: Putumayo: Violencia, Narcotráfico y Guerrilla'; Laura González, 'Capítulo III Seguridad Ciudadana y Seguridad Nacional En La Frontera Colombo-Ecuatoriana: Estado Del Arte de Investigaciones Producidas Entre Los Años 2000-2010' [2012] *Violencia y seguridad ciudadana: algunas reflexiones* 195.

²⁷⁵ *Mamo* is a Chaman who possess the traditional knowledge regarding the use medicinal plants

²⁷⁶ Original transcript in Spanish: "yo tuve una estudiante del Valle del Sibundoy, el papa era un Mamo del putumayo, e íbamos a trabajar con las plantas de allá [Valle del Sibundoy]. Cuando comenzamos a hablar con él [el mamo], llego un día a la universidad vestido de plumas, y pidiéndome que le pagara por la información, y yo le dije no, es que vamos a construir un proyecto donde ustedes van a ganar". Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

of medicinal plants. Her interview data evidences how both parties have widely different perspectives and expectations on the use of medicinal plants for health research and the health industry. The case of the *Mamo*, as recounted by Fiorentino, illustrates that is difficult to create a dialogue on how benefit sharing could take place, as Fiorentino was expecting to construct a long-term project based upon medicinal plants and traditional knowledge, while *the Mamo* was expecting to get an upfront payment. Equally, the failed project in the Choco also indicates how difficult it may be for a research group to find an interlocutor between communities and researchers to carry out the process of publicly consulting communities.

Those experiences, according to my interviewees, led the research group to work with wild plants or cultivable plants and local communities instead. Fiorentino expresses such a desire to work with local communities of peasants (*campesinos*) as follows: “there are other communities that are peasants, and those communities are different” (Translated by the author)²⁷⁷ from ethnic communities. The reason it is different working with these communities is not only because it is not required to obtain prior informed consent, but it is also the fact that *campesino’s* expertise and experience on working in agriculture fit within Professor Fiorentino’s (and, her husband, Javier Barnier’s) vision on how share the benefits of the use of medicinal plants.

In this point, Mr. Barnier’s own experience as a producer, distributor, promoter, importer and exporter of agriculture products for food consumption becomes a key aspect to understand how Professor Fiorentino aims to create a model of benefit sharing with the *campesinos* of *Ricaurte* and the use of the medicinal plant *Dividivi*.

Asking Mr. Barnier about his input in the research on the *Dividivi*, he points out that he supplies the actual biological material, i.e. the plant itself, for the laboratory. In particular, he explains that he brought a well-known technology in Europe to Colombia to tackle the problem of a very low germination in agriculture products such as the tomato, which occurred because “there were

²⁷⁷ Original transcript in Spanish: “hay otras comunidades que son los campesinos, y esas comunidades son diferentes”. Ibid.

no criteria of seed taking” (Translation by the author) resulting in using non-mature seeds which resulted in a 30% germination ratio.²⁷⁸

Mr. Barnier indicated that he was “the first to bring the technology from France to produce young seedlings with a material that is the *peat*, which is a material, an aseptic extract, with very good characteristics”²⁷⁹ (Translation by the author) employed in different harvests such as tomatoes. The use of the *peat*²⁸⁰ has led them to “obtain 80% germinations”. Taking this technology into medicinal plants such as *Dividivi* and *Anamú*, he adds that “producing seedlings in alveolate trays which have as substrate the *peat*, this is how we can reproduce and even manage to sell 20 million seedlings a year of tomato, and in the same way we could produce both the *Dividivi* and *Anamú* with very good quality of seedling” (Translation by the author).²⁸¹ He also points out that they have already created a “seed bank, thinking ahead when they [the research group] start working as such and need to make farms dedicated to the production of the drug” (Translation by the author).²⁸²

This idea of eventually escalating the production of the *Dividivi* in *Ricaurte* necessarily required *campesinos* to cultivate the plant. Efforts are underway, which, in the words of Professor Fiorentino, involve selling to the *campesinos* the plant “for a representative value” which she estimates could vary between 800 to 1000 pesos (approximately 0.30 USD) and “teach[ing] them to grow [the plant] so as to place it as hedgerow or to put it next to other crops and

²⁷⁸ Original transcript in Spanish: “no había unos criterios de la toma de la semilla”. Interview with Javier Barnier, Agronomist Administrator and Entrepreneur, (Bogotá, Colombia, 1st October 2019)

²⁷⁹ Original transcript in Spanish: “yo fui el primero en traer la tecnología de Francia para producir plántulas jóvenes con un material que es la turba, que es un material un extracto aséptico con unas características muy buenas”. Ibid.

²⁸⁰ Mr. Barnier explains that the peat is “is a biological material for the decomposition of forests in northern and southern areas, such as Patagonia, Finland, Norway, the Baltic countries, Canada”. Original transcript: “es un material biológico de descomposición de bosques de zonas nórdicas y sureñas, como son la Patagonia, Finlandia, Noruega, países bálticos, Canadá”. Ibid.

²⁸¹ Original transcript in Spanish: “producir plántulas en bandejas alveoladas como sustrato la Turba, es así como podemos reproducir y inclusive llegar hasta vender 20 millones de plántulas al año de tomate, y de la misma manera podríamos producir tanto el dividivi como el Anamú con muy buena calidad de plantulación”. Ibid.

²⁸² Original transcript in Spanish: “tenemos un banco de semillas pensando en el momento en que empiecen el medicamento a funcionar como tal y se necesiten hacer unas explotaciones dedicadas a la producción del medicamento”. Ibid.

everything, and gradually repopulate the Dividivi; and we would buy the material for now” (Translation by the author).²⁸³ Ideally, Professor Fiorentino aims to use blockchain, a technology that will permit that “as soon as a final product is sold, at once, the benefits are distributed to each of the members of the production chain” (Translation by the author).²⁸⁴ Although Fiorentino acknowledges that the use of blockchain is still hypothetical, due to difficulties in implementing the technology, she believes that by creating a *production chain* everyone would win, from the *campesino* to the final product seller.

However, the interview data shows that the Javeriana research group have not defined the mechanism through which the community as such would benefit. This is because the research group filed and obtained a non-commercial set of mutually agreed terms with the Ministry of the Environment in 2013.²⁸⁵ Hence they are not required by the national authority to set up benefit sharing with the communities, unless they actually commercialise a final product. Nonetheless, even they are not legally obliged to do so at this stage, the Javeriana group is currently working with the Ministry of Environment to secure benefits for the community of *Ricaurte* such as improving schools, land, or training programs on agricultural practices, in the event that a final product is commercialized. Again, therefore, a simplistic story of exploitation and creative compliance with a sub-optimal national legal regime which leaves communities’ rights under-protected is revealed to be more complex than it seems.

In the light of this market-based perspective that mainly involves a “production chain”, it was important to ask Professor Fiorentino about potential risks and challenges to her proposed model of benefit sharing.

²⁸³ Original transcript in Spanish: “enseñarles a cultivarlas para que pongan como cerca vivas, para que la pongan al lado de otros cultivos y todo, y poco a poco se vaya repoblando el Dividivi, y nosotros les compramos el material por ahora”. Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

²⁸⁴ Original transcript in Spanish: “tan pronto se venda un producto final, de una vez se distribuyan los beneficios a cada uno de los miembros de la cadena productiva”. Ibid.

²⁸⁵ See the mutually agreed terms at Ministerio de Medio Ambiente, ‘Contrato de Acceso a Recursos Genéticos y/o Productos Derivados Para Investigación Científica Sin Interés Comercial No. 60 Ministerio de Ambiente y Susana Fiorentina Gomez’ 8 <<https://drive.google.com/file/d/1I5wjzTjeS8VRGMS16LdEAagMIfEe542D/view>> accessed June 5 2018.

Particularly, two questions were raised: (i) what would occur in the hypothetical case that the local community of *Ricaurte* would not accept the offer to participate in Fiorentino's proposed model of production of the plant; and (ii) whether the upcoming of new technologies such as synthetic biology or gene editing could eventually lead to production directly from the actual genetic resources, leaving *campesinos* out of the production chain. As analysed in Chapter Two, one of the current issues in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing is whether technologies that aim to reproduce in laboratories the functionalities of any genetic material would reduce the necessity to access the actual genetic resources and traditional knowledge.

Regarding the first question, Professor Fiorentino and Mr. Barnier were rather skeptical and reluctant to even consider that *campesinos* would oppose growing the plant or participating in any benefit sharing agreement. Pressing on the question, they become rather pragmatic as they said: “don't sell it, Peru sells it, that's why we've already studied it” (Translation by the author).²⁸⁶ In fact, Peru, another member of the Andean Community, is the largest producer of the Dividivi in the world (Peruvians called *Tara*) for leatherworking. This means that the research group could easily, without breaching Decision 391, access the plant in a neighboring country in the event that their proposed model of production is not accepted by local Colombian communities.

On the second question, Professor Fiorentino was confident that technologies such synthetic biology are rather allies than a threat to natural production. This is “because what synthetic biology does is to understand organisms from their complexity. With the dream of being able to reproduce” (Translation by the author).²⁸⁷ This is a dream that is far from fulfilled according to Fiorentino, but it “helps to understand how the disease acts in response to complex plants”

²⁸⁶ Original transcript in Spanish: “no la vendan, Perú la vende, ya por eso nosotros la estudiamos” Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

²⁸⁷ Original transcript in Spanish: “la biología sintética al día de hoy es nuestro mejor aliado, porque lo que hace la biología sintética es entender los organismos desde su complejidad. Con el sueño de poder reproducir”. Ibid.

(Translation by the author).²⁸⁸ The reason why it is so important to understand the complexity of medicinal plants through new technologies such as synthetic biology is because as the plants is complex, diseases such as cancer are equally complex. This is the case of the *Dividivi*, whose therapeutic activity cannot be singularized to one specific molecule, and the cancer, whose symptoms and manifestation in the human body are not a single disorder.

The research group has found that the plant has at least 150 molecules, and each of those molecules is in “a different concentration from the other” (Translation by the author),²⁸⁹ therefore, the research group always aim to get the same extract, hence the final medical product is always 150 molecules. This product has to be tested against cancer patients.

Continuing with her example, Prof. Fiorentino explains patiently that, as there is an inherent complexity in the plant, “the synthetic biology for the sake of doing what the pharmaceutical industry is doing, which is mixing [different] molecules, [...] allows us to understand how the complexity of a plant can improve [and] return the balance to the cancer patient” (Translation by the author).²⁹⁰ She continues with her explanation as follows:

From the patient with cancer is taken out plasma, take out his tumor cells, do a series of tests, to see together what he has; from there we will get a thousand data that we are going to put into a software, and we will take a molecular photo of that cancer patient and we will say: look at this photo is leaner towards red, green, has this spikes standing there, this is the photo of a patient with leukemia. Then we will give [the patient] the phytomedicine [from the Dividivi] that already has another complex photo and we will see what happens to it next. As [the patient] internal photo changes, and we will be able to differentiate

²⁸⁸ Original transcript in Spanish: “ayuda a entender como la enfermedad actúa frente a plantas complejas”. Ibid.

²⁸⁹ Original transcript in Spanish: “cada una esas moléculas esta a una concentración diferente de la otra , y siempre que obtenemos el extracto tenemos la misma foto”. Ibid.

²⁹⁰ Original transcript in Spanish: “la biología sintética en aras de hacer lo que esta haciendo la industria farmacéutica que es mezclar [diferentes] moléculas (...) nos permite entender como la complejidad de una planta puede mejorar, volver al equilibrio al paciente de cáncer”. Ibid

*the patients who improve with phytotherapy, from those that do not improve, and make groups of patients who respond to the phyto[therapy], of patients who do not respond to phytotherapy, that's called personalized phytotherapy, and it's part of a new discipline called network pharmacology.*²⁹¹ (Translation by the author)

She concludes that, as result of this approach, synthetic biology gives great potential to everything because it has allowed “all that ancestral knowledge to be validated today” in medicinal plants. This means that new breakthrough technologies improve the use of those plants without eliminating the need to work with the actual biological material.

The answer to those questions evidences that local researchers, who are already employing cutting edge technologies and scientific approaches such as network pharmacology, are meeting the current access to genetic resources and benefit sharing regulation in Colombia. The interview data indicates, as result, that the Ministry of Environment regulation (Regulation 1346) and Colombian policy in innovation have perhaps led to, or at the very least supported and encouraged, a market-based approach to the use of communities' practices and knowledge on medicinal plants, singularizing the role of communities as only to grow the plant. In other words, although the research group recognised that the community provide insightful information on the anti-inflammatory properties of the plant, benefit sharing in Colombia follows a policy in innovation that does not consider communities' uses – and the knowledge that led to those uses – as innovative, and hence deserving of legal protection.

²⁹¹ Original transcript in Spanish: “El paciente con cáncer sacar el plasma, sacar sus células tumorales, hacerle una serie de análisis, para ver en conjunto que tiene, de ahí vamos a obtener mil datos que vamos a meter en un software, y vamos a sacarle una foto molecular a ese paciente con cáncer y vamos decir: mire esta foto esta más inclinada hacia el rojo, el verde, tiene este picos para allá parados, esta es la foto de un paciente con leucemia. Luego le vamos a dar el fitomedicamento que ya tiene otra foto compleja y vamos a ver que le pasa después, como cambia su foto interna, y vamos a poder diferenciar los pacientes que se mejoran con la fitoterapia, de los que no se mejoran, y hacer grupos de pacientes que responden a la fito, de pacientes que no responden a la fitoterapia, eso se llama fitoterapia personalizada, y hace parte de una nueva disciplina que se llama farmacología de redes” Ibid.

Yet, the difficulties in regulating the technological, economic, political and ethnobotanic complexities surrounding medicinal plants such as the *Dividivi* concern legal protections beyond Colombia's access to genetic resources and benefit sharing law in Colombia. Patents are also a controversial legal field for communities, authorities and local researchers. As analyzed in Chapters 2 and 3, if a patent application contains information related to genetic resources, applicants must disclose such an information according to Decision 486 of the Andean Community, the current patent law in Colombia. This legal obligation that seems to be clear, in practice falls short in terms of regulating all aspects in a complex scientific scenario. The patent granted to the Javeriana group over the derivate products of the *Dividivi* illustrates this problematic issue.

As the research group succeeded in demonstrating the effectiveness of the combination of gallic acids derived from the *Dividivi* for the treatment of cancer, it filed for a patent in the offices of Colombia, the US, and Canada. The first two have already granted to the researchers a patent in the combination of acid gallic.²⁹² Yet, the research group did not disclose in any of those patent applications that the native plant and local communities played any role in the invention. Professor Fiorentino was asked to amplify the reason why they did not disclose the origin of the gallic acid in the patent. In her answer, she illustrates how different was her invention from the natural product as follows:

Within the compounds of the Dividivi that we have identified are gallic acid, and derivatives of the gallic acid, which are in a particular concentration each. So it's not that I take the gallic acid and reproduce

²⁹² The patent was granted in the US in 2018 (Castañeda and others (n 256); Sandoval and others (n 258).) and Colombia in 2015 (Susana Florentino and others, 'Combination of Compounds Derived from Gallic Acid for the Treatment of Cancer' <<https://patentimages.storage.googleapis.com/ba/da/81/a5a8e2b6eccfa8/US9931355.pdf>> accessed May 3 2018.) and it is pending in Canada (Susana Florentino and others, 'Composición Farmacéutica Que Comprende Derivados Del Ácido Gálico' <<http://sipi.sic.gov.co/sipi/Extra/IP/Mutual/Browse.aspx?sid=636609526483865264>> accessed May 3 2018.) There is also an international patent application via PCT (Susana Florentino and others, 'Combination of Compounds Derived from Gallic Acid for the Treatment of Cancer' <<http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/2884784/summary.html>> accessed May 3 2018.); see also Carolina Gómez Pulido, 'Patente Javeriana En Lucha Contra El Cáncer' (*Pesquisa Javeriana*, 2018) <<http://www.javeriana.edu.co/pesquisa/patente-javeriana-en-lucha-contra-el-cancer-2/>> accessed May 3 2018.

the activity of the Dividivi, because we have done it. The gallic acid has to be in a concentration, attached to the ethyl gallate, to the pentagalol glucosa, and it is that mixture that has the activity [to treat cancer]. And that's why the patent has all the possible blends that at that time came to mind that could have activity and were based on our results, and on the characterization of the extract.(Translation by the author)²⁹³

In other words, the patent was not over the natural activity of the *Dividivi* itself, but it was rather the research group's own combination of the *Dividivi* compounds that produces the activity which it is hoped will be able to treat cancer. This means that, despite the fact that the research group recognised the ethnobotanic origins of the *Dividivi* and how local knowledge of the plant led to the extraction of a bioactive component of a native plant, they did not consider that the role of local communities in leading users to discover the therapeutic activity of the *Dividivi* was relevant to include in a patent application because the patent was granted over an activity and product made in the laboratory.

Against this background, the members of the research group were asked whether it was possible to foresee a future in which communities should have a more prominent role in research and development in order to pursue a more inclusive and sustainable model of innovation in medicinal plants. The research group declared themselves open to considering such an agenda. For instance, Mr. Olaya considered that further discussion and dialogue was necessary, so as to have a better understanding of the role of communities in research and development as he says: “we will have to sit down with anthropological work with human science professionals and be able to

²⁹³ Original transcript in Spanish: “Dentro de los compuestos del dividivi que hemos identificado son ácido gálico, y derivados del ácido gálico, que están en una concentración particular cada uno. Entonces no es que yo coja el ácido gálico y reproduzca la actividad del dividivi, porque nosotros lo hemos hecho. El ácido gálico tiene que estar en una concentración, unido al etil galato, al metil galato, a la pentagalol glucosa, y es esa mezcla la que tiene la actividad. Y por eso la patente tiene todas las posibles mezclas que en ese momento se nos ocurrieron que podían tener actividad y estaban basadas en nuestros resultados, y en la caracterización del extracto.” Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

establish that it is the best thing that can be done for [the] community that established that knowledge” (Translation by the author).²⁹⁴ Meanwhile, Professor Fiorentino was more emphatic, in her demand for the Ministry of Environment to play a leading role in setting up a credible framework in which the Ministry carries out public consultation with indigenous and Afro-Colombian communities, as well as assuming the responsibility for the whole process.²⁹⁵ So, at least if we take these statements at face value, the local researchers are aware of the socio-economic dynamics of their work, and the broader contexts for local, indigenous and Afro-Colombian communities. The Javeriana research group distinguish local communities from indigenous and Afro-Colombian communities, which is consistent with at least some of the regulatory environment in which they operate. Their self-understanding is that their activities are not only compliant with relevant legal obligations, but also consistent with seeking a fair recognition of the contribution of those communities with whom they interact in their work. Part of the reason for their beliefs and understandings is a notion of innovation that privileges their ‘scientific’ work as innovative, and treats communities’ knowledge and uses as mere prompts or ‘leads’ for the value-added innovation that they – the local researchers – bring to the Colombian economy.

The Anamú

The *Dividivi* is not the only plant whose medicinal properties the research group from Javeriana University are investigating. As a matter of fact, one of the first plants that Professor Fiorentini analysed to find therapeutic activity against cancer was the *Anamú* (*Petiveria alliacea*). Based upon previous ethnobotanical studies that identify that the plant had been employed in “folk medicine” in Tropical and Central America as antispasmodic, antirheumatic,

²⁹⁴ Original transcript in Spanish: “tendremos que sentarnos con un trabajo antropológico con profesionales de las ciencias humanas y poder establecer que es lo mejor que se puede hacer por esa comunidad que estableció ese conocimiento”. Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

²⁹⁵ Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

anti-inflammatory, antinociceptive, hypoglycaemia, and abortifacient,²⁹⁶ Professor Fiorentino began her journey in researching medicinal plants.

The *Anamú* was not only a plant that scientifically interested Fiorentino as a professional researcher, but it was also a plant that had had a profound impact in her personal life. Fiorentino recounts that, although she wanted to return to France, where she obtained her PhD, she was bounded by her scholarship which demanded that she work in Colombia when her studies were completed. Consequently, she tried to find a way in which she could work on a topic that was interesting to her (i.e. cancer) in both countries (France and Colombia), as well as in combination with her husband's business activities in France and Colombia.²⁹⁷ Those circumstances led her to the study of medicinal plants to treat cancer, including the *Anamú*.

That decision led Professor Fiorentino to face skepticism from colleagues at that time and to deal with the ever-changing legal landscape on access to genetic resources and benefit sharing in the country. On the first issue, Dr. Claudia Urueña points out the difficulties that Professor Fiorentino underwent with colleagues at that time: “the criticism was that why an immunologist (Fiorentino) was playing with nuances [plants]”.²⁹⁸ In this regard, Olaya remembers that colleagues accused Fiorentino of doing something that “was not science” and mocked her saying that she was “becoming a *yerbatera*²⁹⁹”. *Yerbatera* means a seller of plants in urban marketplaces. For scientists, it is a derogatory terminology, implying lack of professionalism. However, the research group is nowadays very optimistic and proud of what Professor Fiorentino and her colleagues have accomplished in Colombia. As an example,

²⁹⁶ Those previous studies are documented by the research group in Claudia Urueña and others, ‘Petiveria Alliacea Extracts Uses Multiple Mechanisms to Inhibit Growth of Human and Mouse Tumoral Cells’ (2008) 8 BMC complementary and alternative medicine 60.

²⁹⁷ Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

²⁹⁸ Original transcript in Spanish: la crítica era que una inmunóloga que se va a poner a jugar con maticas, era la crítica de la comunidad científica. Interview with Claudia Urueña, Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

²⁹⁹ Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

Urueña points out that they are already very well known and respected in Colombia as some of their plant extracts, including the *Anamú*, have been taken forward for clinical trials making them the first Colombia research initiative to have reached that stage in the drug development process.³⁰⁰

Regarding meeting Colombia regulation on access to genetic resources, Fiorentino points out that, as she pioneered the study of medicinal plants in Colombia, she has witnessed the transformation of the regulation from a very strict regulation with low administrative capacity to enforce it, towards a more open and pro-research legislation. Her account suggests that she sought to comply with legal requirements at all stages, but that practical matters impeded this desire for regulatory compliance.

For instance, when Fiorentino applied for the first time for non-commercial mutually agreed terms on the *Anamú*, she faced the lack of capacity of the Ministry in approaching this issue at the time when the implementation of Decision 391 in Colombia was very strict. As mentioned above, different ethnobotanic research indicates that the *Anamú* is a plant used in various regions in the world by different communities, meaning the plant was not a native Colombian plant. However, although Fiorentino tried to explain to the Ministry that “the *Anamú* had a wide distribution” in different geographical locations outside Colombia, hence, it would not be necessary to apply for mutually agreed terms, the Ministry claimed, according to Fiorentino, that “the rule does not clearly say whether the plant was identified here [in Colombia] or not, the fact is that it is endemic here” (Translation by the author).³⁰¹ In other words, despite the fact that there are published papers that proved that the plant was not native only to Colombia, the Ministry considered that it was, solely because it grows in the country

³⁰⁰ Interview with Claudia Urueña, Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

³⁰¹ Original transcript in Spanish: “La norma no dice claramente si la planta fue identificada acá [en Colombia] o no, el hecho es que se encuentra de manera endémica acá” Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

As the Javeriana research group was able to obtain non-commercial mutually agreed terms,³⁰² it continued its investigation to synthesise the plant's therapeutic compounds. This process mainly involved drying the plant, putting it in ethanol, and mixing it with different solvents in order to extract its compounds. Proceeding thus, the research group obtained several extracts.³⁰³ Once the extracts were obtained, the group was able to detect the anti-tumoral activity of those extracts. Consequently, the relevant biological material was sent to Europe, where the French Institute of Natural Products identified the characteristics of the compounds with the aim of purifying them and transforming them into pharmaceuticals to treat cancers such as breast cancer and leukaemia.³⁰⁴ Finally, the research group filed and obtained patents in Colombia, Brazil, Canada, US, and Europe over the extracts, the compounds, the pharmaceutical combinations and the method for sequential administration of the different pharmaceutical combinations.³⁰⁵

Years later, as Colombia changed its policy towards local researchers and innovation in order to facilitate their access to genetic resources, the Javeriana research group obtained prior informed consent from the Ministry of the Environment and reached mutually agreed terms with this ministry in 2018 to establish a “supply chain of the *Petiveria alliacea*”. A closer look at the official documents from the ministry evidences that this set of mutually agreed terms replicated the model of production that Professor Fiorentino and Mr. Barnier proposed in the case of the *Dividivi*, in which local communities grow and harvest the plant to hand it to laboratories to have the bioactive component

³⁰² Dirección de Bosques Servicios Ecosistémicos y Biodiversidad-Ministerio de Medio Ambiente (n 220). File Number: REG 0053

³⁰³ Carolina Navarro, ‘El Anamú, La Inmología y El Cáncer’ [2008] *Pesquisa Javeriana* <https://www.javeriana.edu.co/pesquisa/wp-content/uploads/pesquisa08_02.pdf>. , p 6

³⁰⁴ *ibid.*

³⁰⁵ Susana Fiorentino Gomez and others, ‘Fracción Bioactiva de *Petiveria Alliacea*, Composición Farmacéutica Que Contiene La Misma y Combinación Con Inmunoestimulantes Para Tratar El Cáncer CO6270030 (A1)’; Susana Fiorentino Gomez and others, ‘Bioactive Fraction of *Petiveria Alliacea*, Pharmaceutical Composition Containing Same, and Combination with Immunostimulants for Treating Cancer CA2776446’; Susana Fiorentino Gomez and others, ‘Bioactive Fraction of *Petiveria Alliacea*, Pharmaceutical Composition Containing Same, and Combination with Immunostimulants for Treating Cancer EP2522356 (A2)’; Susana Fiorentino Gomez and others, ‘Bioactive Fraction of *Petiveria Alliacea*, Pharmaceutical Composition Containing Same, and Combination with Immunostimulants for Treating Cancer US8734863B2’; Susana Fiorentino Gomez and others, ‘Bioactive Fraction of *Petiveria Alliacea*, Pharmaceutical Composition Containing Same, and Combination with Immunostimulants for Treating Cancer BR112012009362 (A2)’.

extracted.³⁰⁶ In other words, the contribution of the relevant communities is conceptualised and restricted to merely growing the plant. These communities are not included in the innovation process or other benefits such as the potential commercial benefits of the patents. Again the interview data offers an insight into the views of the local research group: in their self-estimation, they sought legal compliance at all times, even when the regulatory environment seemed illogical and unnecessarily strict to them.

Lessons from the Dividivi and the Anamú

As has been observed in both cases, the Javeriana research group employed a similar approach, which can be summarised as follows: The research group accessed plants which have been previously documented by ethnobotanical research; it synthesised the product; it found that practices and knowledge of communities are not relevant for research and development; it filed and obtained patents globally without disclosing information regarding mutually agreed terms and without carrying out public consultation; and finally, it aimed and aims to establish a model of production in which communities are restricted to growing, harvesting and handing the plant over to laboratories.

Such an approach clearly goes in line with the Colombian central government policy and regulation on encouraging local researchers to easily access genetic resources and traditional knowledge; despite the fact that this would contradict the mandates of Decision 391 and the Constitutional Court on safeguarding communities' practices and knowledge. Further, this approach has been praised by public opinion. For instance, the media is eager to publicly reward the group as an example of how Colombia should exploit its biodiversity.³⁰⁷

³⁰⁶ Resolución 1471 de 2018 por la cual se otorga el Acceso a Recursos Genéticos y Productos Derivados para el Proyecto Denominado: Establecimiento de la Cadena de Abastecimiento de *Petiveria alliacea* dentro de una cadena de aprovechamiento sostenible para la 2018.

³⁰⁷ For instance, two of the largest media groups in the country, *El Espectador* and *Semana*, has praised the research group for its milestones, see: *El Espectador*, 'Descubren Compuestos Activos En Plantas Para Aliviar El Cáncer' *El Espectador* (Bogotá, 10 February 2009) <www.elespectador.com/noticias/salud/articulo116699-descubren-compuestos-activos-plantas-aliviar-el-cancer>; *Semana*, 'Fitomedicamentos Contra El Cáncer: Superando El "Valle de La Muerte"' *Semana Sostenible* (Bogotá, 15 September 2015)

Furthermore, via its institutional sponsor Javeriana University, this research group has been granted more than USD 6m to expand its research focus on other native plants and to establish a similar business model to that of the *Dividivi* and *Anamú* cases.³⁰⁸ Also, this research group is the leading institution behind the multimillion dollar investment of PhairiLab in Bogotá, which aims to create infrastructure for bioprospecting Colombian natural products for health research and health industry in the near future.³⁰⁹

Although both examples could have served as cases of how the understanding of biodiversity from local communities actually adds to the industrial application of natural products, the legal treatment given to genetic resources and to the knowledge of those communities raises important questions about whether Colombian policy of innovation is inclusive, so as to recognise without discriminating any contribution to research and development from all communities, including local, indigenous and Afro-Colombian communities, and whether the government is actually eager to enforce communities' rights in the light of the obligations of Decision 391 and constitutional mandates. This confirms how different interests clash in the use of medicinal plants: while local researchers have created lawful models of carrying out R&D and business in the use of medicinal plants to adjust to the Ministry of Environment regulation, constitutional and Andean (Decision 391) obligations on the protection of communities' practices and knowledge are not met by local authorities.

<sostenibilidad.semana.com/impacto/articulo/fitomedicamentos-contra-cancer-superando-valle-muerte/33842>.

³⁰⁸ Pontificia Universidad Javeriana, 'Proyectos Javerianos En Colombia Científica' (2018) <<http://www.javeriana.edu.co/noticias/noticias?aID=9635872&tID=22767#.Woalk9IzqUk>> accessed 12 July 2018. There is also official documents from the Colombian Patent Office and Colciencias which celebrates this research group approach, see Colciencias, 'Susana Fiorentino y Las Plantas Contra El Cáncer' (*Hablemos de Ciencia Todo el Tiempo*, 2018) <<http://www.todoesciencia.gov.co/susana-fiorentino>> accessed 10 November 2018; Centro de Información Tecnológica y Apoyo a la Gestión de la Propiedad Industrial-CIGEPI, 'Boletín Tecnológico: Productos Fitoterapéuticos' (2015) <www.commonswikimedia.org> accessed November 10 2018.

³⁰⁹ Secretaría de Planeación de Bogotá, 'Implementación de La Plataforma Científica y Tecnológica Para La Obtención de Fitomedicamentos Antitumorales Con Estándares Internacionales Bogotá D.C. | Regalias Bogota' (*Regalía Bogotá Región e Innovación*, 2018).

Furthermore, there are difficulties in creating a meaningful dialogue and establishing interlocutors between ethnic communities and local researchers, as the empirical data on Afro-Colombians in Choco and indigenous communities in the *Valle del Sibundoy* illustrates. The interview with the lead researcher of the Javeriana Group suggests that those ethnic communities are not interested in a dialogue, but rather they are interested in a straightforward transaction. If accurate, this means that the way that those communities approach benefit sharing is exclusively in monetary terms; as a result, those communities are content with the fact that users who are willing to pay the price asked would be able to take their knowledge and practices upstream without including them in the innovation process. This is a call to observe in a different perspective how the International Regime on Access to Genetic Resources should be implemented in practice, because it is not only about driving resources into communities to secure benefit sharing, but also about finding mechanisms to create a dialogue in which users of genetic resources, such as local researchers, and holders of practices and knowledge could advance together to transform those resources into well-being for their own communities.

Although the case of the *Dividivi* indicates that a local community of peasants has not actively been considered in the construction of the *production chain* of the Javeriana research group, it has been possible to initiate a dialogue in which local researchers are approaching the community with technology and promises of growing the plant for potential industrial uses so as to create a sustainable business with them. However, aspects such as prior informed consent and public consultation on how benefit sharing can take place still need to be addressed.

On Colombian innovation policy, the previous sections highlighted that the country's science bureau, Colciencias, has adopted the OECD's Oslo Manual entirely. As a result, the concept of innovation, and the way it is measured and evaluated, respond to an international market perspective. In brief, the Oslo Manual considers as innovative research and development activities from well-placed sectors in markets. Therefore, it does not come as a surprise that the government has addressed public resources to bioprospecting initiatives

such as the Javeriana University projects (i.e. *Dividivi*, *Anamú*, and PhairiLab) without requiring Javeriana University to recognise and share the benefits with communities beforehand.

Such a fragmentation in the state structure is also reflected in enforcing communities' rights. Chapter Three points out how Decision 391, which is part of the Colombian legal system, and the constitution, recognise as pivotal that state agents enforce communities' rights, particularly public consultation, when their cultural, social, and economic values are at stake. The fact that Colciencias does not enforce, nor acknowledge, communities' practices and knowledge in its innovation policy, or in addressing funding to local research, contradicts the Colombian legal system of protection for fundamental rights.

Yet, the cases of the *Dividivi* and *Anamú* also illustrate that other governmental agencies such as the Ministry of the Environment and the Colombian patent office have turned a blind eye on enforcing Decision 391 and constitutional mandates. On the former, the Ministry of the Environment Resolution 1348 does not request that public consultation is carried out with local communities such as the *campesinos* in the *Ricaurte*, despite the fact that Decision 391 required so. This has created a bias on what communities are, leading local researchers to distinguish those groups depending on their ethnic background. Also, the Colombian patent office did not demand that the local university disclose all information regarding the use of the countries' biodiversity and communities' practice and knowledge in the patent application as mandated by Decision 391 and Decision 486. But the lack of enforceability in the case of the *Dividivi* has also an international connotation as the research group has already filled and obtained patents over the combination of gallic acids in Canada and the US, without fulfilling the Andean and Colombian requirements.

Ideally, the Colombian authorities should have approached matters differently in situations such as the case of the *Dividivi*. For instance, Colciencias should include within its innovation policy the contribution from communities in research activities that involves the use of biodiversity. It should also demand

that recipients of public funds consult communities if their practice and knowledge associated with genetic resources are involved. Also, although this would potentially involve an extra burden on local researchers, in both cases, Javeriana University was well aware of the relationship between the plants and local communities. Yet the interviews reveal that the research group is open to constructing potential dialogue with communities. However, it remains a priority for the research group to include *campesinos* in its market based approach in which local communities are invited to grow the plants as a raw material to be extracted and synthesised in laboratories.

Regarding the lack of enforceability, there is a paradox. Although the government has acted to correct the fragmented structure of the state regarding access rules and, even, the granting of patents on inventions derived from genetic resources, those administrative changes have mainly addressed concerns from local researchers such as universities and research groups. This means authorities such as the Ministry of the Environment and the Colombian patent office should have enforced communities' fundamental rights. For instance, the Colombian patent office should have at least requested further information on the inventions that derive from the use of the plants to define how relevant communities' knowledge and practice was in the discovery of the medical properties of the plants. This is especially the case if there are published ethnobotanic research papers that attest to the link between the plant and communities.³¹⁰ As the Colombian patent office did not require this to happen, it is hard to consider how to demand other patent offices comply with rules of another jurisdiction. This is particularly so because the Colombian patent office shares information with different patent offices on

³¹⁰ As it was studied in Chapter Three, any patent applicant should disclose all relevant aspects to carry out the invention to obtain a patent. In the case of invention that employ genetic resources and traditional knowledge associated with those resources, the Andean patent legislation, Decision 486, also requires that the patent applicant disclose all information regarding the origin of the genetic resources and also enclose within the patent the mutually agreed terms reached with the ministry. In any time during the granting process of the patent, the Colombian patent office is obliged to request patent applications such if there are evidence that the invention is based upon genetic resources and traditional knowledge (see Articles, 26 (h), 75 (g) and 275 of the Decision 486).

patent requirements, including the US Patent and Trade Mark Office and the European Patent Office according to international cooperation treaties.³¹¹

It is also fundamental that the Ministry of the Environment works to create a dialogue between communities and local researchers not only to avoid that research centres such as Fiorentino's laboratory drops projects like those in Putumayo and Choco, but also to build trust and long-term relationships between those actors. It is also valuable that the Ministry takes the lead in accompanying public consultation processes with communities so as to secure those communities' rights and to encourage research and development in medicinal plants in Colombia.

Both cases illustrate how the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia is weighted too much in favour of local researchers. This means that Colombia is placing the knowledge and practices of communities into the public domain to the point that those communities do not have even the possibility of being asked whether their practices, uses and knowledge should be employed in research and development activities undertaken by local researchers.

On the contrary, the government, the university and the research group have not taken into account communities' practices and knowledge as a key aspect in research and development in medicinal plants. This reflects the governmental policy that assumes that innovation, including in the use of

³¹¹ There is the Patent Cooperation Treaty (PCT) (Patent Cooperation Treaty, 1970, Washington, as in force from April 1, 2000) which seeks to provide the basis for a common procedure in each Signatory State, including the share of information on patent requirements. There is also The Patent Prosecution Highway (PPH) which can be either a bilateral or a multilateral treaty which allow patent applicants to accelerate the patentability examination in patent offices of other signatures states. Colombia has celebrated 5 bilateral PPH with Spain, USPTO, EPO, Japanese Patent Office and Korean Patent office. Colombia is also part of different multilateral PPH such as PROSUR ((Brazil, Ecuador, Peru, Chile, Colombia, Uruguay, Argentina, Paraguay) and the Pacific Alliance (Mexico, Peru, Colombia and Chile). It is important to mention that despite the fact that the PCT and PPH do not establish rules on genetic resources and traditional knowledge as it occurs in Decision 486, the Colombian patent office through the examination report of the requirements of any invention can inform other patent office of the existence of traditional knowledge associated with genetic resources that can anticipate the novelty claim of the patent application (see Chapter Two).

biodiversity, only originates from holders of technology such as local researchers, and not from Colombia's communities. Such an unbalanced approach towards what can be considered innovative marginalises those communities' traditional knowledge and practices. The lack of enforceability by the government on Colombian protection of communities' rights and the access and benefit sharing rules, as well as an unbalanced approach in innovation, contradict Decision 391 and the Constitutional Court's rulings.

Conclusions

The evolution of the International Regime on Access to Genetic Resources and Benefit Sharing and innovation policies in Colombia demonstrates that the country has gone from a strict policy that sought to counterbalance technological disparity by trading-off genetic resource with technology, towards a policy which centres on encouraging local researchers to employ Colombia's growing research and development capability on genetic resources to develop products and processes. However, such a transformation has always had an underlying assumption that considers that holders of technology are only those who are able to access genetic resources and to contribute with the understanding of biodiversity in specific sectors, and potentially to commercialise products and processes that derive from the utilisation of genetic resources. This view also fits within the commercial practice of local researchers in obtaining patents over the results of those research activities, with the aim of commercialising to upstream users. This is a common assumption that stems from the different developments that led to the establishment of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, the assumption being that biodiversity is a pool of genetic resources that requires scientific and technical expertise to make the availability of such resources valuable.

Therefore, the current policy in Colombia focuses primarily on supporting local researchers. The policy has achieved significant milestones, such as increasing expenditure in research and development, the use of cutting-edge technologies such as synthetic biology to understand the inherent complexity

of medicinal plants and knowledge associated with genetic resources, and leading local researchers to obtain mutually agreed terms. However, it should be considered only a first step in creating a coherent policy on genetic resources which requires inclusion of indigenous, local, and Afro-Colombian communities as well as demanding authorities to enforce communities' rights and access and benefit sharing rules. As a result, it is important to answer the question of how to acknowledge and safeguard the contribution that those communities, through their practices and knowledge, provide for biomedical health research and related industries.

However, before this thesis suggests legal mechanisms through which communities' contribution could be acknowledged, it is also important to discuss another key actor who has also benefited from recent regulation easing the access and benefit sharing regulation in the country: The herbal industry. Therefore, Chapter Five discusses in detail how this growing industry interacts, benefits, and fails to acknowledge indigenous, local, and Afro-Colombian communities' role in the industrial application of medicinal plants

Chapter Five: Communities' Traditional Knowledge and Practices at the Service of the Herbal Industry in Colombia

Introduction

Chapter Four discussed how local researchers, particularly publicly funded researchers in universities, have taken a prominent role in the use of genetic resources for health research and the health industry in Colombia. This includes not only genetic resources, but also genetic resources associated with traditional knowledge. These practices arose as a result of Colombian government efforts to employ genetic resources and traditional knowledge as key aspects in its innovation policy. As a result, Colombia has encouraged local researchers to actively carry out research and development (R&D) into those resources for health research and the health industry.

However, indigenous, local, and Afro-Colombian communities' practices and knowledge are not regarded as R&D activities. Certainly, Colombia only considers that R&D activities take place in industries such as the internet, biotechnology, or pharmaceuticals. Therefore, communities' understanding of Colombia's biodiversity has been taken into the public domain to facilitate local researchers' R&D activities. The data collected in Chapter Four illustrates that there is also a great difficulty to create a meaningful dialogue between local researchers and ethnic communities (i.e. Afro-Colombian and indigenous communities) as the former usually expects a long-term relationship, while the latter aims for a short-term relationship, in which they obtained upfront payment for the access to their knowledge. Chapter Four also highlights that this situation is even more critical for local (non-ethnic) communities such as peasants as the Ministry of Environment and Ministry of State's regulations do not require prior informed consent to users, including local researchers, to access to the practices and knowledge of local (non-ethnic) communities.

This has occurred despite the fact that Colombia has adopted compromises to safeguard and protect those communities' contribution to health research and health industry at the international, regional and national level, including the International Access and Benefit Sharing Regime, and the Andean access and benefit sharing regulation (Decision 391 of 1997) and the Colombian Constitutional Court rulings (see Chapters Two and Three). Such a situation is even more critical as publicly funded researchers are accessing genetic resources associated with practices and knowledge without publicly consulting the communities who hold that knowledge (i.e. without prior informed consent).

This evidences a fragmented state in which the government acts in several directions as it pursues different interests which might run against each other. In the particular case of local researchers and communities' rights, on the one hand, the Andean Community, in which Colombia is a member, and the Constitutional Court, seek to ensure that Colombian authorities enforce the rights, including prior informed consent, that local, Afro-Colombian and indigenous communities have over their knowledge and practice related to genetic resources.

On the other hand, the country aims to advance in terms of capacity building and encouraging innovation in the use of biodiversity for health research in order to make Colombia more competitive in international markets; yet local authorities do not enforce communities' rights, especially the protection of their knowledge over genetic resources. As a result, authorities such as the Ministry of the Environment, Colciencias, the science and technological bureau, and the Colombian patent office have turned a blind eye in enforcing Colombia's access and benefit sharing regulation and constitutional mandates, so as to encourage local researchers to carry out bioprospecting activities. For instance, the Andean Community regulation and the Constitutional Court decisions do not establish divisions between ethnic (Afro-Colombia and Indigenous) and non-ethnic communities (e.g. peasants), while the regulation of the Ministry of Environment does; a situation that has led local researches

to work with plants that are located in areas where there is no presence of indigenous and Afro-Colombian communities.

The state fragmentation in implementing and enforcing the rights of communities over their practices and knowledge in their use for health research is not the only enduring problem in respect of the protection of communities' rights over their practices and knowledge. There are also important aspects to consider in the herbal medicine industry, which involves the use of medicinal plants, and communities' practices and knowledge in fabricating and distributing therapeutic medicinal products. Although medicinal plants have been employed in different cultures and civilizations since ancient times,³¹² herbal medicine has become a crossroad of a wide range of issues that include public health, cultural identity and sustainable development. For instance, the poorest populations in developing countries employ medicinal plants not only because they are cheaper than conventional chemically synthesized medicines, but also because they might be the only available medical treatments in remote areas.³¹³ That is why the World Health Organization (WHO) has stated that herbal medicine is a key aspect in public health, since 80% of the world population relies upon them.³¹⁴ Also, in developed countries, herbal medicine has become popular in treating minor ailments and a cost-effective alternative for personal health.³¹⁵

³¹² For instance, Chinese have employed for centuries *Artemisinin* (sweet wormwood, annual wormwood) to treat fever and malaria, which significance remains nowadays as the World Health Organization has recommended to employed in combination with other anti-malaria synthetic therapies (i.e. the Artemisinin Combination Therapy (ACT)). ACT combines Artemisinin and Lumefantrine, another anti-malaria treatment; Klayman points out that the first mentions of *Artemisinin* medical properties are in the *Recipes for 52 Kinds of Diseases* which was found in a Mawangdui Han Dynasty's tomb from 168 B.C., but modern interest in this plant began in 1967 when the Chinese government made efforts to carry out a systematic review of Chinese medicinal plants; for a summary of *Artemisinin* medical evolution see DL Klayman, 'Qinghaosu (*Artemisinin*): An Antimalarial Drug from China.' (1985) 228 *Science* (New York, N.Y.) 1049., see also WHO, *Global Plan for Artemisinin Resistance Containment* (WHO, 2011)

³¹³ Nahla S Abdel-Azim and others, 'Egyptian Herbal Drug Industry: Challenges and Future Prospects' (2011) 5 *Res J Med Plant* 136.

³¹⁴ WHO, 'WHO Guidelines: Developing Information on Proper Use of Traditional, Complementary and Alternative Medicine' (2004) <<http://apps.who.int/medicinedocs/pdf/s5525e/s5525e.pdf>>.

³¹⁵ Abdel-Azim and others (n 313), pp 136-137

As a result, a significant market for the use of medicinal plants, including phytomedicines, has emerged worldwide. In brief, phytomedicines are bioactive natural products that have pharmacological action and are derived from medicinal plants. Further, the production and distribution of herbal medicines has raised the interest of developing countries as a model of sustainable development.³¹⁶

However, herbal medicines also raise significant regulatory challenges when it comes to communities' practices and knowledge over medicinal plants. Through this chapter, it is shown that there are two aspects of medicinal plants in Colombia that should be addressed to secure a more inclusive herbal industry. First, as the production and distribution of phytomedicines is presented as a model of sustainable development, i.e. the sustainable use of biodiversity for industrial application, the Colombian authorities have created a regulatory framework that aims to facilitate the granting process of marketing authorization for what is called traditional phytomedicines or traditional phytotherapeutic product (See Chapter Three). In particular, it has been allowed to document the therapeutic effect of those pharmaceutical products through traditional knowledge of indigenous, local, and Afro-Colombian communities or proving that the medicinal plants have been used for more than three generations in Colombia. The documentation of those practices and knowledge has been carried out in, for instance, urban marketplaces. These places are where different stakeholders, including the herbal industry, can access genetic resources and the knowledge related to therapeutic effect of those resources; knowledge that is transformed, traded and transmitted by plant sellers or *Yerbateros* in urban markets. That therapeutic effect would otherwise have to be demonstrated by expensive and time-consuming clinical trials.

Despite the fact that the herbal industry is allowed to employ communities' traditional knowledge to fulfil regulatory requirements in marketing

³¹⁶ See for instance Philippines' blueprint on herbal medicines and sustainability: Hilton Y Lam and others, 'Establishing a Blueprint for Nature-Based Products Development and Conservation for the Philippines' (2018) 52 *Acta Medica Philippina* 296.

approvals, this industry is not required to comply with access and benefit sharing rules such as obtaining prior informed consent and signing up to mutually agreed terms with the government, as well as publicly consulting communities to produce and commercialize phytomedicines (see Chapter Two). However, the interest in promoting sustainable business is not the only reason why the herbal industry is not required to comply with the International Regime on Access to Genetic Resources and Benefit Sharing. It is also because the implementation of this regime, as discussed in Chapters Two and Four, was constructed to secure transfer of technology from multinational companies that transform genetic resources into synthesized process or products, but not to “less technological” sectors such as the herbal medicine industry. Yet, the implementation of this international regime in Colombia did not anticipate that it has not been large companies that employ those resources for health research and health industry, but local researchers. It is local researchers, who hold technologies such as biotechnology, who are required to obtain prior informed consent so as to have access to communities’ knowledge. This means that a favourable regulatory approach to market approvals and access to genetic resources for the herbal industry appears to be not only in contradiction with communities’ rights, but also has favoured the herbal industry if compared with regulatory demands on local researchers.

Second, the analysis of the Colombian herbal industry in the light of the International Regime on Access to Genetic Resources and Benefit Sharing and Constitutional mandates on communities’ rights also reflects the difficulty of including different actors that contribute to the production and dissemination of practices and knowledge over medicinal plants. As discussed in Chapter Two, there has been recent scholarly work on the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing which adopts an inclusive and critical scrutiny that identifies the processes lying behind commercialisation of medicinal plants associated with communities’ practices and knowledge. For instance, focusing on Mexico, Hayden reveals a complex network of actors that goes from indigenous communities, road travellers, mine workers, wholesalers of plants, peasants or *campesinos*, to urban markets which create, acquire, develop, sell, and share

the knowledge on medicinal plants.³¹⁷ As a result, it is difficult to identify within the access and benefits sharing regulation, for example, who are the actual holders of communities' practices and knowledge, who should be consulted or what kind of benefit sharing agreements should take place. In the case of Colombia, there have been efforts from academia and the government to document practice and knowledge over medicinal plants, which could potentially help to answer some of those complex questions. For instance, the Ministry of the Environment launched two reports in 2011³¹⁸ and 2017³¹⁹ documenting different communities' practices and knowledge to describe how practices and knowledge have an enormous potential to develop new products for different industries. However, those reports are limited to identifying the therapeutic effects of medicinal plants, rather than carrying out an in-depth ethnobotanical research that could help to solve some of the complex aspects behind the use of medicinal plants so as to enforce communities' rights over their practices and knowledge according to Decision 391 and the Constitutional Court's rulings.

Chapter Five explores these issues in two parts. The first part of the chapter studies the place of medicinal plants and phytomedicines in the Colombian health market. Since the Colombian health system does not provide medicinal plants and phytomedicines to patients, Colombians obtain them either through urban markets or the herbal industry. While working classes (*Clases Populares*) and inhabitants of small settlements obtain medicinal plants in urban markets, well-off classes in large cities get them through the herbal industry. Even though urban markets and the herbal industry cover different markets, the government's regulatory efforts to boost the use of medicinal plants have focused primarily in the latter rather than the former. This is despite the fact the urban markets provide vital therapeutic information on

³¹⁷ Hayden (n 19).

³¹⁸ Henry Yesid Bernal, Hernando García Martínez and German Quevedo Sánchez, 'Pautas Para El Conocimiento, Conservación y Uso Sostenible de Las Plantas Medicinales Nativas En Colombia: Estrategia Nacional Para La Conservación de Plantas' (2011).

³¹⁹ Carolina Castellanos Castro, Carolina Safrony Esmeral and Diego Higuera Diaz, 'Plan de Acción de La Estrategia Nacional Para La Conservación de Plantas de Colombia.' (2017) <<http://www.minambiente.gov.co/images/BosquesBiodiversidadyServiciosEcosistemicos/pdf/Planes-para-la-conservacion-y-uso-de-la-biodiversidad/PlanAccion-BAJA.pdf>> accessed October 13 2018.

medicinal plants to the herbal industry. This is evidenced by interviews with sellers of plants or *Yerbateros* in the most known urban market specialised in medicinal plants in the country: *La Plaza Samper Mendoza* in Bogotá. Also, this section employs the data from interviews with local researchers to show how constraining their legal treatment is, compared to the more favourable normative landscape for the herbal industry, regarding marketing approvals and access to genetic resources.

Such a favourable situation for the herbal industry is even more evident in the different governmental and academic efforts to document medicinal plants in Colombia. The second part of this chapter highlights different ethnobotanical studies which have collected knowledge and practices in urban markets to document medicinal uses and therapeutic activity of plants. This information ends up in the public domain, where the herbal industry can freely access and employ it. Also, this part of the chapter analyses the Colombian governmental efforts to document practice and knowledge of communities through a series of reports and regulatory measures, which do not aim to contribute to identifying the actors behind the use of biodiversity in the herbal industry, but have rather encouraged the commercialisation of phytomedicines. This occurs despite the fact that the government is obliged by Decision 391 and the mandates of the Constitutional Court to protect and safeguard those communities' knowledge and practices.

The Two Paths of the Natural Products Market in Colombia: the Growing Herbal Industry and the Urban Markets

As observed in the previous chapter, genetic resources and the traditional knowledge and practice associated with those resources have a “strategic” value for Colombia’s economic development. As a result, authorities have created a series of administrative mechanisms and policies to boost the use of biodiversity in health research to make Colombia more competitive worldwide in terms of innovation. However, the strategic value of genetic resources and traditional knowledge is not only relevant in Colombia’s innovation policy, but

also in other sectors, particularly in the production of medicines based upon natural products. This means that the use of genetic resources and traditional knowledge is not only focused on local researchers. Although Chapter Four discusses in depth how Colombia's innovation policy has centred primary on local researchers such as universities, who hold key technologies to transform genetic resources and traditional knowledge into products, this chapter uncovers two other important actors in the use of Colombia's biodiversity for medical purposes: the growing Colombian herbal industry and urban markets. Both the Colombian herbal industry and the urban markets compete to interest consumers in alternative medicinal products.

The Colombian health system relies mainly on the use of conventional medicine. It is a system in which medical professionals (nurses, doctors, pharmacists, therapists, etc.) treat diseases using medical devices, surgery, diagnostic and therapeutic methods, and biological and chemical-based products (i.e. pharmaceutical products). As a result, the health system secures free access only to health care products and services that are included in the national mandatory health plan or *Plan de Beneficios en Salud* (PBS).³²⁰ Those products and services which are part of the PBS are approved by the Health Ministry of Colombia after a technical and scientific assessment is carried out to define their efficacy and safety.³²¹ As a result, the Colombian health system provides almost exclusively products and services related to conventional medicine. The Colombian population benefits directly and without previous medical reference by a practitioner from the following health services: Initial emergency care, newborn care, and general and dental medical consultation.³²² In addition, general practitioners can refer patients to other specialized medical consultation (e.g. neurology, psychiatric care, etc.) laboratory tests, medications, hospitalization, low complexity surgical procedures, physical rehabilitation treatments, and various therapies and

³²⁰ Articles 162-169 of Act 100 of 1993

³²¹ Act 1751 of 2015

³²² Ramiro Guerrero and others, 'Sistema de Salud de Colombia' (2011) 53 *Salud Pública de México* s144.

medical devices.³²³ The PBS also covers treatment of high-cost diseases, including AIDS/HIV and cancer.

However, conventional medicines do not dominate the Colombian health market entirely. In fact, 40% of the Colombian population employ alternative or complementary treatments, including the traditional use of medicinal plants and phytomedicines.³²⁴ The Colombian national health system barely includes those treatments in the PBS.³²⁵ Since alternative and complementary medicines are not integrated within the PBS, it is the herbal industry and urban markets which aim to supply the demand for medicinal plants and phytomedicines in the country.³²⁶

Therefore, the alternative medicine market has divided into two main actors. On one hand, there is the herbal industry which produces and distributes phytomedicines, including traditional phytotherapeutic products. As phytomedicines are not part of the PBS, the herbal industry is free to charge patients to access them. On the other hand, there are other patients who, because of different factors (including affordability, access in remote areas, family tradition, etc.), turn to urban markets (*Plazas de Mercado*) or peasant markets (*Mercados Campesinos*) to obtain similar therapeutic treatment that phytomedicines can provide, but which is based on raw medicinal plants and sellers or *Yerbateros*' knowledge associated with those plants. Nevertheless, Colombia authorities are constructing policies and legal rules to prioritise the production and distribution of phytomedicines as an important aspect of Colombian economic sustainable development. This is because there is a

³²³ *ibid.*, p s149

³²⁴ Manuel Ignacio Pinto-Barrero and Paola Ruiz-Díaz, 'The Integration of Alternative Medicine into Colombian Health Care Services' (2012) 12 *Aquichan* 183. See also WHO, 'Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review' (2001) <<http://apps.who.int/medicinedocs/pdf/h2943e/h2943e.pdf>> accessed May 25 2018.

³²⁵ Acupuncture and neural therapy are the only complementary therapies covered by the PBS; further information see: Ministerio de Salud y Protección Social, 'Todo Lo Que Usted Debe Saber Sobre El Plan de Beneficios' (2014) <www.minsalud.gov.co> accessed October 25 2018.

³²⁶ Yet, even if it was integrated it would still be the herbal industry that would supply those products, hence, they would be distributed through the PBS.

growing local industry with an enormous potential in international markets.³²⁷ The next sections study in detail both the herbal industry and urban markets

The Colombian Herbal Industry

The Colombia herbal industry is primary led by local businesses. A recent study points out that the Colombian population consumes USD 253m of phytomedicines per year, which represents approximately 7% of the total of the Colombian pharmaceutical market.³²⁸ Such a market share is expected to grow as this industry has expanded by 500% in the last two decades.³²⁹

An example of such growth is also reflected in the expansion of specialised pharmacies for alternative products, which grew from 20 local pharmacies a decade ago to 500 nowadays, in Bogotá alone.³³⁰ As a result, this industry generates an average of 21,000 direct and 100,000 indirect jobs in the country, through a comprehensive network of laboratories (35) and specialized pharmacies (500) in the production and distribution of phytomedicines.³³¹

It is also expected that the industry will keep growing significantly as Colombia has legalised the production and commercialisation of cannabis for medical purposes.³³² Also, since the national health service does not include traditional and complementary medicines, this industry is highly concentrated among well-off patients and inhabitants of the largest cities of the country. Indeed, 72.5% of the market share of traditional and complementary medicine is

³²⁷ Consejo Nacional de Política Económica y Social, 'Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad' (n 14)., p 14

³²⁸ Nubia Esperanza Ardila Velandia and Claudia Yohana Ariza Ardila, 'Modelo Técnico Financiero y Analisis de Rentabilidad Para La Farmacia Homeopática' (Universidad de Ciencias Aplicadas y Ambientales 2017) <http://repository.udca.edu.co:8080/jspui/bitstream/11158/711/1/TESIS_FINAL_29_DE_AGT_2017.pdf> accessed October 25 2018.

³²⁹ *ibid.*, p34

³³⁰ *ibid.*

³³¹ *ibid.*

³³² El Colombiano, 'Nueva Normativa Para Acceso a Productos a Base de Cannabis' (*El Colombiano*, 2017) <<http://www.elcolombiano.com/negocios/venta-de-productos-naturistas-a-base-de-cannabis-JN6960478>> accessed June 27 2018.

located in four of the largest urban centres of the country (Bogotá, Medellín, Popayan, and Cali).³³³

In the light of such a significant market, the government aims to encourage the industry to produce and distribute products based upon medicinal plants. To that effect, the National Planning Department, the national agency for economic planning, has established as an economic priority the sustainable use of Colombia's biodiversity through regulation that promotes the commercial release of products that are derived from the use of genetic resources such as phytomedicines.³³⁴

However, this represents a crossroad with other stakeholders, specifically, holders of traditional knowledge such as *Yerbateros* in urban markets and, even, local researchers. Particularly, the government strategy has actually facilitated access to the knowledge and practices that exist behind the use of medicinal plants in order to benefit the production and distribution of phytomedicines. Such a policy has materialised as follows.

First, as explained in Chapter Three, through Resolution 1348, the Colombian Ministry of the Environment has exempted the herbal industry in Colombia from meeting the regulation on access and benefit sharing as well as consulting communities in the use of their practice and knowledge associated with genetic resources. Because phytomedicines are not products whose therapeutic activity is associated with isolated and purified molecules, or a combination thereof, as occurs with chemical synthesized products or biological medicines, they are not within the scope of Resolution 1348. In other words, the herbal industry's products do not require prior informed consent or mutually agreed terms as required of other users, such as the pharmaceutical industry. Indeed, native medicinal plants found in ethnobotanical studies are cross-referenced with marketing approvals for phytomedicines, but public records of the

³³³ Alejandra Rojas Rojas, 'Servicios de Medicina Alternativa En Colombia' (2012) 14 *Revista de Salud Pública* 468.

³³⁴ Consejo Nacional de Política Económica y Social, 'Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad' (n 14)., pp 22-23

Colombian Ministry of Environment's mutually agreed terms indicate that the herbal industry has not filed a single application for the use of those plants nor obtained prior informed consent from holders of knowledge associated with medicinal plants.³³⁵ Instead, by 2017, this industry obtained market authorisation for 144 products which include extracts and combinations derived from native and introduced plants in Colombia without requiring the industry to comply with Colombia's access and benefit sharing regulation.³³⁶

Second, the Ministry of Health has facilitated the granting of marketing approval for "traditional phytotherapeutic products" by allowing the industry to employ practices and knowledge associated with medicinal plants to prove efficacy and safety. As a result, according to Decree 2266 of 2004, the herbal industry are exempted from proving therapeutic activity through clinical trials before the *Instituto Nacional de Vigilancia de Medicamentos y Alimentos* (INVIMA), if two conditions are demonstrated: (i) the medicinal plant, either native or introduced, is locally produced; and (ii) there is either documentary proof that the plant has been employed for medical uses by three or more generations in Colombia, or, in case there is no documentary proof, it can be proved by a "competent professional" or the knowledge from "indigenous or Afro Colombian groups".³³⁷ This means that even though the herbal health industry relies on such information, it has no obligation to carry out public consultation when it employs communities' practices and knowledge in the granting process of marketing approvals.

However, as has been discussed in the critical literature on bioprospecting and biopiracy (see Chapter Two), it is difficult to define the complex network of actors that operates in the production of such a knowledge and practices. This

³³⁵ Diaz's study was cross-referenced with both INVIMA, 'Listado de Plantas Medicinales Aceptadas Con Fines Terapéuticos 2017' (2017) <<https://www.invima.gov.co/images/pdf/salas-especializadas/productos-naturales/LISTADO-DE-PLANTAS-DICIEMBRE-2017.pdf>> accessed 3 May 2018. list of marketing approval and mutually agreed terms records of the Ministry of Environment, the Colombian local authority on access to genetic resources, see JA Diaz, 'Informe Técnico. Caracterización Del Mercado Colombiano de Plantas Medicinales y Aromáticas' (2003) <<http://repository.humboldt.org.co/bitstream/handle/20.500.11761/31375/243.pdf?sequence=1&isAllowed=y>> accessed May 3 2018.

³³⁶ INVIMA (n 335).

³³⁷ Articles 2, and 31-36 Decree 2266

means that in terms of the enforceability of the International Regime on Access to Genetic Resources and Benefit Sharing and constitutional mandates it is also difficult to define aspects such as who should be entitled to claim any rights over those practices and knowledge, who should be publicly consulted and what form of benefit sharing should take place. This is even more relevant in the development of a local herbal industry in Colombia which would find it difficult to bear the burden of untangling the complex network of actors behind the use of medicinal plants in order to comply with the access and benefit sharing rules.

Nevertheless, as was discussed in Chapter Four, local researchers, who employ technologies such as synthetic biology or other biotech-related technologies, are obliged to comply with Colombia's access to genetic resources and benefit sharing regulation, if there are ethnic communities associated with medicinal plants such as indigenous and Afro-Colombian groups.³³⁸ Also, whoever wants to introduce a new pharmaceutical product into the market, including those based upon natural products, are required to obtain market approval by proving safety and efficacy of the product (e.g. preclinical trials and clinical trials). Yet, the herbal industry can obtain market approval by employing traditional knowledge to prove that their traditional phytotherapeutic products are safe and effective. This indicates that, at least, there is an unbalanced approach towards holders of technology such as local researchers who bear the legal, administrative and economic burden to, first, obtain prior informed consent and negotiate mutually agreed terms if they want to legally access genetic resources, including genetic resources associated with traditional knowledge, and second, obtain market approvals.

This is an aspect that local researchers such the immunobiology research group of the Javeriana University of Colombia, which have worked for more than two decades with Colombia's medicinal plants to treat cancer, considered problematic. Wilmer Olaya, the regulatory expert of this group, expressed his

³³⁸ Chapter Four criticises that other non-ethnic communities such as peasants are not to be consulted if their knowledge and practices are employed in commercial and non-commercial activities. This has occurred because it is the same Colombian local authorities that have regulated so.

discomfort with the herbal industry which does not need to comply with strict sanitary controls to obtain marketing authorisation, while his research group is making significant efforts to deliver safe and effective medical products, as follows:

What annoys me more is that on Saturday or Sunday, I turn on the TV and watch an arsenal of commercial products [such as] lycopene, brusque coffee, coffee with ganoderma, a lot of products that can certainly have some therapeutic activity, but they are being sold without a reason, without further argument, are simply becoming a fashion choice; and they are using the need of people, [...] [as the herbal industry is] aware that they have cancer, and unfortunately the media [and], some tricks and loopholes in the [sanitary] normative [structures/environment] make these products over-the-counter; and no one has worried about the side effects [...] if it is natural and if it comes from a plant does not mean that it is safe; an overexposure to an extract can generate a toxicity, they can generate liver and kidney damage, [...] and such products are sold right and wrong on television radio without any control³³⁹ (Translation by the Author)

Instead, Mr. Olaya claims that what the Javeriana research group are trying to do with their research on the extract of medicinal plants is to “deliver [a product] with all the technical and scientific certainty from all the years invested in research that is being done here [in the research group]”

³³⁹ Original transcription in Spanish “ a mi me molesta que el sábado o el domingo prender el televisor y ver un arsenal de comerciales de productos, el licopeno, el café de brusca, el café con ganoderma, un montón de productos que sin duda pueden tener alguna actividad terapéutica, pero es que se están vendiendo sin mayor razón, [...], y están utilizando la necesidad de las personas, e incluso la desesperación, porque precisamente trabajamos con una enfermedad a la cual mucha gente llega a tomar cualquier cantidad de diversidad de cosas es por la desesperación que están consientes que tienen cáncer, y lamentablemente medios de comunicación, algunas triquiñuela y cosas laxas en la normatividad hacen que estos productos sean de venta libre, y nadie se ha preocupado por efectos colaterales [...] que por que se natural y porque venga de una planta no quiere decir que sea seguro, una sobreexposición a un extracto pueden generar una toxicidad, pueden generar un daño hepático, renal, [...], y este tipo de productos se venden a diestra y siniestra por radio por televisión sin ningún control” Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

(Translation by the Author).³⁴⁰ Similarly, her colleague, Dr. Urueña points out how beneficial is their research on medicinal plants such as the *Dividivi* if compared with the herbal industry:

*It is not known in what conditions [the herbal industry], what is being produced, what is being sold; we have conditions of good manufacturing practices, we have a physicochemical analysis that is done to raw material as well as to the product, we have toxicity studies that show whether it is effectively toxic or whether is toxic at a certain dose; we have a biological activity quite sustained and reported, all this gives it a great value [versus] what [the herbal industry] normally sell.*³⁴¹

Regarding the regulation on access to genetic resources in Colombia, the lead researcher of the Javeriana Group, Professor Susana Florentino, provides a frank and direct summary of what she believes regarding the fact that her research group has to comply with this regulation, while the herbal industry is excepted from it: “make those who do something more sophisticated pay”³⁴² the price that is involved in dealing with the International Regime in Access to Genetic Resources and Benefit Sharing. In other words, while local researchers, who carry out research and development activities on genetic resources using technologies such as biotechnology, are obliged to bear the burden of complying with access to genetic resources regulation, the herbal industry is off the hook.

³⁴⁰ Original transcription in Spanish: “si vamos a entregar un producto se lo vamos a entregar con toda una certeza técnica y científica de todos los años invertidos en investigación que se están haciendo aca” Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

³⁴¹ Original transcript in Spanish: “no se sabe en que condiciones se produce lo que se esta vendiendo, nosotros tenemos unas condiciones de buenas practicas de manufactura , tenemos uns análisis fisicoquímicos que se le hace a la materia como al producto , tenemos estudios de toxicidad que demuestran que efectivamente es toxico o que es toxico a cierta dosis pero a cierta dosis ya no lo es, tenemos una actividad biológica bastante sustentada y reportada , todo esto le da un valor grandísimo [frente a] lo que [la industria herbal] venden normalmente” Interview with Claudia Urueña, Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

³⁴² Original transcript in Spanish: “póngale a pagar a los que hacen algo más sofisticado” Interview with Professor Susana Fiorentino, Lead Researcher at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 1st October 2019)

The data collected from the interviews with the different members of the Javeriana group provides significant evidence that local Colombian researchers believe not only that the herbal industry is in a ‘regulatory blind spot’ in relation to Colombia’s implementation of its access to genetic resources and benefit sharing obligations. The group also believe that the herbal industry is in different regulatory position with regard to the granting of market approvals for phytomedicines.

Consequently, it appears, first, that there is an unbalanced approach in the use of medicinal plants that does not meet the constitutional and international protection granted to holders of traditional knowledge and practices; and, second, it appears to be unfair to local researchers, in that they are obliged to strictly comply with market approval, and access to genetic resources and benefit sharing regulations, while the legal landscape is significantly more favorable for the herbal industry.

Therefore, a more effective enforcement of the International Regime on Access to Genetic Resources and Benefit Sharing and Constitutional mandates in Colombia would require a delicate balance that includes all different stakeholders: the local herbal industry, communities as holders of knowledge and practices, and local researchers. Although the answer to the question of how to find such a delicate balance is provided in the following chapters, a first step is to identify who the actors behind medicinal plants are. Chapter Four already discussed the role of local researchers in the use of genetic resources, and the traditional knowledge related to those resources. Yet, it has not been observed so far, the role of plant sellers in urban markets or *Yerbateros*. The next section reports on a series of interviews carried out with the aim of untangling the complex, and unique, network of *Yerbateros* in the use of medicinal plants in the main market of medicinal plants in the country: *La Plaza Samper Mendoza* in Bogotá.

*Del campo a la plaza y de la plaza a la casa:*³⁴³ the role of Urban Markets in the Use of Medicinal Plants in Colombia

Urban markets are a central piece in Colombia's strategy in supplying food to its population, particularly *Clases Populares*. In fact, through the first half of the 20th century, the Colombian government placed these markets as an important intersection point between agricultural production in the countryside and supplies of food to urban populations. Such an important connotation of urban markets had its peak in the 1950s as almost half of Colombia's GDP originated in agriculture production.³⁴⁴

However, the relevance of the urban market has lately reduced because of different socio-economic circumstances, which include: (i) violence and internal displacement from agricultural areas to urban centres, which led to a reduction in food production, meaning that urban markets are no longer adequately supplied; (ii) a growing competitive environment from small shops in neighbourhoods (*Tiendas de Barrio*) and large supermarkets (including through the internet); and (iii) a lack of adequate infrastructure to supply and sell agricultural products to consumers.³⁴⁵

Yet urban markets remain an important location not only to meet the food needs of the *Clases Populares*,³⁴⁶ but also to supply the Colombian population with medicinal plants. In that regard, it is in urban markets where patients rely on the knowledge and practices that *Yerbateros* acquire through a complex network of actors that goes from indigenous communities, road travellers,

³⁴³ Literal words of Gerardo Vásquez which translates: "From the Countryside to the Urban Market and from the Urban Market to the House"

³⁴⁴ Rafael Ángel Bravo, 'Galerías y Plazas de Mercado Como Espacio de Conservación Cultural y Producción Audiovisual'; for further information on the role of *Plazas de Mercado* places in supplying the nutritional needs of *Clases Populares* see: Elmer Castaño Ramírez and Blanca Edilia Raigosa Vargas, *Mercados Populares Mayoristas de Alimentos En La Zona Andina Central Colombiana* (Editorial Universidad de Caldas 2001).

³⁴⁵ Ángel Bravo (n 344). pp 250-251

³⁴⁶ There have been important efforts from the national and local governments to maintain, improve and formalize urban markets across the country. For instance there is a guide from the national government on how to construct and improve a *Plaza de Mercado*; see Departamento Nacional de Planeación, 'Construcción y Dotación de Una Plaza de Mercado' (2018) <<https://proyectostipo.dnp.gov.co/images/pdf/plazademercado/PTplazademercado.pdf>> accessed October 26 2018.

mine workers, wholesalers of plants, peasants or *campesinos*. Buyers in these places access not only the actual plants, but also the cumulative practices and knowledge in the use of those plants to treat diseases.

Since urban markets hold such a key role in being a crossroads of different networks and actors, it became fundamental to this thesis to visit and interview *Yerbateros* at the most important urban market specialized in medicinal plants in the country: *La Plaza Samper Mendoza*.

The literature and research on the *Samper Mendoza* are abundant. They concern not only the trade in medicinal plants, but consist in a range of interdisciplinary studies which goes from anthropological research to urbanistic reflections on the transformation of the *Samper Mendoza* over the years, and art-related works.³⁴⁷

Most of those works share a poetic and almost magical realism rhetoric that describes the *Plaza* as part of Colombian heritage. For instance, Barrera and Kuklinski observe this place as non-hegemonic market that defies the unpersonal and “industrialized” world of supermarkets; a market that always attracts and welcomes buyers from different backgrounds who are naively interesting in knowing more about such a universe of plants:³⁴⁸

It is a cosmovisional, diverse and intercultural space. Everything that circulates in the square looks fresh and healthy, it seems that there is a tacit discourse of criticism to what is artificial. In the square everything is available to buyers, without persuasions, without propaganda, the herbs speak for themselves and being arranged on

³⁴⁷ See for instance: Ana María Güiza Posso, ‘Renovación Urbana En El Barrio Samper Mendoza-Simbiosis Entre Las Dinamicas Comercial y Residencial Comunal’ (Bogotá-Uniandes 2011) <<https://repositorio.uniandes.edu.co/bitstream/handle/1992/14617/u442607.pdf?sequence=1>>; María Camila Duque Jamaica, ‘Territorios Otros, Intercambios Otros: La Plaza de Hierbas Samper Mendoza’ (Universidad Javeriana 2016) <<https://repository.javeriana.edu.co/bitstream/handle/10554/22182/DuqueJamaicaMariaCamila2016.pdf?sequence=1&isAllowed=y>>.

³⁴⁸ Gloria Stella Barrera Jurado and Jorge Enrique Kuklinski Sicard, ‘De Los Yerbateros Con Sus Hierbas: Creaciones No Hegemónicas En La Plaza Samper Mendoza’ [2018] *Tabula Rasa* 277.

*the floor evokes peasant life in a fantastic encounter between humans and non-humans, a place full of medicinal energy healing.*³⁴⁹
(Translation by the author)

This view seeks to evoke a peaceful and colorful life of peasants as creators of *Samper Mendoza*, a point in which buyers from different parts of the city, the country and the world can interact with the *Yerbateros* and their medicinal plants.

However, my visit to *Samper Mendoza* and the data collected evidence a less romantic perspective. Since this thesis analyses the International Regime on Access to Genetic Resources and Benefit Sharing and its implementation in Colombia, the data collected illustrates how little impact, or none at all, has this legal framework in the trading of medicinal plants, and communities' practices and knowledge. This means that the objective of that international regime to secure that holders of knowledge are adequately compensated for the use of their knowledge is an idea that is far from even being acknowledged in places such as *Plaza Samper Mendoza*, where plants and knowledge are widely disseminated and placed into the public domain without any compensatory or enforceable mechanism taken place. Also, the data collected lead to uncovering the role of a stakeholder that has not been properly been taken into account in the discussion of benefit sharing, traditional knowledge and genetic resources for health industry and health research: the herbal industry. The following lines of analysis combine data from a series of interviews, photographic records and researcher observations.

My first research visit to *Samper Mendoza* was during the daytime on a Saturday. This day was specifically chosen from my own experience with urban markets since it is a regular day and time for buyers to go to these places to purchase household goods such as meat, fruit and vegetables.³⁵⁰ The market is located in *Los Martires*, a part of the city which was invigorated by the

³⁴⁹ *ibid.*, p287

³⁵⁰ Members of my family sell vegetables and fruits in a stall in the *Plaza Mercado la Concordia* in Florencia-Caquetá in a region in the south of the country in the Colombian Amazon; as a child, I used to go to *la Plaza* at weekends.

National Rail Service. In fact, the Central Station (*Estación de la Sabana*) and the main building of National Rail Service were located in *Los Martires*.³⁵¹ Nowadays, those buildings are partially abandoned, and services are not regular as the train lost relevance in the city and country, being replaced by road transport.

The *Plaza Samper Mendoza* used to be surrounded by ample houses and flats for workers, and their families, who were employed by the National Rail Service. But, as the train service became obsolete, families abandoned the neighborhood. Consequently, houses were replaced by storage facilities (*Bodegas*) and wholesaler buildings.³⁵² Nowadays, buildings and roads are occupied by pickup cars, trucks and street sellers, giving a very informal look to the surrounding of the *Plaza Samper Mendoza* (see Picture 1).



Picture 1: Surroundings of *Plaza Samper Mendoza* during the daytime

As I entered the facilities, it came as a surprise that there was not a prominent trade activity on a Saturday morning. Although there were a few restaurants open in the corridors and the food court, there were only some stalls of plants

³⁵¹ Duque Jamaica (n 347). p 11

³⁵² Güiza Posso (n 347). pp 11-12

open, domesticated animals such as dogs wandering around, and few workers were carrying plants through the corridors and main square on their shoulders or on wooden loading carts. The appearance of a very informal market was prominent (see Pictures 2).



Pictures 2. Daytime at the *Plaza Samper Mendoza*

I was almost immediately informed by a plant seller or *Yerbatera*, who refused to be interviewed, that the main trade in plants occurs only in the late evenings, around 10 pm, on specific days (Monday and Thursdays) until mid-morning of the next day. The exchange of words with the *Yerbatera* was brief and off record: she quickly pointed out that despite the fact that interviews with *Yerbateros* were often undertaken by researchers, she always refused to be interviewed. Moreover, she did not provide further information why she was

reluctant to do so. Yet, the *Yerbatera* strongly recommended that I visit late at night, so as to have a better grasp of how lively and different the *Plaza* was, and so as to be able to interview more candidates.

Although I was a little disappointed not to conclude any interview during daytime, she indicated two potential candidates who could be interviewed: Gerardo Vásquez, a bureaucrat that works for the institute for social economy (IPES Spanish acronym), a local authority that is part of Bogotá's mayoral authority, and manages all urban markets and *Mercados Campesinos* (peasant markets) in the city; and Yaneth Porras, owner of *Yerbas la Mona* (the Blondy's Herbs) who has experience of 37 years in the trade of medicinal plants.

Gerardo Vásquez, at first, refused to go on record, but after a few exchanges of words, he was willing to be interviewed, although he did not want any photograph of him or his place of work to be taken. He basically argued that as a public servant, any declaration which could be misinterpreted had the potential to jeopardize his work. That said, it is particularly interesting that, as he was reading the information sheet and consent form for his interview (see appendixes II and III), he was able to decide that giving an opinion on the record on issues such as the regulation on traditional knowledge and genetic resources did not represent a problem for his role in the IPES.

Consequently, throughout the interview it was striking and palpable that the IPES, a city authority organization, and Mr. Vásquez, who works for that authority, did not have any idea of what the International Regime on Access to Genetic Resources and Benefit Sharing was. For instance, when he was asked if there has been any situation in which sellers or *Yerbateros* were approached to obtain their informed consent or to negotiate any mutually agreed terms, or whatsoever, he quickly pointed out that the practice of any transaction or transfer of information was the "voice to voice". This was as if his understanding that such a communication could not fall within any regulatory structures that require informed consent for sharing of such knowledge, or mutually agreed terms for its use or exploitation by others. Furthermore, he

describes the role of *Yerbateros* as an important element in providing raw material as it occurs with other agriculture products such as flowers:

*[The trade of medicinal plants] bears a resemblance to the flower market, they start selling the bunch of flowers, then they result in selling in boxes, then they result in delivering flower productions.*³⁵³

(Translation by the author)

Mr. Vásquez' words point out not only the fact that the International Regime on Access to Genetic Resources does not have any relevance in medicinal plants trade for local authorities such as IPES, but also that the aim of those institutions is to transform those place of medicinal plants trade into model of business where holders of knowledge on genetic resources can be part only of a chain value in which they only provide the raw material. The 'value added' in the chain (the boxes, the flower productions) is added by other economic actors, not the *Yerbateros*.

Furthermore, other parts of Mr. Vasquez' interview reaffirm the interest of the authorities in making sure that the *Yerbateros*' trade is focused on providing raw material. As he was asked how they deal with visitors to the market, he specifically mentioned that, in the case of tourists, especially international ones, authorities at the *Plaza* make sure that the trade of plants is as open as possible to them with the aim to promote the trade of raw material:

Normally we approach [the tourists], we ask if they are well taken care of, if they have been given an answer, or if they have achieved the goal they are looking for, and some ask the seller's data, possibly to have a link to the raw material. (Translated by the author)³⁵⁴

³⁵³ Original Transcript in Spanish: "tiene un parecido con el mercado de flores, empiezan a vender el manojo de flores, después resultan vendiendo en cajas, después resultan entregando producciones de flores". Interview with Gerardo Vasquez, Employee of the IPES, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁵⁴ Original Transcript in Spanish: "normalmente nosotros lo abordamos, le preguntamos si se encuentran bien atendidos, si se le han dado respuesta, o si han conseguido el objetivo que ellos vienen buscando, y algunos preguntan los datos del comerciante, posiblemente para tener un enlace para la materia prima" Interview with Gerardo Vasquez, Employee of the IPES, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

This indicates that authority's perspective on the value of medicinal plants in *Plaza Samper Mendoza* does not dwell in *Yerbatero's* knowledge, but in the raw material as such. Assuming that the evidence from this interview is typical of the IPES (and there is no reason not to make this assumption, as Mr Vasquez is an ordinary bureaucrat associated with that city authority, this represents an astonishing piece of evidence that the central aim and *raison d'être* of the International Regime on Access to Genetic Resources and Benefit Sharing – i.e. that communities are taken into account in the use of plants for industrial application and participate in benefit sharing – is not even *acknowledged* in one of the most important places of trade of knowledge related to medicinal plants in Colombia. The data collected in the interviews with *Yerbateros* during the daytime and late night provide further evidence on this finding.

Yerbas la Mona and Oscar Sanabria

Yerbas la Mona was one of the few stalls that were open during the daytime. It was right in the middle of the main square of the *Plaza Samper Mendoza*. Yaneth Porras, the owner, was both curious and skeptical about the content of my research. At the same time, she was open to answering most of my questions. Although the interview was short in duration, lasting less than 30 minutes, it allows me to observe the ways in which traditional knowledge related to medicinal plants is transmitted, traded and transformed in practice (See Pictures 3).



Pictures 3. Left: façade of *Yerbas la Mona*. Right: Interview with Mrs. Porras outside *Yerbas la Mona* in *Plaza Samper Mendoza*

Mrs. Porras' trade is a family business, which she has run for 37 years. Her mother was only 12 years old when she started this business. Mrs. Porras' mother is 81 and retired, which means Mrs. Porras is now in charge of the daily operation of the business. This is a family commitment that will be continued, as Mrs. Porras' daughter also works in the stall ("my daughter already knows about plants too"³⁵⁵). Yet, Mrs. Porras does not attribute to herself, nor her family, all the understanding of medicinal plants. In fact, she acknowledged explicitly that she learned what medicinal plants are for from other colleague *Yerbateros* in *La Plaza Samper Mendoza*.

As she has obtained the knowledge on medicinal plants from different sources, she also transmitted to a variety of customers. As the interview was being conducted, it could be observed how different customers approached Mrs. Porras' stall to acquire plants and ask her how to prepare them. For instance, a woman in her mid-fifties asked her for *Chaparro* (*Castela tortuosa*) and whether the plant could help her son-in-law with his sugar levels. Mrs. Porras immediately corroborated the information and went into detail about the properties of *Chaparro* for diabetes.

As I watched how she performed her trade and observed her interactions with her customers, I asked her to describe how she concludes what plant could be more beneficial for each of her customers. Humbly, she explained in detail:

It is not because I believe I am a doctor or anything like that, but I know about diseases and I know what plants you can take for that; that is why I know when they [patients or clients] come to me and tell me 'I need a herb for the headache or have a lot of migraine or that', so I ask them: 'did you already go to the doctor? Have you told them what it is?' Then they [the patients] tell me yes, so [for example] I tell them to take the Comfrey [Symphytum officinale], that the Comfrey

³⁵⁵ Original Transcript in Spanish: "mi hija ya sabe de plantas también". Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

*is for migraine, for triglycerides, cholesterol and rheumatism.”*³⁵⁶
(Translation by the Author)

Although Mrs. Porras’ answer points out that *Yerbateros* do not aim to attribute to themselves full medical training or replace general practitioners in their diagnosis, it also shows that *Yerbateros* genuinely believe that the use of medicinal plants brings greater benefits than conventional medicines. In fact, Mrs. Porras highlighted that in that regard she considered herself a *Naturista*, a “person who helps with natural plants”,³⁵⁷ who has contributed in the wellbeing of their customers. This is a claim that she supported by reference to her customer’s feedback and loyalty. She brings an example to illustrate her point:

*It’s like the gentleman who comes for diabetes and that, I’ve given him Chaparro and it’s been very good for him, because he’s come back to take more, and he’s giving right now to his daughter, who is now having diabetes [...] he was taking insulin that was required to be injected, and right now he is no longer injecting that.*³⁵⁸ (Translation by the Author)

This particular point evidences that *Yerbateros* feel that they play a key role for their customer in their overall well-being, to the point that they even give up conventional medicines, substituting medicinal plants. However, this role

³⁵⁶ Original Transcript in Spanish: “no porque me crea medica ni nada de eso, uno ya sabe las enfermedades y uno ya sabe que plantas puede tomar para eso, yo por eso se que cuando ellos [pacientes o clientes] vienen y me ‘dicen necesito una yerba para el dolor de cabeza o que mucha migraña o esto’, yo les digo: ‘¿ustedes ya fueron al medico? ¿ya les dijeron de qué es?’ Entonces ellos [los pacientes] me dicen que sí, entonces [por ejemplo] les digo que tomen el *Comfrey* [*Symphytum officinale*], que el *Comfrey* es para la migraña, para el triglicérido, el colesterol y para el reumatismo” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁵⁷ Original transcript in Spanish: “persona que ayuda con las plantas naturales” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁵⁸ Original transcript in Spanish: “es como el señor que viene para lo de la diabetes y eso, yo les he dado Chaparro y les ha resultado muy bueno, por que él ha venido a llevar más, y le esta dando ahoritica a la hija, que ahora esta teniendo diabetes [...]él estaba tomando la insulina esa que le mandaban aplicar y eso, y ahoritica ya no se esta aplicando eso” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

of promoting well being through the use of medicinal plants is in effect being taken by another stakeholder: the herbal industry.

As we discussed her different customers, Mrs. Porras also brought up examples of people who are in the herbal industry and have interacted with her. For instance, she identifies *Doña* Carmenza, a homeopath doctor and regular customer, who “comes and buys herbs to make syrups to give people [and] she makes creams and makes vitamins and all that with plants” (Translation by the Author).³⁵⁹ Equally, Mrs. Porras points out that other regular customers include three herbal laboratories, which “take to make remedies for the colon, gastritis” and to “extract in order to pack it in bottles and sell it, or in capsules” (Translation by the Author).³⁶⁰ When I asked her for further details on these customers, she declined to disclose such information (“I don’t give [details] to you”³⁶¹). This was an example of a non-written confidentiality pact that is the result of a long-term relationship of trust and loyalty with her customers.

This insight from the interview with Mrs. Porras raised the further question - however, do customers from the herbal industry also feel bound to that trust-based, unwritten, and probably unspoken pact? Apparently, such a relationship is one way. It depends on the demand for raw material from Mrs. Porras’ stall, in a context where there is no recognition of her own understanding of medicinal plants and the whole network of knowledge behind it (family, colleagues, etc.). In fact, Mrs. Porras points out:

They [referring to everyone who is going to ask about her knowledge on medicinal plants who are not patients] come to ask and they figure

³⁵⁹ Original spanish Transcript: “ella viene y compra verbas para hacer jarabes para brindarle a la gente [...] ella hace cremas y hace vitaminas y todo eso con las plantas” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁶⁰ Original transcript in Spanish: “llevan para hacer remedios para el colon, la gastritis” “sacar el extracto para empacarlo en frasquitos y venderlo, o en capsulas” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁶¹ Original transcript in Spanish: “eso no se los doy”. Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

*out the knowledge so that they get back into that knowledge and do it more [this means that they carry out industrial process into the plant], and change them into their name [then] they put on their papeles [labels].*³⁶² (Translation by the Author)

Although she refused to give details of what medicinal plants, who exactly are those customers, or provide any further details of the transactions, such a statement made by Mrs. Porras reflects that the role of *Yerbateros* and the network of actors behind the uses of medicinal plants have been limited to merely providing the material for industrial application. Pressed on this issue, Mrs. Porras considers that she is not seeking to have any recognition in the industrial application of medicinal plants. She is rather afraid of any potential paperwork that involves consulting her about her knowledge (“no one likes to fill any of that” (Translation by the Author ³⁶³)). Furthermore, she is even concerned that by linking the plants with her knowledge she would be teased or become the subject of mockery. This worry persists, despite the fact that she points out that the herbal industry could charge up to 20 times more for a phytomedicine or herbal preparation whose main extract are the very same plants that she sells at a fraction of the price.

Mrs. Porras’ own perspective on her role and contribution to the understanding of medicinal plants by the health industry led to another question: is it fair? Again, she is very humble in recognizing that what the herbal industry does is “a process in which always money goes out away” meaning that the industry requires resources to “maintain machinery [and] pay for their employees”³⁶⁴ (Translation by the Author). Yet, she still defends her trade: “here we sell the natural, there’s no chemicals, no alcohol [according

³⁶² Original Spanish Transcription: “ellos vienen preguntan [refiriéndose a todos los que van a preguntar que no son pacientes] y averiguan los conocimientos para que ellos mismos volverse a meter a los conocimientos y hacerlo más, y cambiarlos a nombre de ellos [y depues] ellos ponen en sus papeles” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁶³ Original transcript in Spanish: “uno no le gusta llenar nada de eso”. Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁶⁴ Original Spanish Transcription: “ellos tienen que mantener su maquinaria, pagar sus empleados” “un proceso que siempre se va plata”. Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

to her own understanding those are substances employed in any industrial process].”³⁶⁵ (Translation by the Author). Since she was particularly proud of the sale of medicinal plants in *La Plaza Samper Mendoza* and considered it better than those plants and products sold by the herbal industry, I probed her as to whether she felt that the price difference and the fact that their contributions are not recognized by that industry, is fair for *Yerbateros*. She points out that it is customers who prefer to access phytomedicines instead of the natural product:

*Because if you have a headache and you don't want to take the plants, you go to a drugstore [referring to natural pharmacy stores] that sells you a pill, that pill with all the processes that are necessary to make that pill. How many chemicals have they put into it? [...] the plant is more effective.”*³⁶⁶ (Translation by the Author)

Mrs. Porras' words highlight a significant aspect of the way that consumers are being driven away from urban markets for the supply of medicinal plants to natural pharmacy stores. As was pointed out in the previous section, the herbal industry is growing significantly in the country, leading consumers to natural pharmacy stores in malls and supermarkets, instead of going to urban markets (see Pictures 4 and 5). This is despite the fact that the use of medicinal plants as sold in urban markets could be cheaper than getting a “pill” with the extract of the plant. For instance, while a bunch of *Calendula* (*Calendula Officinalis*) to treat different diseases (headache, skin disorders, etc.) in Mrs. Porras' stall costs less than 0.50 US, a box of twelve pills of *Calendula Officinalis*, sold under the trademark Dololed, costs 3.50 USD (See Pictures 6).

As the conversation with Mrs. Porras was coming to an end, it was clear that the mere concepts of benefit sharing or informed consent, which are fundamental in the International Regime on Access to Genetic Resources and

³⁶⁵ Original transcript in Spanish: “aquí se vende lo natural, no tiene nada de químicos, nada de alcohol” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

³⁶⁶ Original Spanish Transcription: “Porque si usted tiene un dolor de cabeza y usted no quiere tomarse las yerbas va es a una droguería le vende una pasta, esa pasta todos los procesos que le han hecho para hacer esa pasta ¿Cuántos químicos no le han metido?[...]es más efectivo la planta” Interview with Yaneth Porras, Plant Seller or Yerbatera, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)

Benefit Sharing, were not even acknowledged in a place of trade of medicinal plants. All these aspects are also reflected in the interview with Oscar Sanabria, the most known *Yerbatero* in *La Plaza Samper Mendoza*, whose time of trade occurs during night time.



Pictures 4. Top: main entrance of *Plaza Samper Mendoza* in Bogotá at daytime. Left: a corridor leading to the main square and *Yervas la Mona*. Right: façade of *Yervas la Mona* in the main square at *Plaza Samper Mendoza*.



Pictures 5. Top: *Centro Internacional* area in Bogotá (*Torre Colpatria* (left of the pic) the second tallest building in the city and *Tequendama* shopping mall on the right of the pic. Left: a corridor in *Tequendama* shopping mall. Right: a *Tienda Naturista* (a natural products pharmacy) in *Tequendama* shopping mall.

Pictures 6. Top: Bunch of *Calendula (Calendula Officinalis)* in Mrs. Porras' stall. Bottom: Pills of *Calendula Officinalis*, sold under the trademark *Dololed*



During the night, *La Plaza Samper Mendoza* becomes a more complex universe; especially as its informal trade seems to be invigorated. The market is absolutely alive: the corridors are full of plants and workers, who sleep in improvised beds, while people who carry plants in wooden loading cars invade every inch of the *Plaza*. The look of the main square seems to be amplified by the amount of plants on the floor and stalls, and their aroma floods the whole environment. For someone who is a new visitor, such aroma is almost intoxicating. Outside, the trucks and pickups multiply by the hour as the trade intensifies (See Pictures 7) . The reason why trade takes place at such time is explained by Mr. Vásquez:

As [the plants] are perishable products, they have a time limit, that is, if they bring the goods [for instance] from Ibagué [see map 1],³⁶⁷ they [the distributors] come with a fair time to get here between five in the afternoon and ten at night to find themselves here in Bogotá [...] The goal of these traders [and] the time of departure is 10 pm. [...] At 1 a.m. buyers who fill the city, who fill the municipalities, and who fill the towns near the district, and even the cities of other departments, begin to arrive because the trucks at dawn are out [between 5am and 7 am [...] to take it to a region where that crop does not grow³⁶⁸ (Translation by the Author)



Map 1. Red Pin: Ibagué. Source Google

³⁶⁷ The capital of the Department of Tolima, which is 3 hours away by car from Bogotá.

³⁶⁸ Original Transcript in Spanish “como son productos perecederos, tienen un tiempo limite, es decir si traen la mercancía de Ibagué, ellos [los distribuidores] se vienen con un tiempo justo para llegar aquí tipo entre cinco de la tarde y diez de la noche para encontrarse aquí en Bogotá [...] La meta de esos comerciantes [y] la hora de partida es las 10 de la noche. [...] A la una de la mañana comienzan a llegar los compradores que surten la ciudad, que surten los municipios, y que surten las poblaciones cercanas al distrito, e inclusive a las ciudades de otros

At night, it can be evidenced that the *Plaza Samper Mendoza* is right at the center of the national trade in medicinal plants. This means that as the plants arrive to this point to be traded, the knowledge and practices behind the use of those plants also transited through a central point. As a result, *Yerbateros* are the recipients, traders and transmitters of the actual plants *and the knowledge related to them* across a wide network that embraces the entire country.

departamentos porque los camiones a la madrugada están de salida [entre las 5 am y las 7 am[...] para llevarlo a una región donde ese cultivo no se da” Interview with Gerardo Vasquez, Employee of the IPES, Plaza Samper Mendoza (Bogotá, Colombia, 28th September 2019)



Pictures 6. *Plaza Samper Mendoza* at night.

As I walked through the corridors and main square of the market, the presence of people who were interested in the uses of plants was easy to spot. I particularly noticed a group of international people accompanied by a Colombian national. I approached the Colombian, who mentioned that he ran a sort of informal laboratory that makes preparations from plants and sells them to an exclusive market. He also claimed that he normally makes tours with international people who are interested in knowing more about plants. Unfortunately, he did not want to go on record, be interviewed, or have pictures taken of him or his companions, and he gave no reasons for declining. But my observations of his activities, and his off-record explanation as recounted above gives further evidence of how the knowledge related to medicine plants flows freely in the *Plaza*.

I was told by several people in the market that the most known *Yerbatero* was Oscar Sanabria. As I approached to Oscar Sanabria, who has been in the business for 26 years, I could identify that he occupied not only different stalls in *La Plaza*, but also a large part of floor of the main square (see Pictures 7). He was already busy ordering the plants that had just arrived, taking and making orders, and ensuring they were dispatched correctly.



Pictures 7. Place of Oscar Sanabria's trade in *Plaza Samper Mendoza*.

Since he was occupied, our interview was constantly interrupted by customers, collaborators and colleagues who came and went. That activity gave me valuable time to form an impression of the *Plaza*. I observed that, although the

trade of plants is a huge operation that includes dozens of *Yerbateros*, customers, truck drivers, workers, security guards, and visitors, the trade was rather smooth and well-organized. This is a business that brings together people who are familiar with each other, but it is also open to visitors such as myself.

With Mr. Sanabria's interview, I corroborated most of the data that was collected with Yanet Porras. For instance, *Yerbateros* such as Mr. Sanabria and Mrs. Porras have inherited their knowledge through their families. The former summarized how he got into medicinal plants as follows: "on my mother's side, it's a business of my family, from my granny; and because she taught my mother, and she taught us."³⁶⁹ (Translation by the Author) He also mentioned that his sons were getting into the family business too.

Also, I explicitly asked Mr. Sanabria whether the herbal industry has affected the *Yerbateros'* trade. He did not hesitate to point out that sales "have fallen out of the way"³⁷⁰ because natural pharmacies "have launched so much essence [according to his own understanding those are preparations made by the herbal industry], so much irrigation [i.e. how Mr. Sanabria describes phytomedicines]."³⁷¹ (Translation by the Author). However, Mr. Sanabria did not have any customer from the herbal industry because they pay much less than other customers. He even recognized that he used to work with them but "it doesn't give the *base* [i.e. a word that Mr. Sanabria uses to explain that the price does not even cover the actual cost of growing and trading the plant]. It doesn't give the *base* for the reason that they ask in quantity and they're going to pay a lot cheaper, so it doesn't work for us"³⁷² (Translation by the Author). This is particularly alarming because it is not only the fact that stakeholders such as the herbal industry directly affect his business, but also this industry does

³⁶⁹ Original transcript in Spanish: "por parte de mi mamá, es un negocio de mi familia, desde mi abuelita; y pues ella le enseño a mi mama, y ella a nosotros" Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁷⁰ Original transcript in Spanish: "si se han bajado harto las ventas". Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁷¹ Original Spanish Transcription: "por lo que han sacada tanta esencia, tanto riego"

³⁷² Original Spanish Transcription: "hace muchos años trabajamos con ellos, pero es que no da la base, no da la base por el motivo que ellos piden en cantidad y van a pagar mucho más barato, entonces no nos sirve" Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

not even concern itself with making a sustainable trade with *Yerbateros* for their use of medicinal plants. This is despite the fact, as pointed out above, that the government aims to make the herbal industry a sustainable business in the use of biodiversity.³⁷³

Against this background, I brought the issue if he had any knowledge regarding benefit sharing or informed consent. Surprisingly, he actually mentioned that he had been told about it: “A person did tell me: ‘don’t start giving interviews for that reason’, because it could bring serious consequences for me, and that was beneficial to others.” Immediately, I asked him why it could bring serious consequences for him, he answered:

that they did not explain to me but they did tell me not to give interviews, and I said to them: ‘I do not know’ if they just ask the questions for what such a plant serves, I answer them, I do not see that that is a bad thing; and they told me that ‘other people did benefit, but what are you benefiting for?’ ³⁷⁴ (Translation by the Author)

Continuing with his explanation about his perspective on benefit sharing of his knowledge, he continued explaining the reasons why he was willing to share his understandings of medicinal plants: “All I do is collaborate with you, and I don’t know what you guys are going to do, if you make money or trade this interview” (Translation by the Author).³⁷⁵ However, what seems to be a collaborative spirit from *Yerbateros* such as Mr. Sanabria and Mrs. Porras to share their knowledge, turns out to be a way to content themselves because of promises that other stakeholders have already made to them. Mr. Sanabria brought different examples in which researchers from unidentified

³⁷³ Consejo Nacional de Política Económica y Social, ‘Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad’ (n 14).

³⁷⁴ Original transcript in Spanish “una persona si me dijo, que no me pusiera a dar entrevistas por ese motivo, porque podría traer circunstancias graves para mi, y eso era beneficio para ellos mismos” “ahí sino me explicaron pero si me dijeron que no pusiera a dar entrevistas, y les dijo que pues no, que simplemente le hacen las preguntas para que sirva tal planta, pues uno les contesta, yo no veo que eso se nada malo, y me dijeron ellos si se beneficia, ¿pero usted de que se esta beneficiando?” Interview with Oscar Sanabria, Plant Seller or Yerbatero, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁷⁵ Original transcript in Spanish: “yo lo único que hago es colaborarle, y ahí si no se que harán ustedes, si ganan plata o hacen un comercio con esta entrevista” Interview with Oscar Sanabria, Plant Seller or Yerbatero, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

universities and people interested in his trade interviewed him, and even went to his town in *La Mesa* to obtain information about his understanding of the uses of medicinal plants and the crops.

Two particular examples from Mr. Sanabria's interview illustrate how those stakeholders have made *Yerbateros* promises about their knowledge, which eventually they were unable to keep. The first example involves a group of researchers from an unidentified university:

About a year and a half ago, four or six came from a university, and asked me: 'how much is my business worth? How much are the plants worth?': I told them: 'the stall like stands worth four or five million [pesos]³⁷⁶, [but] she said to me: 'well, I will buy from you that merchandise but that merchandise is useless to me, it is just for a study'. That was the answer of the lady.³⁷⁷ (Translation by the Author)

Clarifying the point, Mr. Sanabria expressed in his own words what the researcher said to him:

I can buy from you all that merchandise, and I return to you the merchandise, I give it back to you, back out there at four in the morning, I only needed it to study, nothing else.³⁷⁸

Although further details of this conversation were not provided, it can be interpreted to the effect that the failed transaction sought to appropriate Mr. Sanabria's medicinal plants for a period of time, and, potentially, also to use his knowledge, without even disclosing what the researcher aimed to achieve. Expressions such as "that merchandise is useless to me" and "I only needed it to study, nothing else" illustrates the way that *Yerbateros* such as Mr. Sanabria

³⁷⁶ Between 1200 and 1500 USD

³⁷⁷ Original transcript in Spanish: "Hace como un año y medio, vinieron cuatro o seis de una universidad, y me preguntaron ¿Cuánto vale mi negocio? ¿Cuánto valen las plantas?: Yo les dije, así como esta el puesto cuatro o cinco millones, me dijo: bueno yo le compro esa mercancía usted pero esa mercancía no me sirve para nada, solo para un estudio. Esa fue la respuesta de la señorita". Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁷⁸ Original transcript in Spanish: "Yo le puedo comprar toda esa mercancía, y yo su mercancía se la regreso, se la regalo otra vez por ahí a las cuatro de la mañana, solo la necesitaban para estudiar, nada más" Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

perceive how people interested in medicinal plants disregard the role of *Yerbateros* as holders of knowledge.

The second example is cruder because it involves a visitor from outside the country who made Mr. Sanabria promises about how commercially successfully Mr. Sanabria's understanding of medicinal plants would be:

*A gentleman came, a U.S. retired person, he wanted to set up business with us to take a plant to another country, to take to another department, because we had a gold mine. I told him it may not be a gold mine, but at least it provides us with food to eat. [The U.S. gentlemen insisted to him] that he [Mr. Sanabria] had a lot of power with the plant. [The gentlemen promised to Mr. Sanabria:] 'if I set up a business with you, I would install the business that you want', as to assemble machinery. ¡ Mejor dicho que no nos pinto! [Better said what he doesn't paint us!]*³⁷⁹ (Translation by the Author)

Of course, the U.S. gentlemen has not come back to set up the promised business or exploit Mr. Sanabria's gold mine. Nevertheless, Mr. Sanabria immediately raised a remarkable issue about his role and responsibility of the *Yerbatero*; he was genuinely concerned about the side effects of the medicinal plants if there was a potential large scale business: "I told [the U.S. gentlemen], that it has to be studied [...] what the plant is useful for; how many properties the plant has" in order to understand the side effects of the plants.³⁸⁰

The concern of the *Yerbatero* with the side effects of medicinal plants, and their associated responsibility is a point that Mr. Sanabria insistently

³⁷⁹ "Mejor dicho qué no nos pinto" is a colloquial expression that is normally employed to describe promises made by someone who exaggerate what he can actually do. Original transcript in Spanish: "vino un señor, un pensionado de estados Unidos, el quería montar negocio con nosotros para llevar planta a otro país, para llevar a otro departamento, que porque nosotros teníamos una mina de plata, le dije puede que no sea una mina de plata, pero al menos si le deja para comer" el señor les insistió "que tenia mucho poder con las plantas" le prometia "donde yo llegue montar un negocio con ustedes, yo le instalo el negocio que usted quiere, que disque para montar maquinas, mejor dicho que no nos pinto". Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁸⁰ Original Transcription in Spanish: "yo le dije, eso toca estudiarlo" por los efectos secundarios de un medicamento "para así mismo poder trabajar" "para que sirve, que tantas propiedades tiene la planta" Interview with Oscar Sanabria, Plant Seller or *Yerbatero*, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

mentioned throughout the interview. For instance, when he was talking about the *Anamú* he mentioned that it “serves to regulate cancer, but it is very strong, it cuts the view a lot, [...] it has to be taken, but in a very controlled way”.³⁸¹ In those words, Mr. Sanabria can be observed as a person who not only believes in what he does and knows about medicinal plants, but also as a person who believes in his responsibility with the well-being of his customers, or perhaps better, his patients. Something that in his own words make him “feel well” because people assure him that he has *levantado*³⁸² them.

To summarise this section, the evidence collected in the *Plaza Samper Mendoza* illustrates the complexity of the traditional knowledge and practices that lie behind the use of genetic resources by the health industry in Colombia. This means that, for instance, forcing the herbal industry to untangle such a complex network would result in profound effects on this sector. However, the data collected also shows a policy and legal landscape that is particularly favorable for the herbal industry, which represents an unbalanced approach towards local researchers and holders of knowledge such as the *Yerbateros*. Regarding the former, the interviews with the research group at Javeriana University indicate that, while local researchers, who employ “sophisticated technologies” need to provide scientifically and technically robust proofs to obtain marketing approval, the herbal industry can obtain marketing approval by documenting traditional knowledge, which means this industry does not need to cover the cost of preclinical or clinical trials. Also, the interviewees consider it is unfair to local researchers, in that they have to comply with the regulation on access to genetic resources and benefit sharing regulations, while the herbal industry is not subjected to this legislation.

Regarding the holders of knowledge, the International Regime on Access to Genetic Resources and Benefit Sharing is not even acknowledged in places of trade of medicinal plants such as *Plaza Samper Mendoza*, meaning that the

³⁸¹ Original Transcription in Spanish: “sirve para regular el cáncer, sino que es muy fuerte, corta mucho la vista” “toca tomarlo, pero muy controlado”. Interview with Oscar Sanabria, Plant Seller or Yerbatero, Plaza Samper Mendoza (Bogotá, Colombia, 30th September 2019)

³⁸² *Levantado* is a colloquial expression that literally translated “raised”, but whose meaning is to make people recover from an illness.

knowledge and practices behind the uses of those genetic resources are placed into the public domain. As a result, local authorities such as IPES and the herbal industry transform the role of *Yerbateros* as providers of the raw material into a mere chain value for the herbal industry. This is despite the fact that the government aims to make the herbal industry a sustainable business in the use of biodiversity.

However, this is not the only way in which authorities are placing knowledge and practices into the public domain, so stakeholders such as the herbal industry can freely access them. An ongoing effort to document those uses is also placing them into the public domain.

Documenting Information on Medicinal Plants

The analysis above shows that, in practice, it is difficult to determine who 'holds' knowledge that sits behind the use of medicinal plants. Further, even if those persons could be identified, it is far from clear how they should be publicly consulted and what benefit sharing mechanism should be put in place. Since Colombia has not been able to answer those questions, knowledge and practices ended up being simply placed into the public domain. As a result, anyone can freely access it without publicly consulting those actors or meeting any legal requirements. However, in an effort to comply with the UN Convention on Biological Diversity's goals of conservation and sustainable use of biodiversity, the government and scholars have been documenting such practices and knowledge.

Since 2003, there has been increasing literature and research on the medicinal properties and potential commercialisation of plants in Colombia. Díaz carried out one of the pioneering ethnobotanical studies in the country which identified the plants most employed by specialized pharmacies, laboratories and urban markets.³⁸³ For instance, this study found that the most popular plants in the production of phytomedicines by laboratories were *Caléndula*

³⁸³ Díaz (n 335).

(*Calendula officinalis*), Alcachofa (*Cynara scolymus*), and Valeriana (*Valeriana officianalis*).

None of those plants are native to Colombia, yet they are all locally cultivated. Moreover, the same study also found that both urban markets and laboratories also commercialized native species for medical purposes. These include: Sauco (*Sambucus nigra*) employed as expectorants;³⁸⁴ Totumo (*Crescentia cujete*) used in the treatment of respiratory and bronchial affections;³⁸⁵ Diente de León (*Taraxacum officinale*) to treat liver conditions, and lower cholesterol and uric acid levels;³⁸⁶ Anamú (*Petiveria alliacea*) employed in patients with cancer;³⁸⁷ Sangre de Dragon (*Croton lechleri*) used in the treatment of gastritis and ulcers, and a curative of skin disorders;³⁸⁸ and Prontoalivio (*Lippia alba*) employed as an analgesic.³⁸⁹ A key aspect of Diaz's study is that most of the information on the medical properties of all six plants was collected from interviews with sellers in urban markets. For instance, it was in the urban markets of 7 different cities (Bogotá, Medellín, Cali, Ibagué, Villavicencio, Manizales, and Armenia) where the study found that the Sangre de Leon was sold to treat gastritis, ulcers, and skin disorders.³⁹⁰

Similarly, Quintero et al. carried out a study in the use of 26 medicinal plants in Bogotá's urban markets.³⁹¹ Quintero et al. not only researched the alleged medical properties of different plants, but also asked sellers for the traditional uses and medical practices related to the plants, and how they recommend buyers to prepare them.³⁹² Through numerous interviews with sellers, Quintero et al. were able to document what are the most popular plants, what diseases those plants can treat and how *Yerbateros* recommend patients to prepare them. For instance, this study found that the Albahaca (*Ocimum*

³⁸⁴ *ibid.*, p 32

³⁸⁵ *ibid.*, p 37

³⁸⁶ *ibid.*, p 41

³⁸⁷ *ibid.*, p 49

³⁸⁸ *ibid.*, p 57

³⁸⁹ *ibid.*, p 64

³⁹⁰ *ibid.*, pp 57-58

³⁹¹ Sara Emilia Giraldo Quintero and others, 'Descripción Del Uso Tradicional de Plantas Medicinales En Mercados Populares de Bogotá, DC' (2015) 13 Nova 73.

³⁹² *ibid.*, p 75

americanum) is employed in the treatment of stomachache, colon complications, and kidney stones. Other plants and uses include: Caléndula (*Calendula officinalis*) used in swelling conditions, ulcers, gastritis, etc.; Cidrón (*Aloysia citriodora*) for digestive disorders and blood circulation; Cola de caballo (*Equisetum bogotense*) to treat kidney stones and employed as a diuretic; Manzanilla (*Matricaria chamomilla*) used for headaches, muscle relaxation, stress and so on; and Ruda (*Ruta graveolens*) employed to treat women's womb complications.³⁹³ Although most of the plants studied were non-native of Colombia, the actual practices and knowledge that reveal the medical properties and ways to prepare them were obtained from interviews with *Yerbaeros* in those urban markets.

More recently, Pabón et al. researched medicinal plants for infectious diseases (urogenital, respiratory, gastrointestinal, and skin and eye infections) in *La Plaza de Mercado Samper Mendoza*.³⁹⁴ Among the 122 plants researched, the study confirmed Díaz' and Quintero et al.'s findings concerning the medicinal properties of plants such as Calendula, Manzanilla and Cola de Caballo.³⁹⁵ However, this research has a wider scope than those of Díaz and Quintero et al. In fact, the interviews with sellers in *Samper Mendoza* led the research team to trace practices and knowledge up to three family generations of sellers. The study offers clues that such knowledge and practices were obtained from different regions of the country, such as Cundinamarca, Tolima, Valle del Cauca, Choco, Amazonia and Caquetá. Unfortunately, this study is limited in its scope, and only briefly mentions the geographical origin of those practices and knowledge without unravelling the complex network of actors behind those practices and knowledge.

All in all, the interest from researchers in documenting practice and knowledge on medicinal plants in urban markets reveals how important *Yerbateros* in urban markets are in providing information to help us understand Colombia's

³⁹³ *ibid.*, p 77

³⁹⁴ Ludy C Pabón, Martha F Rodríguez and Patricia Hernández-Rodríguez, 'Plantas Medicinales Que Se Comercializan En Bogotá (Colombia) Para El Tratamiento de Enfermedades Infecciosas' (2017) 16 *Boletín Latinoamericano y del Caribe de Plantas Medicinales y Aromáticas* 1 529.

³⁹⁵ *ibid.*, p 532

biodiversity. However, ethnobotanical research in *Plazas de Mercado* has fundamental problems in how it is conducted. First, there are no mechanisms in which *Yerbateros* are taken into account, in terms of how the information that they provide would be employed. This is because such a contribution, as soon as it leaves those urban markets, becomes part of the public domain. Second, the ethnobotanic research carried out in *Plazas de Mercado* only tells a part of the story of the practices and knowledge associated with plants, because *Yerbateros* are only a part of the complex network of actors behind the contribution that helps us to understand Colombia's biodiversity.

In addition, the Colombian government has sponsored two reports that collect further information on different communities' (Afro-Colombian, local and indigenous) practices and knowledge associated with medicinal plants. Under the umbrella of conservation and sustainable use of Colombia's biodiversity, in 2011 and 2017 the Ministry of the Environment commissioned reports that aim to create alternative businesses which contribute to the protection of environment, according to the UN Convention on Biological Diversity goals of conservation and sustainability.

However, a key aspect of both reports is that they call for improving the understanding of knowledge and practices of medicinal plants by seeking further efforts to collect such information without carrying out public consultations. For instance, the 2011 report calls authorities to safeguard and restore traditional knowledge associated with medicinal plants by creating *in situ* collections of those plants, and promoting that holders share those practices and knowledge with academics and scientists.³⁹⁶ The report makes no mention of whether communities should be consulted before those activities takes place. Nor does the report establish any mechanism to secure benefit sharing. Furthermore, the 2017 report highlights that the importance of collecting the knowledge and practices of communities lies in the necessity of protecting them since they constitute "an intangible heritage of the country and humanity".³⁹⁷ In other words, this report states that the importance of

³⁹⁶ Bernal, García Martínez and Quevedo Sánchez (n 318)., pp 157-158

³⁹⁷ Castellanos Castro, Safrony Esmeral and Higuera Diaz (n 265), p 58.

conserving practices and knowledge does not rest in securing the fundamental rights of communities over such information, but rather in the fact that these practices and knowledge belong to the country and humanity in general. This approach is far from that required by the UN regime on Access to Genetic Resources and Benefit Sharing.

In line with those reports, Colombian authorities have also been promoting the documentation of practices and knowledge to facilitate the commercialisation of traditional phytomedicines. For instance, there is the *Vademécum Colombiano de Plantas Medicinales*, which is the Colombian official pharmacopeia for medicinal plants elaborated by the Specialised Working Group of Natural Products of the Ministry of Health.³⁹⁸ This document officially collects the species used in Colombia for medicinal purposes. It also provides specific information on plant parts, stem, fruits, roots, or the plant as a whole. Additionally, the *Vademécum* mentions the phytotoxic properties of the plant, their method of consumption and therapeutic form. This document also gives information on the traditional uses of the plants. Notwithstanding, holders of traditional knowledge and practices are not previously consulted on whether they want to include their knowledge and practices in a public document.

But the fact that communities are not consulted in the documenting process of medicinal plants is not the only problematic aspect of the regulation. The *Vademécum* is not only a public and official document that collects information on the medical properties of plants, but it is also a pharmacopeia that assists the producers of herbal medicines in proving the therapeutic value of phytomedicines so as to obtain marketing authorisations.³⁹⁹ This means that it is the Colombian government itself, through the Ministry of Health, which promotes the collecting of information on practices and knowledge associated with genetic resources to facilitate the commercialisation of phytomedicines without previously consulting right holders.

³⁹⁸ For further information of the *Vademécum* see Sala Especializada de Productos Naturales (n 213).

³⁹⁹ See Article 3 of Decree 2266 and Resolution 2834 of 2008 of the Ministry of Health

This means that those academic and governmental efforts to document practices and knowledge on Colombian biodiversity do not aim to unravel the complex network of actors so as to enforce Decision 391 and the constitution, but they have instead served to place into the public domain those practices and knowledge, where sectors such as the herbal industry can easily access and use them. As observed in the case of academic research in urban markets, those investigations have a limited scope as they only obtain information directly from *Yerbateros* rather than analysing further actors who are responsible for revealing practice and knowledge.

Instead, the scope of that research and those official documents can be used for different purposes other than simply documenting Colombia's biodiversity and traditional knowledge for conservation and sustainability. In fact, studies such as those of Díaz, Quintero et al., and Pabon et al. have served to prove the therapeutic effect of medicinal plants. When the plants commercialised in urban markets are cross-referenced with marketing approvals for phytomedicines, it can be observed how the herbal industry benefits from the documented knowledge and practices on the medicinal use of native and introduced plants. For instance, public records of traditional phytomedicines' marketing approvals indicate that the Albahaca is registered for stomach ache, as was found in urban markets in Quintero et al.'s study. Similar evidence exists for other plants such as Caléndula, Cidrón, Cola de caballo, Manzanilla, Ruda, Sauco, Totumo, Diente de León, Anamú, Sangre de Dragon, and Prontoalivio.⁴⁰⁰

As a result, the herbal industry greatly benefits from publicly funded research, as it employs such information for the production, distribution, and obtaining market authorisation for phytomedicines. However, this is not only the result of a designed approach by the herbal industry towards such knowledge and practice, but it also departs from the interest of Colombian authorities in

⁴⁰⁰ The study of Quintero and others (n 295) was cross-referenced by the author with the National Health Authority, Instituto Nacional de Vigilancia y Control de Medicamentos y Alimentos (INVIMA), list of phytomedicines approved for commercialisation see INVIMA (n 335).

engaging the industry when it uses them, as was demonstrated in the previous section.

Therefore, it is important to question how this process of documentation of communities' practice and knowledge could have a more balanced approach that benefits both the herbal industry and communities. Ideally, those academic and, especially, governmental efforts should be addressed to create an inclusive industry. Consequently, the collection of information relating to medicinal plants in Colombia should not be constructed exclusively in terms of identifying the therapeutic value of those genetic resources, but also in ways that help to identify who are the actors behind the medicinal plants and how much they have contributed to unravelling the therapeutic value of medicinal plants. In that way, it would be possible to require, through a set of regulatory mechanisms applicable to the herbal industry, a responsibility to publicly consult communities when the industry employs their practices and knowledge to produce, distribute, and obtain marketing authorisations.

Conclusions

This chapter analysed the market for medicinal plants, which includes two main actors: the herbal industry and urban markets. While the former has been favoured by a supportive regulatory framework, and a sustainable policy on the use of biodiversity for the production and distribution of phytomedicines, the latter has not been included in the country's strategy of sustainable use and conservation of Colombia's biodiversity. This is despite the fact that it is in urban markets where practice and knowledge in the use of medicinal plants flows to the public. Although it is difficult to unravel the complex network behind the use of medicinal plants so as to identify who contributes to the understanding of medicinal plants, and also how, there are efforts to document those plants and their indigenously and locally known curative properties and uses.

However, as this chapter explains, the documenting of indigenous, local, and Afro-Colombian communities' practices and knowledge associated with

medicinal plants has placed such information into the public domain, where anyone can access and employ it without publicly consulting those communities. Similarly, under the umbrella of conservation and sustainability, the Colombian government itself has also documented those practices and knowledge in two different reports and the official pharmacopeia for phytomedicines.

In one of those reports, it has even been suggested that communities' contribution is something that belongs to the country and even to humankind in general. The effect is that communities cannot decide whether their knowledge should be documented and, consequently, launched into the public domain to be employed. This is the case with the herbal industry which has benefited from those documenting efforts and from regulations on medicinal safety and efficacy, in order to produce and distribute phytomedicines in Colombia.

It is also important to notice that while another stakeholder, local researchers, who access genetic resources, including traditional knowledge related to those resources, are required to comply not only with access and benefit sharing, and market approval regulation, in case they want to commercialise a final product, the herbal industry is not subjected of any of those requirements.

Although the herbal industry is a growing sector and contributes to the sustainable economic development of the country, it cannot be left outside of the scope of Decision 391 rules or the Constitutional Court's rulings since it clearly benefits from practices and knowledge that do not belong to the industry. It follows that it is important to create a balance between the interests of the growing herbal industry and local researchers, and the protection of indigenous, local, and Afro-Colombian communities' rights over their practices and knowledge. The next chapter proposes legal alternatives to achieve such a balance.

Chapter Six: Sustainable and Inclusive Innovation in Health Research and Health Industry

Introduction

As observed in Chapter Two, the main objective of the International Regime on Access to Genetic Resources and Benefit Sharing, which includes the UN Convention on Biological Diversity, the Bonn Guidelines, and the Nagoya Protocol, is that developing countries rich in biodiversity can obtain, through a compensatory mechanism, benefits from the utilisation of genetic resources by allowing access-control to them. In other words, what the International Regime on Access to Genetic Resources and Benefit Sharing intends to achieve is that those who employ genetic resources as a source (i.e. users) to bring products and process into the market, share the benefits of their inventions such as transfer of technology or joint ownership of intellectual property rights. The International Regime on Access to Genetic Resources and Benefit Sharing requires Members of the UN Convention on Biological Diversity to create legal and administrative mechanisms to secure benefit sharing. Those mechanisms include prior informed consent, mutually agreed terms, and mechanisms of compliance. Equally, the regime also calls on members to include communities in the negotiation of terms and conditions of access and the benefits that arise from the utilization of those resources associated with their knowledge.

However, the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries rich in biodiversity has brought different dynamics which have been overwhelming for those countries. This is observed, as analysed in Chapters Three, Four and Five, in Colombia. As Colombia has grown in economic terms and has an ambitious agenda to make the country more competitive in international trade, it has designed its science and technology policies in line with the Oslo Manual,⁴⁰¹ leaving aside other practices and knowledge from local,

⁴⁰¹ OECD and Eurostat (n 216).

indigenous, and Afro-Colombian communities associated with genetic resources in its innovation policy towards the use of biodiversity.

This has occurred despite the fact that, in the case of Colombia, those communities have been entitled – by constitutional mandates and the Andean regulation (Decision 391) – to fundamental rights over their economic and sociocultural relationship with biodiversity (see Chapter Three). As a result, there is a fragmentation within the state regarding the protection of those communities’ knowledge and practices. While there is a market-oriented policy to benefit local researchers, there are constitutional and regional mandates that have been ignored by local authorities in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing (see Chapter Four).

Further, the herbal industry has brought a significant regulatory challenge regarding the use of medicinal plants for the production and distribution of traditional phytomedicines. For instance, the therapeutic effect of those pharmaceutical products can be demonstrated by the documentation of traditional knowledge of indigenous, local, and Afro-Colombian communities or by proving that the medicinal plants have been used for more than three generations in Colombia. That therapeutic effect would otherwise have to be demonstrated by expensive and time-consuming clinical trials. Yet, the herbal industry is not required to comply with access and benefit sharing requirements, such as obtaining prior informed consent and signing up to mutually agreed terms with the government, as well as publicly consulting communities to produce and commercialize phytomedicines (see Chapter Five). This also reflected in the fact that the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing was designed to secure benefit sharing from holders of important technological assets, that transform genetic resources into products and process, but not to “less technological” sectors such as the herbal medicine industry. Even more, the analysis of the Colombian herbal industry also reflects the difficulty of including different actors that add value in the use of Colombian biodiversity.

Such a situation is not only a matter of breaching the Colombian constitutional mandates and Andean legislation, but also it is a matter of justice towards those communities that have long been victimised by landowners, paramilitary groups, guerrilla warriors, drug barons, corrupt elites, etc. through Colombia's long history of violence and exclusion (see Chapter One).

To provide a response to these problems, this chapter and the following one propose to continue with the analysis of Colombian actors and conditions in health research and the health industry. The previous chapters describe the different dynamics and problems behind the use of communities' knowledge and practices associated with genetic resources for health research and the health industry. This chapter seeks to make a normative claim to justify a more inclusive health industry and health research, in which different actors' knowledge over genetic resources is recognised and effectively protected through the innovation process.

In order to move towards a more inclusive approach to the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, it is necessary to protect and safeguard *all* activities that add value to the use of biodiversity, including the use of technologies such as biotechnology, traditional knowledge, local practices and overall to include *all* actors and conditions that are involved in the use of biodiversity for different sectors such as health. This claim to inclusion can be accommodated within Sen's Capability Approach. Sen's framework seeks to secure more inclusive economic development by asserting that people's well-being cannot be assessed exclusively in economic terms such as per capita income. The Capability Approach rather focuses on people's conditions, i.e. what people are capable of doing and being, so they can live a life according to those doings and beings, (or so called functionings), making life worth living. In that way, Sen includes within economic analysis different aspects of life, which go beyond maximisation of wealth or property, in order to entitle people and communities to pursue what they consider a good or worthwhile life.

More specifically, the Capability Approach provides a platform for setting out to achieve specific goals. It does this by evaluating specific conditions in the form of functionings, what people are capable of being or doing. Eventually, a bundle or list of functionings are put together to create a capability. A capability entitles people to freely choose among a list of functionings as to how to achieve that particular capability. For instance, the capability for education could encompass a list of functionings such as reading, writing or having access to educational material. Without the choice among the functionings, people's freedom to choose a life worth living is compromised and they are excluded from full participation in society. Translating this approach into the thesis, local, indigenous, and Afro-Colombian communities in Colombia should be afforded a full choice of functionings – capabilities of doing and being – through the ways that Colombian law and practice enables their engagement with its innovation industries, including health research and the health industry. Since innovation, and the way that is measured, is biased towards holders of technology in industries such as health, the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia should be designed to include the different conditions behind the use of biodiversity in the form of functionings, what local, indigenous, and Afro-Colombian communities are capable of doing and being.

This chapter explores the claim that there should be a capability for sustainable innovation in health research and the health industry (or capability for sustainable innovation in general) in developing countries rich in biodiversity. In particular, the chapter considers that, since communities' practices and knowledge associated with genetic resources have a constitutional protection, they should also be included in the innovation policy of the country; policy that aims to improve and make the country's scientific capability competitive in international markets, as well as promoting the sustainable use of medicinal plants in the herbal industry. This chapter then introduces a list of components upon which such a capability could be constructed, i.e. functionings, in Sen's terms. Those functionings provide a frame through which Colombian implementation of the International Regime

on Access to Genetic Resources and Benefit Sharing can be evaluated, in order to move towards a more inclusive approach in Colombia, through suggesting practical legal reforms.

Although this thesis has argued that the Colombian market-oriented policy and law behind innovation and sustainable development is accountable for creating a sub-optimal situation for communities, it does not distance itself entirely from Colombia's aspiration of using its biodiversity to further its economic development and increase its scientific and technical capacity.

The data collected in Chapters 4 and 5 points out that there are two stakeholders, i.e. local researchers and the herbal industry, that aim to consolidate Colombia's policy of sustainable use of biodiversity, whose main aim is to bring products and process to the market without due consideration to other actors and conditions: on one hand, local researchers such as the Javeriana research group, are emphatic to stress that "innovation lies in the possibility of taking all these resources [Colombia's biodiversity and communities' practices and knowledge] and making them useful for society" (Translation by the author);⁴⁰² a laudable objective that seeks to make genetic resources and the practices and knowledge related to them available to society in the form of pharmaceutical products to treat disorders such as cancer. It also aims to create a chain of value in which local communities of peasants, whose knowledge and practices led the research group to the autoinflammatory properties of the *Dividivi*, are place to grow the crop. Nevertheless, local communities, and their practices and knowledge, have not been acknowledged as innovative.

On the other hand, the government has been successful in promoting a growing herbal industry in the use of biodiversity as part of its strategy of

⁴⁰² Original transcript in Spanish "la innovación esta en poder en tomar todos estos recursos [biodiversidad colombiana, y practicas y conocimiento de las comunidades] y convertirlo en algo útil para la sociedad" Interview with Wilmar Olaya, Agriculture Engineer and Regulatory expert at the Immunology Javeriana Research Group, Javeriana University (Bogotá, Colombia, 19th September 2019)

sustainability.⁴⁰³ As a result, the herbal industry has benefited from a favourable legal and policy landscape, which has allowed the industry to freely access genetic resources to distribute and produce phytomedicines, including traditional phytotherapeutic products, as well as employing those resources and communities' knowledge to prove safety and effectiveness of their products. Yet, communities that have transformed, transmitted and trade practices and knowledge in urban markets, such as *Yerbateros* in the *Plaza Samper Mendoza*, have seen their business affected by this industry and their knowledge freely disseminated and placed into the public domain. Also, the regulation of phytomedicines, including traditional phytomedicines, has been unbalanced towards local researchers, as they are required not only to comply with access and benefit sharing regulation, but also with stricter marketing approval procedures, while there are no similar obligations applicable to the herbal industry.

Therefore, what this thesis suggests, and particularly this chapter, is to secure that Colombian law and policy properly acknowledge the different actors (communities, local researchers and the herbal industry) and conditions behind the use of genetic resources for health industry and health research. The reason that this thesis is more focused on the position of various Colombian communities, and especially local (peasant) communities, is because, as has been observed in the previous chapters, those communities have not benefited from the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, whereas local researchers and the herbal industry have benefited, to some less or greater extent, from different policies and regulations that aim to recognise their role in the use of medicinal plants. The objective of this thesis fits within the Capability Approach as, through a normative claim (i.e. an inclusive sustainable innovation), the thesis aims to add information that brings into view social aspects, more explicitly communities' concerns, that have been ignored in the

⁴⁰³ Consejo Nacional de Política Económica y Social, 'Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad' (n 14)., p22

development of an economic agenda and a market perspective in the use of biodiversity in an specific country.

The first part of the chapter discusses Sen's Capability Approach and correlates his economic analysis of countries' economic development with the different problems that are highlighted in the previous chapters. In particular, this part highlights that innovation and its measurement in countries' productivity leaves out other aspects of capability, such as the valuable contribution of the network of actors and conditions behind biodiversity. To make a more inclusive innovation in health research and the health industry, practices and knowledge from communities should also be considered. This would require that, in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, what communities are capable of doing and being (i.e. functionings) should be included. The second part of the chapter puts that claim into material effect, in the form of outlining a capability for sustainable innovation. This also allows, in the third part, to establish a list of relevant functionings. The overall aim of this chapter is to provide an approach that the following chapter can employ, in order to make concrete and practical proposals on how to address current deficiencies in Colombian implementation of the International Regime on Access to Genetic Resources and Benefit Sharing and the role of communities in innovation.

Sen's Capability Approach and the Capability for Sustainable Innovation

Sen's work criticises the way in which countries' economic development is evaluated since the assessment is carried out in economic terms such as growth in GDP per capita, rather than placing people at the centre. As a result, Sen proposes to evaluate whether people have the capability to live a good life through an evaluation of what they are cable of doing and being. Therefore, poverty, for instance, is not defined in terms of income, but it is studied as the deprivation of the capability to live a good life, a life in which people are able to be well educated, well nourished, have shelter or have access to public

transportation. Since Sen centres on human capabilities, what people can do and be, his work is known as the Capability Approach.⁴⁰⁴

The Capability Approach provides a platform for achieving specific legal or policy goals in the form of a capability, by evaluating the specific people's conditions. This is what people are able of being or doing so as to achieve that capability. People's conditions are framed in the form of a bundle or list of functionings, which are put together to create, and therefore, achieve the capability. To that end, people are entitled to freely choose among the list of functionings, so as to determine how to achieve that particular capability. For instance, as already noted above, a capability for education could encompass a list of functionings such as reading, writing or having access to educational material. Therefore, a state of capability is one in which people can freely choose and combine from a list of functionings the kind of education they consider worth receiving. Another example is the capability to mobilise, which includes functionings such as walking, riding a bicycle, taking public transport, and so on. In this example, the entitlement that the capability to mobilise provides is the freedom that people possess to choose one of those functionings to achieve that particular capability. Without the functionings, people are denied a capability, and are as excluded from society as if they were living in material poverty.

Sen's Capability Approach takes as the centre of its analysis people and freedom of choice, rather than other measures of quality of life such as contentment, e.g. the pleasure that is produced by owning certain commodities; or the allocation of resources. In that regard, the Capability Approach observes that means such as commodities or wealth cannot be the only measure of well-being, but it is also important to observe people's own conditions.⁴⁰⁵ Take poverty and disability as an example: A way to evaluate

⁴⁰⁴ Sen elaborates the capability approach throughout different papers, but the first one in which he actually mentions a particular capability is Sen, 'Equality of What?' (n 22). He eventually went on forming its theory in specific task such as poverty and quality of life in Amartya Sen, 'Poor, Relatively Speaking' (1983) 35 Oxford Economic Papers, New Series Oxford Economic Papers 153. or human development in Amartya Sen, *Development as Freedom* (Oxford University Press 1998).

⁴⁰⁵ Amartya Sen, 'Freedom of Choice' (1988) 32 European Economic Review 269.

whether a person is living in poverty is by observing if he or she is above or below the per capita income; however, there are conditions that vary the way that income can affect people's functionings such as geographical location, gender or disabilities.⁴⁰⁶ If there is an exclusive focus on income, a disabled person would just require more income than a full functional individual to not be considered poor; but distribution of income does not consider that there are other valuable things that makes life worth living since disability also deprives people from carrying out valuable activities such as taking public transport, participating in the workplace or political life, or being able secure access to proper care.

Consequently, Sen proposes to give further information on how people fare in a particular society by analysing functionings. Continuing with the example of poverty and disability, for Sen it is important to analyse, apart from income, how disabilities would deprive people from transforming income into functionings such as being educated, being well nourished, having shelter or taking public transport, rather than just meeting an index such as per capita income. People are placed at the centre, not material income or wealth. Furthermore, Sen's approach also acknowledges that people's own conditions make them vary the way that they want to transform resources into proper functionings, e.g. being well nourished would depend on people's body size, special food requirements (gluten free or vegetarian), gender, etc., rather than giving them food or having contentment from eating a good meal.⁴⁰⁷

The idea of placing people at the centre and acknowledging their conditions is thus also in line with Sen's freedom of choice. Indeed, Sen claims that an important element is people's freedom to select from alternatives that are presented to them, so they can decide what kind of life they want to achieve accordingly to what they are capable of doing or being.⁴⁰⁸ As a result of its intrinsic value, freedom of choice ought to recognise the existence of a great diversity of conditions that have an impact on each individual's way to achieve

⁴⁰⁶ Sen, *Development as Freedom* (n 404). p 88

⁴⁰⁷ Sen, 'Freedom of Choice' (n 405). p 277-278

⁴⁰⁸ *ibid.* p 278

functionings. To that end, Sen structures each capability as a set or “bundles of functionings”⁴⁰⁹ within which people have the freedom to choose. Therefore, as people are presented with a list of functionings to achieve a capability, they are entitled to select the life that they want to lead. By providing people with genuine opportunities to choose the kind of life that they wish, Sen’s Capability Approach offers an alternative to an economic analysis or approach to structuring society, including its laws and policies.⁴¹⁰

Sen’s work, therefore, represents an opportunity to analyse people’s own conditions, in the form of capabilities or bundle of functionings, and entitle them to the ability to choose, so they can live a life worth living. However, it is now important to explain how capabilities and the list of functionings is constructed to establish normative claims, and whether Sen’s approach can be extended beyond a descriptive analysis. This is important because this thesis aims, as discussed above, to establish a normative claim which would then provide a framework in which the complexities and “messiness” of the law can be addressed, and law and policy changes can be justified on the basis of their greater inclusivity.

Although Sen’s Capability Approach focuses on including societal goals within economic analysis, his work is not restricted exclusively to that area. Rather, it has been deployed to understand a broad range of issues, including the implementation of international treaties in developing countries, at issue in this thesis. For instance, Chon pointed out the importance of discussing a “capability for education”⁴¹¹ in the context of developing countries’ implementation of international treaties on copyright such as the World Intellectual Property Organization’s (WIPO) Berne Convention for the Protection of Literary and Artistic Works, since the exclusivity rights granted by copyrights on educational and scientific works limits people’s ability to access textbooks. Clague takes a similar task on the global structure of patent

⁴⁰⁹ *ibid.*

⁴¹⁰ As mentioned above, such analyses seeks to solve the problem of well-being, by focusing on what is good for people in terms of happiness, i.e. how to make prevail pleasure over pain, or by allocating resources.

⁴¹¹ Margaret Chon, ‘Intellectual Property from Below: Copyright and Capability for Education’ (2007) 40 UC Davis Law Review.

regulation, especially TRIPs, and biotechnological inventions, since this treaty has long benefited economic interests over developing countries' ability to respond adequately to, for instance, pandemic diseases such as HIV/AIDS.⁴¹² The reason why the Capability Approach can be deployed in these different types of contexts is because it is a framework that is able to encompass many modalities that affect people's capability of being or doing. Since people's capability can be affected by economic decisions, regulations and policies, it is possible to employ the Capability Approach in a wide range of interdisciplinary work, including socio-legal studies like this thesis. The Capability Approach is not a fixed theory, but a flexible analytical tool whose nature permits it to be used to set up normative claims in the form of a capability. Once established, an evaluation can be carried out to achieve a specific capability in different scholarly and other contexts.

Having discussed why the Capability Approach can be employed in areas beyond economics, the current analysis should move towards how the bundle of functionings and the capability are constructed. It needs to be mentioned in the first place that, since the Capability Approach is a dynamic framework that helps to solve different aspects in people's lives, and which prizes autonomy of choice, the Capability Approach always requires as much flexibility as possible. That is why Sen himself argues that there cannot be a fixed or canonical list of capabilities or functionings, but those need to be selected according to the purpose(s) that are to be accomplished. For instance, selecting a list of functionings to achieve the capability to live a good life, would be completely different from the list of functioning to achieve the capability to appear in public; hence, Sen considers that selecting a list of functionings should respond to variables such as priorities as well as the specific goal to be achieved.⁴¹³ For example, capabilities for people who live in a least developed country are very different from those in developed countries, since the former aims to solve basic needs such as sanitation or basic human rights, while (at least in theory) citizens in a developed country, who can already count on those

⁴¹² Julie Clague, "Patent Injustice": Applying Sen's Capability Approach to Biotechnologies' (Springer Netherlands 2006).

⁴¹³ Amartya Sen, 'Capabilities, Lists, and Public Reason: Continuing the Conversation' (2004) 10 *Feminist Economics* 77.

basic needs, aim to achieve diverse social goals, such as gender equality among children.

Nevertheless, Sen does not oppose the creation of a list of capabilities for specific purposes such as measuring poverty in specific countries or creating a list of basic human rights. On this point, for example, Nussbaum, from a philosophical perspective, articulates a list of capabilities based upon human dignity, which should be included in every country's constitution.⁴¹⁴ Yet, Nussbaum does not preclude the possibility of reviewing her list of capabilities to continuously adapt it to new circumstances.⁴¹⁵

Since the Capability Approach offers a framework that can be employed in interdisciplinary work to set normative claims in the form of capabilities and carry out an evaluation of people's conditions (i.e. functionings), it is possible to provide a framework in which the variables identified in the previous chapters can be addressed.

Nevertheless, there are aspects in which the Capability Approach is continuously challenged. For instance, the impossibility of constructing a full account of justice or theory of justice. This is to create a theory in which people and institutions can agree a set of principles that regulate all aspects of life.⁴¹⁶ Yet, authors such as Nussbaum have developed partial theories of justice based upon the Capability Approach to justify a set of capabilities which should be the cornerstone of any institution and law in any country ("the Central Human Capabilities").⁴¹⁷ However, Nussbaum's lists of capabilities have faced

⁴¹⁴ Martha Nussbaum, *Frontier of Justice: Disability, Nationality and Species Membership* (Harvard University Press 2007). Nussbaum initially proposed her list of capabilities in Martha Nussbaum, *Women and Human Development: The Capabilities Approach* (Cambridge University Press 2000)., see also Martha Nussbaum, 'Capabilities as Fundamental Entitlements: Sen and Social Justice' (2003) 9 *Feminist Economics* 33.

⁴¹⁵ Nussbaum, *Frontier of Justice: Disability, Nationality and Species Membership* (n 414)., p 76

⁴¹⁶ For instance, 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, and parties which are usually considered to be rational. Additionally, parties are motivated to come an agreement because there is a mutual advantage for those who participate in the construction of the social contract. Author's such as Kant, and, more recently, Rawls argue that such a mutual benefit can be expressed in terms of an overlapping consensus of what can be considered fair or how to achieve justice.

⁴¹⁷ Nussbaum, *Frontier of Justice: Disability, Nationality and Species Membership* (n 414)., pp 76-78

criticisms since she does not provide a full explanation on why those capabilities are listed as fundamental for any democracy.⁴¹⁸ Similarly, Sen has been criticised for not giving further explanation on what is the actual reasoning behind creating any functioning and capabilities, rather than establishing an objective moral person to define those aspects. Yet, Sen and Nussbaum point out that functionings and capabilities can be created by a dialogue or consensus in a democratic context. Although that explanation might still fall short of giving a full account of justice, the Capability Approach has not been constructed, particularly Sen's approach, to create a theory or define a set of moral norms. It rather seeks to create a framework in which inequalities in any given scenario (developed and developing countries, conservative or liberal societies, etc.) are addressed, to entitle people with a freedom of choice.

Another aspect in which the Capability Approach is currently challenged is that this approach is too individualistic, being almost impossible to accommodate to protect communities. This is a crucial point for this thesis, which is concerned with communities' entitlements within the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia. A problematic aspect of the lack of any collectivist consideration in Sen's approach is that it could lead individuals pursuit of their own well-being to clash or override another individuals' well-being. As a result, it is difficult for the Capability Approach to create collective capabilities,⁴¹⁹ including capabilities for groups such as local and indigenous communities. This is because Sen's normative approach centres in individuals rather than groups of people. In fact, Sen's analysis focuses on entitlements that can be granted exclusively to individuals (e.g. being well nourished, well educated, etc.). Also, the construction of capabilities departs precisely from what *individuals* are capable of being and doing (functionings), aspects that are rather difficult to extend to collectives. Additionally, it is argued that if there is a conflict between

⁴¹⁸ Robert Sugden, 'What We Desire, What We Have Reason to Desire, Whatever We Might Desire: Mill and Sen on the Value of Opportunity' (2006) 18 *Utilitas* 33.

⁴¹⁹ Solava Ibrahim, 'From Individual to Collective Capabilities: The Capability Approach as a Conceptual Framework for Self-Help' (2011) 7 *Journal of Human Development and Capabilities*; Michael Murphy, 'Self-Determination as a Collective Capability: The Case of Indigenous Peoples' (2014) 15 *Journal of Human Development and Capabilities* 320.

collective capabilities and individual capabilities, the former could triumph over the later, limiting individual freedom to carry out the life that people want to pursue.⁴²⁰ Finally, for capability theorists such as Robeyns, it is only possible to consider collectives as a mechanism to pursue individual well-being.⁴²¹

Yet, recent academic critique claims that matters of justice, inequality and well-being cannot be understood as to exclusively to individuals in a traditional liberal political view.⁴²² This has been even more prominent in local and indigenous communities,⁴²³ which experience a collective sense of injustice when their ability to function as a community is affected by, for instance, exploitation of natural resources (e.g. gold, oil, etc.). This means that although the analysis of being and doing might apply strictly to individuals, there are actions or functionings that take place at the collective level. For instance, in the matter of this thesis, *Yerbateros* in the *Plaza Samper Mendoza* have acquired, transformed and transferred practices and knowledge associated with genetic resources throughout collective channels (family, urban markets, roads, communal land, etc.). Equally, local communities of peasants in the *Ricaurte*, whose knowledge and practice led researchers to the anti-inflammatory characteristics of the *Dividivi*, have not been identified and acknowledged as the community that contribute to the understanding of that medicinal plant. An individualist perspective would observe communities' practices and knowledge as a mechanism to enlarge individual rights over

⁴²⁰ Francesca Rosignoli, 'Categorizing Collective Capabilities' (2019) 11 *Partecipazione & Conflitto* 813.

⁴²¹ Ingrid Robeyns, *Wellbeing, Freedom and Social Justice: The Capability Approach Re-Examined* (Open Book Publishers 2017) <<https://www.openbookpublishers.com/product/682>> accessed March 8 2019.

⁴²² Schlosberg D and Carruthers D, 'Indigenous Struggles, Environmental Justice, and Community Capabilities' (2010) 10 *Global Environmental Politics* 12

⁴²³ For further information on different approaches of collective capabilities such as ethics and economic development see Sikkema SW, 'The Capability Approach as an Account of Minimal Well-Being That Does Justice to Indigenous Peoples' (Utrecht University 2018) <<https://dspace.library.uu.nl/handle/1874/368519>> accessed 7 March 2019); Bockstael E and Watene K, 'Indigenous Peoples and the Capability Approach: Taking Stock' (2016) 44 *Oxford Development Studies* 265; Merino R, 'An Alternative to "Alternative Development"?: Buen Vivir; and Human Development in Andean Countries' (2016) 44 *Oxford Development Studies* 271

those practices and knowledge, denying the ability of communities as a whole to decide over them.

That is why it is so important to extend the analysis of capabilities to communities to the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia. This is because, as was already pointed out, although the Regime intends to recognise all actors involved, the compensatory mechanism of benefit sharing reflects a market-oriented approach. It only considers individual holders of technologies who are the ones capable of adding value to the use of genetic resources for industries such as health. This means that the contributions from communities' practices and knowledge are considered as mere "leads" in the development of products and process, but communities are not counted as actors capable of adding value.

Also, the compensatory mechanism fails short of the realities of research and development, and the industrial utilization of medicinal plants in Colombia. For instance, the data collected in Chapter Four illustrates the difficulties in creating a dialogue between local researchers, and Afro-Colombian and indigenous communities on benefit sharing, leading to clashing interests; i.e. while local researchers were expecting to create long-term relationships to investigate traditional knowledge associated with genetic resources, those communities were expecting a straightforward monetary transaction. Equally, Chapter Five's interviews and documentary analysis suggests that the compensatory mechanism of the International Regime on Access to Genetic Resources and Benefit Sharing is biased towards holders of technology or "sophisticated technologies", leaving outside its scope the herbal industry; a sector that has accessed genetic resources and employed *Yerbateros*' and other communities' knowledge and practices without sharing the benefits of the utilization of genetic resources.

As the compensatory mechanism of benefit sharing is the reflection of a market-oriented approach in the use of biodiversity, this thesis aims to analyse how to include those complexities in the use of biodiversity for industry. To

that end, this thesis proposes to set up a normative claim in the form of the capability for sustainable innovation that aims to recognise what different actors are capable of doing and being (functionings) so as to recognize the contribution they make and entitle them to inclusion in the country's utilisation of genetic resources.

The Capability for Sustainable Innovation in Health Research and the Health Industry

What is the capability for sustainable innovation? The first aspect that needs to be analysed is why it is necessary to talk about innovation, and particularly innovation in the use of biodiversity. Innovation is fundamentally connected with the development of output and productivity of countries, meaning that the activities from different sectors and industries in the creation of new products, services and processes are an important contribution to economic development. Thus, these activities are measured to define policies on how countries can increase innovation. Since these activities differ depending on what economic sector or industry is being evaluated, the mechanism for measuring is rather more complex than indices such as per capita income. Yet, those measurements represent a market-oriented perspective.⁴²⁴ For instance, traditionally, innovation focuses on R&D in high technology sectors such as the pharmaceutical industry, but since there has been a new market boom in information technology, innovation measurements have been addressed to include services which do not necessarily involve R&D in a traditional sense.

But does innovation in a market-oriented perspective involve other aspects such as social concern? There are significant scholarly works and policy papers from different organisations which demonstrate that is not only possible but also desirable to include other aspects beyond markets.⁴²⁵ In the particular

⁴²⁴ The Oslo Manual was originally conceived for industries that addressed important resources to R&D for products and process such as the auto industry or pharmaceuticals; however, due to new economic and technological realities such as internet, it has been also included services; OECD and Eurostat (n 216)., p 8

⁴²⁵ For instance, there is the *Vienna Declaration: The Most Needed Social Innovations and Related Research Topics* which points out that there is a paradigm shift in the innovation system, which was constructed on a technology-oriented paradigm and has transformed into

case of the Capability Approach, although there is a lack of scholarly work on innovation, there have been authors that pointed out that innovation, including social innovation, has an important correlation, albeit unexplored, with the analysis of capabilities.⁴²⁶

Because the analysis of capabilities seeks to address concerns from actors that are not normally taken into account in economic analysis, the way that innovation is understood for economic development in developing countries rich in biodiversity should also consider, for instance, how local and indigenous communities contribute to different activities of innovation in the use of biodiversity.

As biodiversity can contribute significantly in the development of new products and processes, it is worth studying why biodiversity is also an opportunity to make innovation more inclusive. There are studies that estimate that approximately 700 new medicines from 1981-2010 were based on compounds, mainly small molecules, which originate in, or are derived from genetic resources.⁴²⁷ Also, Newman and Cragg have indicated that 49% of the 175 small molecules approved to treat cancer between the 1940s and 2014 in the US were based upon genetic resources.⁴²⁸ Additionally, Oldham et al.'s paper on patent activity on biodiversity estimates that the research and development in genetic resources is very low as it represents only 4% of

a knowledge and services-based society. This critical change demands the inclusion of social innovation. Further information see: CSI Challenge Social Innovation, 'Vienna Declaration: The Most Needed Social Innovations and Related Research Topics', *Innovating innovation by research-100 years after Schumpeter* (2011) <https://www.zsi.at/object/news/1891/attach/Vienna_Declaration_version_01_for_discussion.pdf> accessed January 31 2019; Sridhar Venkatapuram, *Health Justice: An Argument from the Capabilities Approach* (Polity 2011); Robert P van der Have and Luis Rubalcaba, 'Social Innovation Research: An Emerging Area of Innovation Studies?' (2016) 45 *Research Policy* 1923; Robert Grimm and others, 'Social Innovation, an Answer to Contemporary Societal Challenges? Locating the Concept in Theory and Practice' (2013) 26 *Innovation: The European Journal of Social Science Research* 436.

⁴²⁶ There is no scholarly work that discusses what a capability of sustainable innovation is, and, even, until recently, there is no much research into innovation at all within the capability analysis; see Enrica Chiappero-Martinetti, Christopher Houghton Budd and Rafael Ziegler, 'Social Innovation and the Capability Approach—Introduction to the Special Issue' (2017) 18 *Journal of Human Development and Capabilities* 141.

⁴²⁷ Steven M Ogbourne and Peter G Parsons, 'The Value of Nature's Natural Product Library for the Discovery of New Chemical Entities: The Discovery of Ingenol Mebutate' (2014) 98 *Fitoterapia* 36.

⁴²⁸Newman and Cragg (n 85).

taxonomically described species on the planet.⁴²⁹ Since innovation in the development of medicines based upon natural products illustrates the outstanding debt that humans owe to biodiversity, the loss of biodiversity would represent without doubt a lost opportunity to find promising compounds that could eventually led to life-saving treatments and improvement of people's life conditions.⁴³⁰ That is why the idea of sustainability aligns with the use of technology that employs genetic resources in a way that it does not destroy biodiversity and its components, including genetic resources.

However, in the particular case of Colombia, the other actors should also be considered as part of the innovative process in different industries since they have been granted constitutional protection regarding their relationship with the country's biodiversity (see Chapter Three). This is even more relevant as Colombia aims to employ its biodiversity as a key aspect in economic development. It is important to point out that this country has permanently considered biodiversity as competitive advantage in international markets, making its use a key aspect in its economic development, sustainable use of biodiversity and the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing (see Chapter Four).

Yet, the analysis of Colombia clearly exemplifies that, as the government has adopted a market-oriented perspective in the use of its biodiversity, it has not enforced the fundamental rights of communities regarding the use of their practice and knowledge for health research, despite the fact there are constitutional rulings and Andean legislation that requires Colombian authorities to protect such rights. The data collected in Chapter Four unmasks how the government implementation of the International Regime on Access to Genetic Resources has led local researchers to work on plants that have no relationship with indigenous and Afro-Colombian communities; yet, if the

⁴²⁹ Oldham, Hall and Forero (n 89).

⁴³⁰ 'Human Rights Council Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment' (2017) <http://srenvironment.org/wp-content/uploads/2017/09/A_HRC_34_49-Final.pdf> accessed June 4 2018., paragraphs 13-14.

plant has a relationship with local communities such as peasants, it is not mandatory to carry out public consultation with them. Additionally, Chapter Four also points out particular challenges to users who aspire to work closely with indigenous and Afro-Colombian communities but have found difficulties to establish a dialogue in how to share the benefit from the utilisation of genetic resources. This is even more problematic in the herbal medicine industry in Colombia, which benefits from indigenous and local knowledge and practices, to identify therapeutically benefits of plants and, eventually, commercialise them. Since this industry does not employ technologies to define the therapeutically effects of medicinal plants, the scope of their activities has not been considered to be subject of the International Regime on Access to Genetic Resources and Benefit Sharing. Furthermore, the interviews with *Yerbateros* in the *Plaza Samper Mendoza* bring convincing testimonies on how, despite the fact these communities of plant sellers are open to sharing their knowledge with patients to treat diseases such as diabetes and cancer, and actors who want to exploit their uses commercially, the growing herbal industry is taking over the commercialisation of medicinal plants at the expense of *Yerbateros*. Additionally, Colombian authorities and scholarly efforts at documentation has been limited to the therapeutic activity of the plant, rather than collecting information regarding who are the actors that led to the discovery and understanding of these therapeutic effects of the plants (see Chapter Five).

All in all, innovation cannot be observed and assessed in a market-oriented perspective exclusively, in which only holders of technology, either local or overseas users of genetic resources, are seen as those who contribute to the added value of biodiversity. That is why it is important to set up as a goal to formulate a capability for sustainable innovation in which the herbal industry, local, indigenous and Afro-Colombian communities are considered also to be holders of technology. Although the analysis of capability would not provide a complete answer to all dynamics and complexities that are behind medicinal plants, it can provide a procedural approach under which all those aspects can be taken into account as Colombia implements the International Regime on Access to Genetic Resources and Benefit Sharing. Hence, the proposed

capability seeks to explore how developing countries rich in biodiversity, particularly Colombia, should include within the concept of innovation in the use of biodiversity for the health industry and research the different actors that are currently ‘invisible’ and so have been left behind.

This task is possible to achieve through the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, because it leaves policy room for countries to adapt this international treaty to local conditions. In fact, although the Nagoya Protocol is cautious in not granting express property rights or setting up a *sui generis* property system for traditional knowledge,⁴³¹ its wording suggests that holders of traditional knowledge, especially that associated with genetic resources, are to be considered, as countries make their regulatory dispositions to grant access to users of genetic resources. Article 8 (j) of the UN Convention on Biological Diversity only requires countries to respect, preserve and protect traditional knowledge as well as to involve their holders in benefit sharing, and the UN Convention on Biological Diversity does not require countries to regulate any particular aspect of prior informed consent from local or indigenous communities. However, Article 7 of the Nagoya Protocol takes a step further by calling on countries to take measures to ensure that prior informed consent of indigenous and local communities is obtained when there is access to traditional knowledge associated with genetic resources.

As the Nagoya Protocol goes into detail on what countries should “take into consideration” regarding traditional knowledge associated with genetic resources, it can be observed that the protocol aims to give further guidance

⁴³¹ The reason why there has been problematic to establish a *Sui Generis* system of protection on traditional knowledge has been the difficulty to even find a consensus in key aspects such as definitions of traditional knowledge. For instance, since 2001 the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization has been negotiating the creation of an international instrument related to IPRs and access to genetic resources and traditional knowledge. The negotiations have produced only drafts or ‘consolidated documents’ without any potential chance to achieve a *Sui Generis* system of protection for lack of consensus between developing and developed countries. See an example of the drafts treaties of the ICG: Intergovernmental Committee on Intellectual Property and Genetic Resources, ‘Consolidated Document Relating to Intellectual Property and Genetic Resources’, *WIPO/GRTKF/34/4* (2017) <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_34/wipo_grtkf_ic_34_4.pdf> accessed 31 July 2017.

on relevant aspects that Members of the Nagoya Protocol shall observe as they implement these measures such as local or indigenous communities' customary laws, community protocols and procedures (Article 12). The Nagoya Protocol does not, however, go as far as imposing on countries specific obligations of how prior informed consent from those communities should take place;⁴³² leaving countries enough legal room to freely implement Article 7 and 12 of the Nagoya Protocol to suit local conditions and goals or aspirations. Furthermore, Article 22.3 of the Nagoya Protocol calls on countries to assess capacity to develop their own endogenous research, which requires countries to recognise communities' contribution in the innovative process and entitle them to define how to place their practices and ancient knowledge in the industry and research.⁴³³

As observed, the Capability Approach offers a procedural mechanism to include many of the complexities and, particularly, the different actors behind the use of biodiversity for health research and health industry in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. In particular, a normative claim in the form of a capability for sustainable innovation in health research and the health industry, which requires a list of functionings, is proposed here. But before the list of functionings associated with a capability for sustained innovation in health research and the health industry is explained in detail, it is important to explain why the Capability Approach has been adopted in this thesis over other approaches or theories.

Why the Capability Approach?

Why does the Capability Approach provide a better perspective for implementing the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia than other similar approaches? There are two reasons. First, the International Regime on Access to Genetic Resources and Benefit Sharing has excessively focused on allocating ownership of genetic

⁴³² Morgera, Tsioumani and Buck (n 74)., pp 217-218

⁴³³ Jonas, Bavikatte and Shrumm (n 73).

resources to developing countries rich in biodiversity, which left behind the complexities that involve biodiversity. Indeed, the third objective of the UN Convention on Biological Diversity gave ground to developing countries rich in biodiversity to focus on allocating ownership control over specific goods (i.e. genetic resources) with the aim that those countries can fairly exchange them with other open-ended category of goods (i.e. benefit sharing), e.g. technology or royalties, from users of genetic resources.⁴³⁴ This has led to an implementation of the UN Convention on Biological Diversity which is limited to national, country or, even, community, membership as developing countries rich in biodiversity intended to counterbalance inequalities, especially the technological gap between them and developed countries, with an “exchange of goods and fulfilment of contractual obligations”.⁴³⁵ This means that those who benefit from the exchange of those goods are those who are part of a country rich in biodiversity or part of a community who holds the knowledge or practices over medicinal plants, or at least where the genetic resources are located. This can certainly be to the detriment of economic development as the exchange of goods and fulfilment of access to genetic resources and benefit sharing requirements can place a burden on those who add value to biodiversity through technology or growing sectors that represent an alternative for sustainable development, as is the case with the herbal industry. Also, a purely distributive approach has led to the distancing of communities and users of genetic resources and has undermined even the possibility of establishing a dialogue between them. The experiences of the lead researcher of the Javeriana research group with members of indigenous communities at *Valle del Sibundoy* and Afro-Colombian groups in the Choco region indicate that the local Colombian researchers were unable to even begin a dialogue on what terms benefit sharing should take place, since members of those communities were aiming to obtain monetary benefits, while the research group was seeking a long relationship in the development of medicines based upon on those communities’ knowledge.

⁴³⁴ This model is also known as commutative justice, see Bege Dauda, Yvonne Denier and Kris Dierickx, ‘What Do the Various Principles of Justice Mean Within the Concept of Benefit Sharing?’ [2016] Biotethical Inquiry.

⁴³⁵ *ibid.*, p 287

Alternatively to such an allocation of resources based exclusively upon geographical aspects, authors such as De Jonge, Korthals, Schroeder, and Pisupati⁴³⁶ have sought to extend the third objective of the UN Convention on Biological Diversity beyond country or community membership established in the Convention, to a distributive model of justice, in which goods should be distributed due to the moral duty which society has towards those who are in need; for instant, global efforts to prevent and treat diseases.

Therefore, this approach claims the benefits that arise from the utilisation of genetic resources should not be allocated to specific countries or communities, but ought to be distributed to those who are in need or under a condition of inequality.⁴³⁷ This can be seen as reflected in some of the provisions of the Nagoya Protocol. For instance, Article 10 of the Nagoya Protocol calls on parties to create a global multilateral benefit sharing mechanism to support conservation and sustainability of biodiversity not in specific countries but globally.

However, the distribution of goods based upon people's needs rather than country membership does not recognise the existence of conditions that differ from country to country, or community to community. In fact, global distribution of goods heavily relies on allocation of resources, rather than considering particular aspects that are specific to each country. This means that, despite the fact that distribution of goods grants a general normative claim, it does not take due account of all the varieties and complexities that the use of biodiversity involves. If those particular conditions are not taken into account, a purely redistributive approach could in practice mean that some communities have to relinquish their practices and knowledge to others who claim to be in need or under a condition of inequality.⁴³⁸

⁴³⁶ Korthals and De Jonge (n 109); De Jonge and Korthals (n 109); Schroeder and Pisupati (n 42); Schroeder and Lucas (n 42).

⁴³⁷ Dauda, Denier and Dierickx (n 434)., p 291

⁴³⁸ There is also other mechanism that focuses on allocating goods to increase specific skills: capacity building. Yet, this is not an equal term to the capability approach; although they might complement each other. Capacity building involves the importance of increasing specific skills and abilities.⁴³⁸ However, if capacity building initiatives aim to exclusively allocate resources, it could rather add an extra burden since those who carry out those initiatives do not have the skills and abilities to make most of the resources provided. That is why is necessary to

Also, Sen's Capability Approach offers an alternative to utilitarian theories. The latter analyse the problem of well-being by focusing on what is good for people in general in terms of happiness, i.e. how to make prevail pleasure over pain, or by allocating resources. In fact, such well-being theorists (e.g. utilitarians) do not observe circumstances that surround everyone.⁴³⁹ On the one hand, if there is a focus on what can satisfy a person, it can result in creating unequal measures. For instance, a woman could accept to be paid lower than a man for carrying the exactly type and amount of work as long as she is happy about having an income. On the other hand, if the priority is allocating resources or goods, the issue of compensating communities for the use of their practices and knowledge in medicinal plants by granting them with ownership, will not necessarily lead to the creation of further opportunities since communities differ culturally and socially in the way to transform those resources, such as plants, into well-being.⁴⁴⁰

That is why the idea of capability for sustainable innovation in health research and the health industry offers an alternative analytic frame through which it is possible to set up a normative claim and a flexible procedure to achieve the proposed capability. Following a Capability Approach, the main objective of the International Regime on Access to Genetic Resources and Benefit Sharing should thus be interpreted and implemented in a form that not only seeks to benefit countries' economic development, but also to include communities in the decision-making processes in health research and the health industry. An inclusive and sustainable innovation in the form of capabilities can be achieved if communities' conditions are facilitated by considering lists of functionings (i.e. doings and beings). This means that the analysis of the relevant

complement such initiatives with the Capability Approach as to entitle people to enhance local resources, initiatives and ownership. Further information see: Deborah Eade, 'Capacity Building: Who Builds Whose Capacity?' (2007) 17 *Development in practice* 630. Alexandre Apsan Frediani, 'Sen's Capability Approach as a Framework to the Practice of Development' (2010) 20 *Development in practice* 173.

⁴³⁹ Although well-being theory is not an exclusive matter for utilitarians, they largely emphasis in the importance to maximise well-being. See for instance, Bentham's work on the principle of utility, which highlights that the matters that govern mankind are pleasure and pain, Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation* (Oxford, Clarendon Press 1823).

⁴⁴⁰ Martha Nussbaum, 'Capabilities and Human Rights' (1997) 66 *Fordham Law Review* 273.

capabilities does not necessarily contradict the scope of the International Regime on Access to Genetic Resources and Benefit Sharing, but on the contrary, an interpretation in the light of this approach can fulfil the policy making space that the wording of the Regime leaves to Members, particularly Colombia, as they implement this international framework.

Second, the reasoning behind Decision 391 and the Colombian Constitutional Court rulings on securing a balance between economic development and communities' rights finds echoes in the Capability Approach. Chapter Three points out that the 1991 Colombian Constitution and the rulings of the Constitutional Court have stressed the importance of reconciling, on the one hand, economic development and international trade, and, on the other hand, other social and cultural concerns, including the rights of local, indigenous and Afro-Colombian communities. Judicial decisions from this high tribunal have obliged authorities to include communities in the decision-making process of projects that involve the exploitation of non-renewable natural resources and trade-related aspects such as the implementation of the International Convention for the Protection of New Varieties of Plants 1991 in Colombia, a treaty designed to protect plant breeders' rights (see Chapter Three). Equally, Decision 391 highlights that genetic resources, as well as communities' practices and knowledge related to those resources, are not only of "strategic value" to the Andean sub region.⁴⁴¹ It calls on Andean Community state members to recognise that communities have the right to decide on the use of their knowledge and practices if someone is interested in accessing traditional knowledge associated with genetic resources (Article 7).⁴⁴²

As observed, the constitutional mandates and Decision 391 seek to create a balance between economic development and communities' rights. Equally, Sen's analysis opposes neither economic development nor international trade, but rather it calls on stakeholders (e.g. governments, international

⁴⁴¹ See Paragraph 4 of the Preface of the Decision 391 on the Common Regime on Access to Genetic Resources of 1996.

⁴⁴² See the Preamble of the Decision 391, which mentions that it "recognises the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution"

organizations, etc.) to place people at the centre of economic analysis and policy to bring a flexible and balanced approach to achieve social goals such as inclusion. By placing people at centre, it is possible to evaluate people's conditions in terms of what they are capable of doing and being.

Translating Sen's Capability Approach into the constitutional rules and Andean legislation, and the scope of the thesis, a balanced approach would not seek to create an unnecessary burden in health research or deprive the herbal industry of growing in economic terms, but it would aim to include communities as a key factor in Colombia's health research and health industry. Following Sen's line of reasoning, it would be possible to include communities within health research and the health industry if their contribution is analysed in terms of what communities are capable of doing and being (functionings). As functionings are established, communities would be entitled to select and combine from a list of functionings, which forms the capability for sustainable innovation, so they can decide how to participate in health research and the health industry when their practice and knowledge are employed.

[The List of Functionings](#)

In this thesis, the list of functionings has a practical purpose. Previous chapters carried out an evaluation of Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing and its impact for health research and the health industry, exposing the "messy" realities of law in practice on the ground. That thick description shows important exclusions from enjoyment of the benefits of Colombian biodiversity, particularly for certain communities in Colombia. The list of functionings is the basis for solutions on how to achieve the proposed capability for sustainable innovation. Those solutions rely on communities having the freedom to combine and choose from that list, in order to achieve the capability for sustainable innovation.

The list of functionings is based upon securing inclusive innovation in the health industry and health research in the regulation of access to genetic

resources. Yet, it does not pretend to be a fixed list. Each functioning can be subject to a continuing debate as to the very nature of the Capability Approach permits constant discussion of each of its key elements.

Possessing Genetic Resources for Benefit Sharing

Since developing countries rich in biodiversity enjoy significant availability of genetic resources, they have adopted the International Regime on Access to Genetic Resources and Benefit Sharing, which allocates ownership access control over genetic resources to those countries with the aim that they could demand users to share benefits that arise from the utilisation of those resources.

However, the allocation of property control over resources or the granting of ownership control over resources to developing countries rich in biodiversity has not led to effectively recognised and protection of communities' practices and knowledge. It has rather created almost an exclusive monopoly over the utilization of genetic resources without recognising those communities' contribution. As a result, practices and knowledge are driven into the public domain for health research and the herbal industry.

Therefore, what should be assessed is not whether genetic resources are key sources or commodities to obtain royalties or payments, but rather what actors and conditions are behind leading developing countries rich in biodiversity to achieve a specific goal, i.e. the capability for sustainable innovation. The functioning related to possessing genetic resources for benefit sharing evaluates whether developing countries rich in biodiversity systems of ownership control of genetic resources acknowledge the existence of communities' practices and communities.

As a result, this functioning renders material and practical the Colombian constitutional principles of "recognition and protection and cultural diversity" of indigenous and Afro-Colombian communities, as well as the protection of local communities' socio-economic relationship with their environment, since

the Constitutional Court calls on authorities to recognise “the practices and traditional knowledge of ethnic people and peasants, communities” as Colombia implements international treaties such as the International Regime on Access to Genetic Resources and Benefit Sharing.⁴⁴³ In other words, Colombian sovereignty over genetic resources cannot rule out the rights that communities have over their traditional knowledge and practices associated with those genetic resources.

Being Able to Take Part in the Industrial Application of Genetic Resources and the Benefits that Arise from it

This functioning requires an assessment of who is participating and how they participate in the research into genetic resources. It is important to evaluate this aspect, because the different contributions that occur in research activities should include not only those who hold technology to carry out investigation or those who can place products and service in the market, but also those who can contribute to R&D and the commercialisation of goods and services through their practices and knowledge. As a result, the capability for sustainable innovation in health research and the health industry should include communities in the industrial application of genetic resources and entitle them to participate in the benefits that arise from the utilization of their practices and knowledge associated with genetic resources. In order to put in practice this functioning, it is necessary to define a mechanism to establish a dialogue, in which stakeholders are identified and contributions in the use of genetic resources for health research and health industry are recognised too.

Being Able to Add Value to Health Research and the Health Industry

The functioning of being able to add value to health research and the health industry assesses to what extent industries in developing countries rich in biodiversity have entitled all actors, e.g. local researchers, and the knowledge and practices from local and indigenous communities, particularly in the

⁴⁴³ C-1051 of 2012, Constitutional Court; Recommendation 2017-00057-00 of the Consultant Body of the Council of State

health industry and health research, to decide whether or not to participate and how to participate in the decision-making process. Since this functioning aims to recognise the participation of different actors in health research and the health industry, it also analyses what legal mechanisms of compliance should take place to enforce those actor's rights. In particular, it assesses the current legal mechanism to secure compliance with the International Regime on Access to Benefit Sharing such as the Ministry of Environment regulation on access to genetic resources, and Ministry of State guidelines on public consultation, and evaluates whether it is desirable to establish new mechanisms of compliance with norms that impacts the herbal industry, such as marketing approvals.

Conclusions

This chapter has introduced a normative element, with the aim of being able to make practical proposals to address the problems with the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, particularly the lack of recognition and protection of practices and knowledge from local and indigenous communities in adding value to the use of biodiversity for industry and research. The chapter proposes employing an analysis of capabilities, an approach which is championed by Sen. Sen contributes to the study of economic development by placing at the centre of his analysis people's conditions, preferences and choices. These choices take the form of specific conditions that embody functionings (beings and doings). This approach has already been adopted in interdisciplinary work, similar to this socio-legal inquiry into access to genetic resources and benefit sharing in Colombia.

This chapter proposes and justifies the capability for sustainable innovation in health research and the health industry, which aims to include what indigenous and local communities are capable of doing and being in adding value to the use of biodiversity. This chapter also introduces the list of functionings that serves to address the complexity of the law with the aim of achieving the proposed capability.

Chapter Seven: The Capability for Sustainable Innovation for the Health Industry and Health Research: Amending Colombia's Implementation of the International Regime on Access to Genetic Resources and Benefit Sharing

Introduction

This chapter brings together all the different aspects discussed above, and the findings of previous chapters, to propose a solution to the thesis' main research question: How should Colombia, a developing country rich in biodiversity, implement the International Regime on Access to Genetic Resources and Benefit Sharing in order to recognise the contribution from local, indigenous, and Afro-Colombian communities' practices and knowledge in adding value to the use of genetic resources for the health industry and health research? Chapter Seven provides a cohesive analysis of Colombian law and policy in practice, building to a proposal for a revised approach to implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in that country. The chapter begins by summing up the argument so far.

This thesis focused on the International Regime on Access to Genetic Resources and Benefit Sharing, its implementation in Colombia, the protection of communities' practices and knowledge associated with genetic resources, and the health industry and health research in the country. It showed the different ways in which the local, indigenous, and Afro-Colombian communities' practices and knowledge associated with genetic resources in Colombia has been ignored in health research and the health industry. This has occurred despite the fact that the industry and research rely on those practices and knowledge, and the fact that Colombia is bound to protect and secure the rights of communities in the use of biodiversity according to Decision 391, which implements the International Regime on Access to Genetic Resources and Benefit Sharing in the Andean sub-region and the country, and according to the rulings of the Constitutional Court.

Chapter Two introduced the key aspects of the International Regime on Access to Genetic Resources and Benefit Sharing and carried out a review of the evolution of this international instrument. Chapter Two revealed a range of discussions from questions of geopolitical and economic balancing of power between the global north and the global south, intellectual property rights, ethics, and justice, as well as sustainability and conservation of the world's biodiversity. There was also discussion of the relationship between communities and genetic resources, and whether the International Regime on Access to Genetic Resources and Benefit Sharing actually compels members of this international treaty to protect communities' practices and knowledge.

Chapter Two explained that there has been a constant search for recognising and protecting communities' rights over their practices and knowledge, as the International Regime on Access to Genetic Resources and Benefit Sharing has evolved from the UN Convention on Biological Diversity to the Nagoya Protocol. However, that evolution has focused particularly on downstream stages of R&D (e.g. botanical gardens, research centres, etc.), leaving upstream users unscathed. This means that as communities' practices and knowledge go upstream in R&D, it can potentially fade away as users employ technology to isolate and synthesize genetic resources for industrial production and research. Further, since the Regime on Access to Genetic Resources and Benefit Sharing has focused on industries that employ such technologies, it has left in a "blind spot" other industries, particularly the herbal industry, which employ practices and knowledge associated with genetic resources. This means that, in general terms, with the exception of EU's recent legislative efforts that make this industry fulfil access and benefit sharing requirements, the herbal industry is not obliged to comply with it.

Chapter Three centred its discussion on Colombia's implementation of the International Regime on Access to Genetic Resources and Benefit Sharing through Colombian constitutional rulings, the Andean Decision 391, and the administrative decisions taken by different ministers of the central government. Chapter Three highlighted that, based upon the fundamental

principle of “recognition and protection of ethnic and cultural diversity” of indigenous and Afro-Colombian communities, as well as the protection of local communities’ socio-economic activities related to the environment, the Constitutional Court has sought to reconcile, on the one hand, economic development and international trade, and, on the other hand, other social and cultural concerns, including the rights of local, indigenous, and Afro-Colombian communities. As a result, this court has established that all branches of government should protect and enforce communities’ rights in any circumstance that involves a state action or inaction.

In response to those constitutional requirements, the government has promulgated two decrees (Decrees 2164 and 1745 of 1995) that aim to protect the cultural and ethnic identity of indigenous and Afro-Colombian communities by granting them community land (*Resguardos* and *Tierras de las Comunidades Negras*, respectively), recognising their own form of government and laws, and securing that they are previously consulted if there is any project that might affect their communal lands. Although neither decree extends rights such as community land to local (or non-ethnic) communities, the Constitutional Court in different rulings has extended the right of being publicly consulted if action or inaction of the State or other actors affect their socio-economic relationship with the environment. These decrees and constitutional rulings were established in the context of exploitation of non-renewable resources such as gold and oil, and infrastructure projects.

Translating this analysis into genetic resources and traditional knowledge, Decision 391 calls on members of the Andean Community, including Colombia, to recognise that communities have the right to decide on the use of their knowledge and practices if someone is interested in accessing traditional knowledge associated with genetic resources (Article 7). The scope of protection of communities’ rights in Decision 391 also found echoes in the Constitutional Court’s rulings. For instance, the court emphasised that Colombia has the exclusive “faculty to use [genetic resources] and take

advantage of them economically according to their own interests”,⁴⁴⁴ while it should recognise and respect the rights of *all* communities over their practices and knowledge.⁴⁴⁵

However, Chapter Three also pointed out that a series of administrative decisions seemed to contradict Decision 391 and the Constitutional Court rulings. In fact, through a number of administrative decisions, the Ministry of the Environment and Ministry of State has eased the rules on access to genetic resources and public consultation to local researchers. For instance, these decisions appear to ignore any role that local communities (e.g. peasants) might play in leading local researchers to employ medicinal plants for health research, as the Ministry of Environment and the Ministry of State only require prior informed consent if there is an ethnic community (i.e. indigenous and Afro-Colombian communities) involved. This means that the government discriminates against some communities in order to facilitate access to genetic resources. Also, the Ministry of the Environment has *de facto* exempted the herbal industry, which produces and distributes phytomedicines, from obtaining communities’ prior informed consent because phytomedicines are not products whose therapeutic activity is accredited to isolated and purified molecules, or combination thereof, as occurs with chemical synthesized products or biological medicines. Additionally, the herbal industry also employ traditional knowledge and practices to prove the therapeutic activity of traditional phytomedicines to obtain marketing approval. This means that the herbal industry does not need to prove therapeutic activity with expensive clinical trials. Nevertheless, the industry is not obliged by law to carry out public consultation as it employs communities’ practices and knowledge in the granting process of marketing approvals, even if they belong to indigenous and Afro-Colombian communities.

Chapter Four exemplifies the contradiction that exists between, on the one hand, governmental decisions and policies on health research, and, on the

⁴⁴⁴ C-519 of 1994, Constitutional Court

⁴⁴⁵ C-1051 of 2012, Constitutional Court; Recommendation 2017-00057-00 of the Consultant Body of the Council of State

other hand, the constitutional mandates and Decision 391 in protecting communities' practices and knowledge. This is evidenced in Colombian innovation policy and through a small dataset collected in interviews with a representative research group based at Javeriana University related to the use of two medicinal plants for health research. On the innovation policy, a fragmented implementation of the International Regime on Access to Genetic Resources and Benefit Sharing can be observed, as Colombian central authorities are pursuing an economic agenda to make Colombia more scientifically competitive in international markets according to the OECD's Oslo Manual of innovation. This has occurred despite the fact that such a policy has led authorities to ignore the role of communities' practice and knowledge associated with genetic resources in adding value to health research. This means that Colombia's innovation policy contradicts its own Constitutional Court rulings and Decision 391.

This fragmentation can also be observed in the cases of two medicinal plants, which were investigated by the research group from Javeriana University. Throughout the analysis of the development of therapies deriving from two medicinal plants (*Dividivi* and *Anamú*), it was shown how in practice the *Dividivi* has historically interacted with *campesinos* of *Ricaurte's* socio-economic activities, and how that interaction led the research group to identify the anti-inflammatory properties of the plant. Those properties have been transformed into phytotherapeutic cancer treatments. The research group materialise the hopes of Colombia in transforming genetic resources and practices and knowledge associated with those resources into medicinal products that could benefit not only the country's technical and scientific capacity, but also the population as a whole. It is also fundamental to notice that the research group has, in its view, complied in full with the Ministry of the Environment's and Ministry of State's regulations on access to genetic resources and prior informed consent, as well as being a beneficiary of public funding. However, the research group does not acknowledge the practices and knowledge of the local community of peasants as innovative, which means it did not recognise any contribution from communities when it reached mutually agreed terms with the Ministry of the Environment. Consequently,

the research group filed and obtained patents locally and globally without disclosing information on communities' practices and knowledge related to the plants and without carrying out public consultation. However, the research group has sought to engage with the community by unilaterally establishing a production chain in which the research group facilitated the introduction of an improved seed of the *Dividivi* to communities, and *campesinos* of these communities are consigned to growing, harvesting, and handing the plant over to laboratories.

Equally, the data collected in Chapter Four also indicate a lack of dialogue between local researchers and ethnic communities. The testimony of Professor Fiorentino, the lead researcher of the Javeriana group, regarding her own experience with *Afro-Colombians* in Choco and indigenous in the *Valle del Sibundoy* provides a critical perspective of the compensatory mechanism of the International Regime on Access to Genetic Resources, since ethnic communities were apparently interested only in a straightforward monetary transaction. This means that communities seek to obtain recognition for their contribution in pure economic terms without due consideration of how to create a dialogue in which users of genetic resources, such as local researchers, and holders of practices and knowledge could advance together to transform those resources into well-being.

Chapter Five centred its analysis on the use of medicinal plants by the herbal industry. It explained how the marketing of herbal medicines works in Colombia. Firstly, there is the herbal industry which has benefited from a supportive regulatory framework and a sustainable policy on the use of biodiversity for the production and distribution of phytomedicines, particularly traditional phytomedicines. As part of its strategy of sustainable use of Colombia's biodiversity, the government has allowed this industry to prove the therapeutic effect of traditional phytomedicines through communities' knowledge and practices without consulting communities. There are also the *Yerbateros* in urban markets, which have not been included into the strategy of sustainable use of Colombia's biodiversity. Yet, it is in urban markets where practice and knowledge in the use of medicinal plants

are transferred to those who not only acquire the actual plants, but also access the knowledge and practices behind the use of those plants. This is evidenced in the small dataset of interviews with the *Yerbateros* in the *Plaza Samper Mendoza*, whose knowledge is widely disseminated to different stakeholders including patients and actors from the herbal industry. The herbal has even affected *Yerbateros*' business activity, as it has driven away customers from urban markets such as *Plaza Samper Mendoza* to specialist outlets for alternative products (i.e. *tiendas naturistas*). Furthermore, there is also an unbalanced legal approach towards local researchers if compared with the herbal industry. While the former are required to comply with both access and benefit sharing, and market approval, regulations, the herbal industry is not subjected of any of those requirements. Additionally, Chapter Five also detailed the difficulty in defining who the actors behind the use of medicinal plants actually are, so as to identify how they contribute to the understanding of medicinal plants.

Against this background, Chapter Five also identified that there have been efforts from academia and the government to document medicinal plants, which could potentially help to answer some of those complex questions. However, such efforts have a limited scope, since they aim to identify only the therapeutic effects of medicinal plants. This means that the documenting of traditional knowledge and practices does not seek to solve some of the complex aspects behind the use of medicinal plants so as to enforce communities' rights over their practices and knowledge according to Decision 391 and the Constitutional Court's rulings.

As Chapters Three to Five described the difficulties in recognising and safeguarding communities' practices and knowledge for health research and the health industry in Colombia, Chapter Six asked whether health research and the health industry in a market-oriented perspective could involve other aspects, such as social concerns. Chapter Six pointed out that it was possible to do so by including social concerns such as communities' rights in Colombian innovation policy. This chapter argued for inclusion of communities in Colombian innovation policy by relying on the Capability Approach.

Because the Capability Approach seeks to place what people are capable of being, or doing, within an economic analysis, the way innovation is analysed in Colombia should also consider how local and indigenous communities contribute to different activities of innovation in the use of biodiversity for health research and the health industry. As a result, Chapter Six argued that communities should also be considered as part of the innovative process in health research and the health industry since they have been granted constitutional protection. In that way, Colombia can address the particular circumstances of communities' practices and knowledge associated with genetic resources, as this country employs those resources for economic development.

Through the Capability Approach, Chapter Six set up as a goal the formulation of a capability for sustainable innovation in which holders of technology, the herbal industry, local, indigenous, and Afro-Colombian communities are considered. Even though the Capability Approach would not provide a complete answer to all dynamics and complexities behind medicinal plants, it provides a procedural approach under which all those aspects can be considered as Colombia implements the International Regime on Access to Genetic Resources and Benefit Sharing. In brief, the capability for sustainable innovation, and its functionings, in health research and the health industry seeks to include within innovation laws and policies communities that have currently been left behind. As a result, communities would be entitled to decide whether or not and how to take part in health research and the health industry.

This analysis leads to recommendations on how the International Regime on Access to Genetic Resources and Benefit Sharing should be implemented in Colombia to establish more inclusive forms of innovation in health research and the health industry. To that end, Chapter Seven brings together the different components of the thesis to address its core research question: How should Colombia, a developing country rich in biodiversity, implement the International Regime on Access to Genetic Resources and Benefit Sharing, in

order to recognise the contribution from local, indigenous, and Afro-Colombian communities' practices and knowledge in adding value to the use of genetic resources for the health industry and health research?

The thesis has set up a normative claim in the form of the capability for sustainable innovation in health research and health industry. This claim, in turn, is formed by a list of three functionings. Hence, the legal amendments suggested by that claim spring from those functionings. Therefore, this chapter is divided into three parts. The first part discusses the functioning of possessing genetic resources for benefit sharing, which assesses how to address the problem of placing communities' practice and knowledge into the public domain. This is constructed through the analysis of the Constitutional Court rulings which aim to balance economic development and state sovereignty over natural resources and genetic resources. The second part explores the functioning of being able to take part in the industrial application of genetic resources and the benefits that arise therefrom, in which is discussed how the Colombian innovation policy could help identify who contributes and how communities add value to the use of biodiversity for health research and the health industry. The final part studies the functioning of being able to add value to health research and the health industry, which proposes legal mechanisms to enforce communities' rights, particularly public consultation. The conclusion summarises the findings of this chapter in the form of the concrete legal amendments Colombia should implement, so as to achieve the capability for sustainable innovation in health research and the health industry.

Possessing Genetic Resources for Benefit Sharing: Addressing the Problem of Placing Practices and Knowledge into the Public Domain

The first aspect to be evaluated in the analysis of the capability is related to ownership control over genetic resources. This is analysed first because most of the debate in biopiracy and bioprospecting, as well as the ethics behind the International Regime on Access to Genetic Resources and Benefit Sharing and intellectual property rights, depart from the discussion of property control on

genetic resources and traditional knowledge and practices associated with those resources. Chapter Two points out that, since developing countries rich in biodiversity enjoy large availability of genetic resources, they have adopted the International Regime on Access to Genetic Resources and Benefit Sharing, which allocates ownership access control over genetic resources to those countries with the aim that they could demand users to share benefits that arise from the utilisation of those resources. Based upon that ownership control, the International Regime on Access to Genetic Resources and Benefit Sharing establishes that users of genetic resources require prior informed consent and must reach mutually agreed terms according to the law of developing countries rich in biodiversity (see Article 1 of the UN Convention on Biological Diversity).

However, the granting of ownership control over resources to developing countries rich in biodiversity does not necessarily lead to the recognition and protection of communities' practices and knowledge. On the contrary, the allocation of ownership control on genetic resources almost exclusively to the state through the concept of sovereignty has let those practices and knowledge into the public domain for health research and the herbal industry.

For instance, as Colombia enjoys exclusive ownership control over its genetic resources, it has implemented the International Regime on Access to Genetic Resources and Benefit Sharing in a way that facilitates access to genetic resources to local researchers (see Chapter Three), such as publicly funded universities and research centres, to encourage them to make use of biodiversity for health research. In fact, Decrees 1375 and 1376 of 2013, and Resolution 1348 of 2014 ease the access and benefit sharing rules, particularly for non-commercial research, which is normally conducted by local researchers. As local researchers are those who normally carry out non-commercial research, requirements such as prior informed consent and mutually agreed terms, demand a simple procedure in which it is not necessary to provide detail on the use of genetic resources, since non-commercial research usually involves activities such as collecting and sampling of those resources.

However, as occurred in the case of the *Dividivi*, a local research group employed the knowledge and practices of a local communities of peasants to identify the anti-inflammatory properties of the plant with the aim of using such properties to treat cancer. Although Constitutional rulings call on authorities to recognise and protect practices and knowledge of communities, the research group was not obliged to consult with local communities since the Ministry of Environment's regulation only requires them to carry out prior informed consent procedures with the Ministry of State if there is involvement of ethnic (i.e. indigenous and Afro-Colombian) communities. As a result, *campesinos* in the region of *Ricaurte* were not even acknowledged in their contribution to leading to this group to the medicinal properties of the *Dividivi*. Even more, as the research turned into a commercial investigation, i.e. the group filed and obtained patents in Colombia and worldwide, it was evidence of how holders of technology appropriate those contributions because they are placed into the public domain, as authorities do not demand that local communities be involved (see Chapter Four).

Additionally, the national herbal industry benefits from the practices and knowledge of ethnic and local communities because it acquires information on how to elaborate traditional phytomedicines and demonstrates effectiveness and safeness for obtaining marketing authorisation (Decree 2266 of 2000; see Chapter Five). For this case, the government has explicitly granted an exception from compliance with the access and benefit sharing regulation in Resolution 1348, without even considering how such a regulation also places into the public domain the knowledge and practices from *all* communities, including indigenous and Afro-Colombian communities, which makes it possible for this industry to produce and distribute its products.

Therefore, what should be observed in this functioning is not whether genetic resources are key sources or commodities to obtain benefit sharing for developing countries rich in biodiversity, but rather what actors and conditions are behind those resources, to acknowledge and secure the value of

their contribution to the use of biodiversity. This is why the functioning related to possessing genetic resources for benefit sharing includes *all* relevant actors.

For the particular case of Colombia, the Constitutional Court has provided some grounds on this functioning as it has already mentioned in the case of 1991 International Convention for the Protection of New Varieties of Plants. The implementation of the 1991 International Convention for the Protection of New Varieties of Plants in Colombia was an internationally agreed compromise to secure greater protection to plant breeders over new varieties. The core of the Colombian Constitutional Court rulings was that the government could not establish a system of property rights over new varieties for plant breeders if other actors, whose socio-economic and cultural activities depended on agricultural plants, were not considered. In particular, the Constitutional Court considered fundamental that the government should include the participation of communities in the implementation process through public consultation. As the government did not consult communities, the Constitutional Court pointed out that authorities were ignoring both “the practices and traditional knowledge of ethnic people and peasants, communities” and “the rights that such communities may have over traditional or native varieties, particularly those that do not circulate within commercial and technological channels”.⁴⁴⁶ Although this public consultation was an ongoing effort which has not materialized in any legal or policy document, the Constitutional Court ruling illustrates that what is important is not to create a parallel plant breeder system, but to include communities in any decision making process that might threaten their relationship with agricultural plants.

The legal reasoning of the Constitutional Court is an appealing alternative to the broader discussion as to what sort of rights can be secured to holders of traditional knowledge over genetic resources. Indeed, there is not even an international consensus on how to approach this difficult question. For example, as the core treaty of the International Regime on Access to Genetic

⁴⁴⁶ C-1051 of 2012, Constitutional Court

Resources and Benefit Sharing, the UN Convention on Biological Diversity granted only property rights on genetic resources to states, it calls on countries in its Article 8 (j) to respect, preserve, and protect traditional knowledge as well as to involve holders of traditional knowledge in benefit sharing. However, the UN Convention on Biological Diversity does not require countries to regulate any particular aspect of prior informed consent from local or indigenous communities (see Chapter Two). The Nagoya Protocol, which is also part of the International Regime on Access to Genetic Resources and Benefit Sharing, took a step further by calling on countries to take measures to ensure prior informed consent of indigenous and local communities was obtained when there was access to traditional knowledge associated with genetic resources and to consider different aspects such as customary laws, community protocols, and procedures (see Chapter Two).⁴⁴⁷ Similar dispositions are found in the Decision 391 of the Andean Community.

However, those international provisions provide rather broad considerations, and yet not are legally binding commitments for countries, meaning that the International Regime on Access to Genetic Resources and Benefit Sharing does not grant property rights over traditional knowledge to communities. This reflects how difficult it is to secure rights over genetic resources to communities when traditional knowledge is involved. As analysed in Chapter Two, there is an inconclusive debate on the legal treatment regarding traditional knowledge and genetic resources in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore of the WIPO. The intergovernmental committee sought to address concerns from developing countries rich in biodiversity on the misappropriation of knowledge and practices on genetic resources in intellectual property rights, but the intergovernmental committee negotiations have reached a stalemate because parties have not agreed whether there should be a *sui generis* property regime or what sort of rights should be granted to communities.

⁴⁴⁷ Morgera, Tsioumani and Buck (n 59)., pp 30

However, as studied in Chapter Three, the Constitutional Court has set up a precedent on the sovereignty of the state to exploit natural resources (e.g. gas and oil) and the rights of communities which can also be extended to genetic resources. This court has mentioned that – despite the fact that natural resources such as oil and gold are exclusively property of the state – their economic exploitation should not go against ethnic and peasant communities’ cultural, social, and economic rights. That is why before the government carries out any economic activity of exploitation on natural resources, communities should be consulted. Furthermore, constitutional case law relating to the International Convention for the Protection of New Varieties of Plants also demonstrates that, although Colombia has acquired international trade compromises to grant exclusive rights to plant breeders, the Constitutional Court ordered the suspension of the implementation of the 1991 International Convention for the Protection of New Varieties of Plants until the rights of ethnic and peasant communities over those plants were consulted.

A similar analysis could be conducted in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia. In fact, through Decrees 1375 and 1376 of 2013, and Resolution 1348 of 2014, the government has placed into the public domain practices and knowledge associated with medicinal plants. As part of its policy of facilitating access to genetic resources to local researchers so as to increase the country’s scientific capacity, Decrees 1375 and 1376 exempt local researchers from the access and benefit sharing requirements when they carry out non-commercial activities, specifically the collection and sampling of genetic resources. Also, Resolution 1348 points out that access and benefit sharing rules only apply when users carry out (i) activities on native species *in situ* or *ex situ*, including virus and viroids, which involve either the isolation of functional and non-functional units of DNA and RNA, as found in nature; or (ii) there is isolation of one or more molecules, including micro and macromolecules, produced by the metabolism of an organism.

None of those administrative decisions state that the use of practices and knowledge associated with genetic resources as lead information constitutes

an activity that falls within the scope of the access and benefit sharing requirements. Since those regulations affect communities' rights over their practices and knowledge, the government should amend those regulations by establishing that the use of *any* communities' practices and knowledge associated with genetic resources constitutes an activity of access as established by Decision 391, hence, local researchers or other actors, particularly the herbal industry, should consult those communities.

As a result, the functioning of possessing genetic resources for benefit sharing would demand that Colombia, based upon its constitution and the rulings from the Constitutional Court, secures a position such that neither local researchers nor the herbal industry can employ practices and knowledge from indigenous, local, and Afro-Colombian communities, without consulting them. Therefore, Decrees 1375 and 1376 of 2013, and Resolution 1348 of 2014 should be amended to include, as an activity of access, the use of indigenous, local, and Afro-Colombian communities for health research and the health industry. However, to secure those communities' rights, it is also necessary to sort out aspects such as who are the right holders of traditional knowledge and practices, and how those holders actually add value to the use of Colombia's biodiversity for health research and the health industry.

Being Able to Take Part in the Industrial Application of Genetic Resources and the Benefits that Arise from it

This functioning requires an assessment of who is involved in research into genetic resources, and how they participate. It is important to analyse this aspect of capability because the different contributions that occur in research activities should include not only contributions from those who hold technology to carry out investigations, or those who can place products and service in the market, but also those who can contribute to R&D and the commercialisation of goods and services through their practices and knowledge. As a result, the capability for sustainable innovation in health research and the health industry should include communities in the industrial application of genetic resources and include them in the benefits arising from

the utilization of their practices and knowledge associated with genetic resources.

First, this functioning requires identifying who contributes and how communities contribute in adding value of biodiversity for health research and the health industry. As discussed in Chapter Two, this is a critical issue in debates on biopiracy and bioprospecting, and a particularly relevant aspect of this thesis because it has been pointed out on different occasions how complex it is to give a simple legal response to the “messiness” behind the use of biodiversity. However, the case analysis of Colombia, and particularly, its innovation policy can provide a platform for untangling the complexities behind practices and knowledge associated with genetic resources.

As discussed in Chapter Four, Colombian innovation policy does not include the practices and knowledge of communities as they do not fit within international standards adopted by Colciencias, the country’s science bureau. This has led to a fundamental problem with the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in developing countries rich in biodiversity such as Colombia, which is that such an implementation seeks to leave R&D intact to benefit holders of technology, including local researchers. This means that it is considered that only those who employ technology are considered to be innovative. However, such an assumption is not only found in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing in Colombia, but is rooted in the way Colombia defines and measures innovation (see Chapter Four).

Certainly, Colombia only considers innovative the R&D activities of holders of technology, including local researchers. Colciencias, which is in charge of addressing resources and measuring what can be innovative, has defined as innovative the R&D activities from industries such as the pharmaceutical industry (see Chapters Three and Four). This has been the result of Colombian interest in employing international standards of innovation to become a more competitive economy, not only among developing countries but also within

developed countries. In particular, Colciencias adopted in its entirety the model of innovation of the Organisation for Economic Co-operation and Development (OECD).

The OECD is a club of countries (mainly developed ones) which share common policies to evaluate economic development. Since 1992 it has published the guidelines for collecting and interpreting innovation data, also known as the Oslo Manual, which mainly focuses on data collected from the government, sectors, and industries that create new products, processes, and services in a variety of areas such as information technology and biotechnology (see Chapter Four).⁴⁴⁸ These data primarily focus on how the production of knowledge and information is addressed towards industries. The Oslo Manual does not consider other forms of production of innovation, including traditional knowledge associated with genetic resources and local practices.

As innovation is only defined and measured by R&D activities from the industry as requested by international organizations such as the OECD, practices and knowledge from indigenous, local, and Afro-Colombian communities are not considered to be innovative in Colombia. Such an approach has the potential to bring benefits for Colombia R&D's capabilities and competitiveness in sectors such as health, but it also disavows the role of communities in adding value to biodiversity for the health industry. This has been reflected in different white papers in Colombia, which seek to engage local researchers to access genetic resources by easing access and benefit sharing rules and encouraging patenting in inventions deriving from genetic resources to allow them to commercialise to the upstream stage.⁴⁴⁹

⁴⁴⁸ OECD and Eurostat (n 216).

⁴⁴⁹ Chapter Four makes an analysis of different white papers in Colombia and concludes that Colombia economic policy and international trade has led them to adopt a model of innovation that follows international standards and ignores other forms of innovation; see Consejo Nacional de Política Económica y Social, 'Documento Conpes 3527 Política Nacional de Productividad y Competitividad' (n 217); Consejo Nacional de Política Económica y Social, 'Documento Conpes 3866 Política Nacional de Desarrollo Productivo' (2016) <<http://www.colombiacompetitiva.gov.co/prensa/informes/Conpes-3866-de-2016-Politica-desarrollo-productivo.pdf>> accessed 10 October 2017; Consejo Nacional de Política Económica y Social, 'Documento Conpes 3697 Política Para El Desarrollo Comercial de La Biotecnología a Partir Del Uso Sostenible de La Biodiversidad' (n 13); Consejo Nacional de Política Económica y Social, 'Bases de Un Plan de Acción Para La Adecuación Del Sistema de Propiedad Intelectual a La Competitividad y Productividad Nacional' (2008)

As a result, Colciencias has supported and even addressed public resources to local research to employ genetic resources and practices and knowledge associated with those resources for health research. This was clearly exemplified in the cases of the two medicinal plants (*Dividivi* and *Anamú*) (see Chapter Four), employed by a local research group, which have received public funds via Colciencias, without due recognition of communities' practices and knowledge.

Also, as communities' practices and knowledge are not considered to be innovative (see Chapters Three and Four), the academic and governmental efforts to document have centred exclusively in the therapeutic effects of medicinal plants. However, the documenting process does not aim to include communities in the industrial application of the medicinal plants. On the contrary, the documentation has served the herbal industry to prove the safeness and effectiveness of phytomedicines to obtain marketing approvals without due recognition of communities' input in health industry (see Chapter Five).

Consequently, it is important to answer the question of how the contribution from communities can be considered innovative in Colombia. The answer to that question can be found in the International Regime on Access to Genetic Resources and Benefit Sharing. The Nagoya Protocol calls on states to assess their capacity in carrying out 'endogenous research to add value to their own genetic resources'. Although the Nagoya Protocol does not define what endogenous research means, what this treaty aims to include as research in genetic resources is not only activities related to the use of technologies such as biotechnology, but different activities developed around a community's customary laws, protocols, and procedures.⁴⁵⁰ A similar reasoning can be found in the jurisprudence of the Constitutional Court in the International Convention for the Protection of New Varieties of Plants cases when it calls on

<http://www.disanejercito.mil.co//recursos_user///DISAN_EJERCITO/LABORATORIO_DE_REFERENCIA_E_INVESTIGACION/NORMATIVIDAD/conpes_3533_-_plan_nacional_propiedad_intelectual_-_2008.pdf> accessed June 6 2018.

⁴⁵⁰ Jonas, Bavikatte and Shrumm (n 73).

the government to safeguard the practices and knowledge of communities related to plants as they do not circulate within “commercial and technological channels”.

Therefore, Colombia’s innovation policy should be reconstructed to include innovation that is not produced within a market-oriented policy. That is why this thesis has claimed that is not only desirable to include those practices within Colombian innovation policy, but also necessary, so as to harmonise constitutional mandates and Decision 391 with the Colombian market perspective on innovation. This would require that the Colombian scientific authority, Colciencias, include within its innovation assessment of researchers and research groups “endogenous research” that adds value to genetic resources. Such an approach would demand a change in the policies on competitiveness and innovation in Colombia which are drafted in governmental white papers such as the National Policy for the use of Biodiversity or Colombia Competitive plans.⁴⁵¹ If communities’ practices and knowledge were included in the construction of innovation policy, it would also be possible to harmonise the fragmented implementation of the International Regime on Access to Genetic Resources and Benefit Sharing as it reconciles the rulings of the Constitutional Court with the administrative decisions from central government.

Also, indigenous and Afro-Colombia communities have a legal framework (Decreets 2164 and 1745 of 1995, respectively) that defines who can be a member of those communities, sets up principles to recognise their own form of government, customs and laws, grant them communal land, and the right to be publicly consulted if their ethnic and cultural integrity might be affected. This means that users of genetic resources, including local researchers, have already a framework that help them to identify ethnic communities across the country. Although local communities have not the same rights of those ethnic communities such as communal land, if the action or inaction of the State or other actors could potentially affect their socio-economic relationship with the

⁴⁵¹ Ministerio de Ambiente (n 223).

environment, the Constitutional Court has granted them on different occasions in a case by case approach the right to be publicly consulted to assess the impact of the action or inaction and to establish measures to overcome those difficulties. This imposes an extra burden on local researchers, but as in the cases of the medicinal plant *Dividivi*, the research group had already identified which local community employed the plants to treat different diseases. Further, the efforts to document the therapeutic activity of plants should be addressed to identify the different actors behind the use of biodiversity for the health industry, rather than serving to prove safeness and effectiveness of medicinal plants to obtain market approvals. Both of these proposals involve changes in policy rather than in formal law.

However, a problematic issue is the difficulty in establishing a dialogue between users of genetic resources and indigenous and Afro-Colombian communities in the use of their knowledge and practices associated with genetic resources for health research. For instance, the impossibility to reach an agreement on benefit sharing between Afro-Colombian communities in Choco and indigenous groups in the *Valle del Sibundoy*, with the Javeriana research group, is according to its lead researcher due to a clashing perspective on the compensatory mechanism of the access and benefit sharing regulation. To provide solutions, it is necessary to facilitate mechanisms in which those communities can create a dialogue with users of genetic resources. To do so, the government could intermediate between those stakeholders to advance a dialogue that could define how communities can participate in research and development, and establish benefit sharing agreements that could lead communities to transform those resources into functionalities that enable them to function as a community. Since the Ministry of Environment has worked closely with local researchers and it is the national authority responsible for the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing, it could be designated as the authority to oversee such a dialogue.

All of the above proposals mean Colombia should amend its innovation policy in three respects: (i) by including “endogenous research” that adds value to

genetic resources within its innovation assessment of researchers and research groups; (ii) by requiring the government to document not only the therapeutic value of medicinal plants, but also to identify the different actors behind the practices and knowledge of the plants; and (iii) the government through the Ministry of Environment should also intermediate between users of genetic resources and communities to establish a dialogue in which their practice and knowledge are recognised in order to define what form of benefit sharing should take place. In particular, it must be observed that driving resources into communities is not the only mechanism to secure the adequate protection of their rights, but the government should watch that those communities are able to transform those resources into functionalities that enable them to function as a community.

Being Able to Add Value to Health Research and Health Industry

The functioning of being able to add value to health research and the health industry assesses to what extent industries in developing countries rich in biodiversity have entitled all actors, e.g. local researchers and the knowledge and practices from indigenous, local, and Afro-Colombian communities, particularly in the health industry and health research, to effectively decide whether or not to participate, and how to participate in the decision-making process when their practices and knowledge are involved. This particularly involves the creation of mechanisms of compliance. In other words, if Colombia seeks to effectively include communities in its innovation policy, it become fundamental to establish mechanisms of compliance in order to secure that communities can exercise their rights in R&D and industry in practice.

There have been different proposals for establishing a mechanism of effective compliance with the International Regime on Access to Genetic Resources and Benefit Sharing. At first, developing countries rich in biodiversity, such as the Andean Community, established in Decision 391 administrative procedures and criminal sanctions to make users of genetic resources comply with Andean legislation. Those mechanisms were created with the aim of deterring particularly multinational companies from accessing illegally those countries'

genetic resources. In addition, although the UN Convention on Biological Diversity did not contemplate it, the Andean Community establishes the requirement of disclosure of origin in patents in Decision 486, the Andean legislation on patents, as a mechanism that aims to link patent provision with the International Regime on Access to Genetic Resources and Benefit Sharing to secure enforceability of the latter; if users fail to disclose such information, patents are denied or nullified (see Chapter Three).

However, since patents are limited by territory, users are not obliged to disclose origin in another jurisdiction which does not establish a similar requirement. For instance, the US does not contemplate such a requirement. In the case of other developed countries, there is not a consolidated common position, even between countries which belong to the same regional organisations, leading to different forms of disclosure origin. For instance, Belgium, Denmark, Germany, and Sweden (all EU members) have implemented disclosure of origin in their national patent legislations, but other EU members such as France and Spain have not implemented any disclosure of origin provision.⁴⁵² However, the implementation of disclosure of origin does not mean that those measures are necessarily effective. For instance, in Norway, despite the fact that disclosure of origin is compulsory, there are as yet no cases of disclosure of origin.⁴⁵³ This means that, despite the fact that members of the Andean Community have established such a requirement, it is difficult to implement globally because of the different approaches on disclosure of origin.⁴⁵⁴

⁴⁵² 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)

⁴⁵³ Morten Walløe Tvedt and Ole 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. pp 383-402; see also Morten Walløe Tvedt, 'Norwegian Experiences with ABS' [2015] *Implementing the Nagoya Protocol* 175.

⁴⁵⁴ Chapter Two analysed how an international patent disclosure of origin has been an issue in different forums including the World Trade Organization and the initiatives in the ICG of WIPO, in the latter it was proposed to establish a disclosure of origin in the Patent Cooperation Treaty (PCT) of WIPO, which assists patent applicants in protecting their inventions throughout different jurisdictions. However, none of those initiatives have been fruitful due to opposition from Countries such as the US.

There are other initiatives that do not focus on granting property rights, but are defensive measures against misappropriation (see Chapter Two). For instance, the Traditional Digital Knowledge Library in India seeks to put traditional knowledge associated with genetic resources in internet databases with the aim of making patent offices and courts dismiss patent protections to inventions on the basis that the invention does not fulfil the patent requirement of novelty and non-obviousness.⁴⁵⁵ Also, Peru has established a national database for traditional knowledge associated with genetic resources, in which local and indigenous communities decide whether to include their knowledge in the database, how much they want to share, and with whom they want to share it.⁴⁵⁶ Furthermore, this protection regime also establishes “licenses” for those users who want to access those resources, a measure that facilitates users’ compliance with prior informed consent and mutually agreed terms. In addition, developed countries’ courts and patent offices have embraced traditional knowledge and practices as part of the conditions that should be assessed to determine patent requirements. For instance, the British House of Lords (now Supreme Court) indicated that documented description of traditional uses of medicinal plants, although not described in chemical terms, serves as a proof of lack of novelty in patents.⁴⁵⁷ Also, the US Patent Office has employed references to the use of a traditional Chinese medicine to anticipate patent claims, hence denied them for lack of novelty.⁴⁵⁸

Because of those initiatives and approaches, the International Regime on Access to Genetic Resources and Benefit Sharing has also taken steps towards an international database. Article 15 of the Nagoya Protocol calls countries, particularly developed ones, to adopt mechanisms of compliance to ensure genetic resources employed within their territory have been lawfully accessed

⁴⁵⁵ See website: <http://www.tkdl.res.in/>; for further discussion see: Gaudillière (n 116).

⁴⁵⁶ The Peruvian Collective Knowledge Protection Regime or Ley que Establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas vinculados a los Recursos Biológicos (Ley 27811 de 2012)

⁴⁵⁷ *Merrell Dow Pharmaceuticals Inc v. HN Norton & Co Ltd* [1996] R.P.C. 76 (HL) in Dutfield, ‘A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent-Based Biopiracy’ (n 111)., pp 242-243

⁴⁵⁸ *ibid.*, p 243, see also: Board of Patent Appeals and Interferences of US Patent and Trade Office, *Ex Parte Pfizer, Inc.* (2009) at <http://ipwatchdogs.com/cases/viagra_bpai_decision.pdf> accessed September 20 2014

according to the access and benefit sharing regulation of the country that provides the genetic resources and considering traditional knowledge associated with those resources. Therefore, Article 17 of the Nagoya Protocol defines what those mechanisms are in order to monitor the compliance of users of genetic resources. These include checkpoints such as patent offices or other administrative agencies, and the Internationally Recognized Certificate of Compliance, which aims to secure that the flow of genetic resources and traditional knowledge is in accordance with the International Regime on Access to Genetic Resources and Benefit Sharing (see Chapter One).

An example of how the Internationally Recognized Certificate of Compliance and checkpoints might work is EU Regulation 511/2014, which creates a comprehensive mechanism of compliance for the European Union (see Chapter Two). This Regulation sets up specific measures to monitor users' compliance. In particular, the EU Regulation requires member states and the EU Commission to request publicly funded research to comply with access and benefit sharing rules from the country of origin and other users should demonstrate that they have complied with access and benefit sharing rules when the product needs marketing authorisation, or if there is no need for marketing authorisation, when the product is placed on the market in the EU for the first time.⁴⁵⁹ The EU regulation also indicates publicly funded users can prove that they lawfully accessed genetic resources and traditional knowledge through any information and relevant documents issued by a national authority in a developing country rich in biodiversity, including an Internationally Recognized Certificate of Compliance, as proof of compliance (see Chapter Two).

Since developed countries such as the EU member states are establishing user measures of compliance, such measures can only operate as long as there is a similar structure that actually oversees access to genetic resources and traditional knowledge in developing countries rich in biodiversity. However, developing countries rich in biodiversity do not deploy a similar structure to

⁴⁵⁹ Implementing Regulation 2015/1866

those established by the EU. Although India is currently issuing a number of important Internationally Recognized Certificates of Compliance,⁴⁶⁰ other developing countries rich in biodiversity do not have the infrastructure to implement that approach.⁴⁶¹ For instance, the Colombian national authority that oversees compliance with the International Regime on Access to Genetic Resources and Benefit Sharing, the Ministry of the Environment, has reached more than 200 mutually agreed terms (see Chapter Three), yet it has not issued the first Internationally Recognized Certificate of Compliance. Even more, a close analysis of the different mutually agreed terms in Colombia indicates that there are not even the first mutually agreed terms with local, indigenous, and Afro-Colombian communities. It is also alarming that users such as the research group of Javeriana University in the *Dividivi* case is obtaining patents on inventions derived from practices and knowledge of different communities without having publicly consulted them, despite the fact that they should have disclosed such information in the patent application (see Decision 486). Also, as repeatedly noted above, the fact that the herbal industry does not need to comply with access and benefit sharing rules indicates a clear lack of effective mechanism to safeguard communities' contribution.

Against this background, how could Colombia improve compliance to secure that those communities' contribution is safeguarded? A first step would be to make a practical reality the fundamental right of public consultation in the implementation of the International Regime on Access to Genetic Resources and Benefit Sharing. According to the Constitutional Court's precedent on public consultation, as observed in Chapter Three, communities have the right

⁴⁶⁰ India was the first country to issue an IRCC in 2015, ever since this country has issued more than 100 IRCC; for further information see Secretariat of the UN Convention on Biological Diversity, 'The First Internationally Recognized Certificate of Compliance Is Issued under the Nagoya Protocol on Access and Benefit-Sharing' <<https://www.cbd.int/doc/press/2015/pr-2015-10-07-abs-en.pdf>> accessed 3 July 2018. See also Secretariat of the UN Convention on Biological Diversity, 'Access and Benefit-Sharing Clearing-House: India' <<https://absch.cbd.int/countries/in>> accessed July 3 2018.

⁴⁶¹ For a comprehensive qualitative analysis of how difficult is to implement the Internationally Recognized Certificate of Compliance in developing countries rich in biodiversity see Nicolas Pauchard, 'Access and Benefit Sharing under the Convention on Biological Diversity and Its Protocol: What Can Some Numbers Tell Us about the Effectiveness of the Regulatory Regime?' (2017) 6 Resources 11.

not only to be consulted, but also to decide over specific activities when their rights could be affected before such activity, by either the state or any other agent, takes place. Although this precedent has been designed in the light of the exploitation of natural resources such as oil and gold, it should be implemented in line with the International Regime on Access to Genetic Resources and Benefit Sharing, particularly, the Nagoya Protocol which requires countries to adopt mechanisms to secure prior informed consent from communities (see Chapter Two).

To protect the fundamental right of public consultation and the Nagoya Protocol in practice, Colombia could observe the approaches of India and Peru, which have not only created databases on traditional knowledge, but have also adopted legislation allowing communities to decide whether they want to include their practices and knowledge in those databases, how they want to include it, and whether they allow users to access to such information. Colombia could adopt such legislation. In the event of conflicts between the interest of keeping communities' practices and knowledge secret and the interest of getting products based upon those practices and knowledge such as medicines into the market, Chapter Two points out that the Nagoya Protocol requires countries to pay due regard to situations such as lack of access to medicines. In those cases, the Colombian Constitutional Court could interpret the relevant legislation in such a way as to strike the adequate balance between communities' rights and the public interest of facilitating access to medicines. Finally, a Colombian database of traditional knowledge could also be consulted by patent offices, including the Colombian patent office, to decide whether users lawfully accessed practices and knowledge, and complied with disclosure of origin in patents.

In addition, the protection of public consultation would also require inclusion of the herbal industry within Colombia's access and benefit sharing regulation. It has been pointed out throughout this thesis that this industry benefits significantly from the knowledge and practices of communities without recognising their input. The industry can even employ such an input to obtain market authorisation. Therefore, in order to include this industry within the

access and benefit sharing regulations, Colombia could adopt a similar approach to that of the EU in Regulation 511/2014, in which users should disclose information related to their compliance with access and benefit sharing rules in market authorisation processes or, if this is not required, before the product reaches the market. Such a requirement would also represent an equal legal treatment for both the herbal industry and local researchers. As noted in Chapter Five, local researchers criticise the fact that the herbal industry is excepted *de facto* from the obligations of the implementation of access and benefit sharing rules in Colombia as local researchers are required to comply with that regulation and prove through expensive clinical tests the safeness and effectiveness of their phytomedicines. Therefore, a requirement that this industry must disclose information related to the use of practices and knowledge for their own benefit would give an equal legal treatment with local researchers too. Also, this requirement will necessarily engage the herbal industry with communities such as *Yerbateros*, whose economic activity have been affected by this growing industry, since it would require the industry to obtain prior informed consent from *them*. Colombia should include within the Decree 2266, which regulates the production and distribution of phytomedicines, including traditional phytomedicines, in Colombia, a disclosure of origin as a requirement to obtain a marketing authorisation, and in the event in which a product does not require marketing authorisation, it would be required to disclose origin before the product reaches the Colombian market.

To sum up this point, (i) Colombia should make enforceable public consultation within the access and benefit sharing regulations, through the creation of a public database related to traditional knowledge and practices, in which communities can decide whether they want to include their practices and knowledge in those databases, how they want to include it, and whether they allow users to access to such information for industrial application; (ii) the database can also help to determine whether users of genetic resources are disclosing information as they file patent applications. Also, (iii) it would require that the herbal industry disclose information in marketing

authorisation processes, so as to make this industry comply with Colombia's access and benefit sharing regulations.

Conclusions

This thesis has fitted the normative claim of the capability for sustainable innovation in the health industry and research within the 1991 Colombian Constitution and the rulings of the Constitutional Court on protecting community rights, particularly in the exploitation of natural resources such as gold and oil. It has been highlighted that since the Constitutional Court has aimed to strike a balance between the exploitation of natural resources and community rights, it has created an important precedent that can be extended in the utilization of genetic resources and traditional knowledge so as to balance the interest of the Colombian authorities to employ genetic resources and traditional knowledge for health research and the health industry, and acknowledging the contribution that local, indigenous, and Afro-Colombian communities made in adding value to the use of biodiversity. As the proposed capability is justified within Colombia's constitution and the rulings of the Constitutional Court, it is possible to suggest amendments to Colombian law, policy and practice, which would address what has been discussed throughout the thesis with the analysis of functionings.

On possessing genetic resources for benefit sharing, since Colombia placed into the public domain knowledge and practices of communities, it would not necessarily be necessary to create a *sui generis* system but it would rather require the country:

- I. To amend Decrees 1375 and 1376 of 2013, and Resolution 1348 of 2014 as to establish that the use of practices and knowledge of indigenous, Afro-Colombian communities constitutes an access activity which demands users, including local researchers, and the herbal industry, to obtain prior informed consent and reach mutually agreed terms with communities.

Regarding the functioning of being able to take part in the industrial application of genetic resources, it demands inclusion of communities'

practices and knowledge into its innovation policy. In particular, it would require:

- II. To include “endogenous research” that adds value to genetic resources within its innovation assessment of researchers and research groups.
- III. To require the government to document not only the therapeutic value of medicinal plants, but also to trace and identify the different actors behind the practices and knowledge of the plants.
- IV. To entitle the Ministry of Environment to create a dialogue between users of genetic resources and *all* communities in order to advance in mechanism to reach agreements on benefit sharing

In the functionings of being able to add value to health research and health industry, it would require that Colombia effectively make concrete public consultation in the regulation of access and benefit sharing. This would require Colombia:

- V. To create a public database related to traditional knowledge and practices, in which communities can decide whether they want to include their practices and knowledge in those databases, how they want to include them, and whether they allow users to access to such information for industrial application.
- VI. The database should also help determine when users of genetic resources are not disclosing information as they require patents.
- VII. To amend Decree 2266 to require that the herbal industry disclose information in marketing authorisations when the industry employ practices and knowledge to obtain marketing approvals for traditional phytomedicines in order to make this industry comply with Colombia’s regulation of access and benefit sharing.

Appendix I Schedule of interviews


Date and time	With whom	Where	Notes
19/09/2019 3:18 pm	Wilmar Olaya	Immunology Laboratory Javeriana University (Bogotá- Colombia)	Mr. Olaya is a researcher and the regulatory expert of the immunology research group.
19/09/2019 3:18 pm	Claudia Urueña	Immunology Laboratory Javeriana University (Bogotá- Colombia)	Dr. Urueña is one the researchers and leading authors in different papers of the immunology group at the Javeriana University
28/09/2019 10:48 am	Yaneth Porras	Plaza Samper Mendoza- Bogotá Colombia	Mrs. Porras is an experienced plant seller and owner of a stall at the Plaza Samper Mendoza
28/09/2019 11:38 am	Gerardo Vazquez	Plaza Samper Mendoza- Bogotá Colombia	Mr. Vazquez is a bureaucrat that works for the institute for

			social economy (IPES Spanish acronym), a local authority that is part of Bogotá's mayoral authority, and manages all urban markets
30/09/2019-01/10/2020 Midnight (12:00 am to 12:30 am)	Oscar Sanabria	Plaza Samper Mendoza-Bogotá Colombia	The most well-known medicinal plant seller of the Plaza Samper Mendoza
01/10/2019 7:20 pm	Susana Fiorentino	Barnier and Fiorentino's home	Professor Fiorentino is the lead researcher of the immunology research group of the Javeriana University. A well-respected scientist and expert in the use of medicinal plants in Colombia. With almost 30 years of experience
01/10/2019	Javier Barnier	Barnier and Fiorentino's	Mr. Barnier is Professor

7:20 pm		home	Fiorentino's partner, who has professionally accompanied and support her career. He is an agriculture manager, a businessperson, and an expert in exporting and importing agriculture products.
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Appendix II Participants Consent Form

Wilmar Olaya



Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto		
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	X	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	X	
Acepto participar en el proyecto.	X	
Entiendo que participar en el proyecto incluirá ser entrevistado	X	
Entiendo que participar en el proyecto incluirá ser grabado en audio	X	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	X	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	X	
Cómo se utilizará mi información durante y después del proyecto		
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	X	
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	X	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	X	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	X	
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	X	
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores		
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	X	

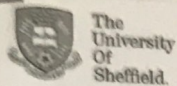
Nombre del participante [impreso]

Firma

Wilmar Olaya

Fecha

19/Septiembre/2019



Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

Marque las casillas apropiadas	Sí	No
Participar en el proyecto		
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	X	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	X	
Acepto participar en el proyecto.	X	
Entiendo que participar en el proyecto incluirá ser entrevistado	X	
Entiendo que participar en el proyecto incluirá ser grabado en audio	X	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	X	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	X	
Cómo se utilizará mi información durante y después del proyecto		
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	X	
Entiendo que la información sobre mi papel en la organización de la que formó parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	X	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	X	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	X	
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	X	
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores		
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	X	

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GamScanner

Firma Claudia Urueña Fecha 19/09/2019



Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto	Si	
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	Si	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	Si	
Acepto participar en el proyecto.	Si	
Entiendo que participar en el proyecto incluirá ser entrevistado	Si	
Entiendo que participar en el proyecto incluirá ser grabado en audio	Si	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	Si	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	Si	
Cómo se utilizará mi información durante y después del proyecto	Si	
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	Si	
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	Si	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	Si	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	Si	
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	Si	
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores	Si	
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	Si	



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Firma

[Handwritten signature]

Fecha

[Handwritten name: Yaneth Porras]



Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana


Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto	<input checked="" type="checkbox"/>	<input type="checkbox"/>
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Acepto participar en el proyecto.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que participar en el proyecto incluirá ser entrevistado	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que participar en el proyecto incluirá ser grabado en audio	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cómo se utilizará mi información durante y después del proyecto	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Nombre del participante [impreso]

Firma

Fecha 28 07 2019




Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto	Y	
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	Y	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	Y	
Acepto participar en el proyecto.	Y	
Entiendo que participar en el proyecto incluirá ser entrevistado	Y	
Entiendo que participar en el proyecto incluirá ser grabado en audio	Y	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	Y	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	Y	
Cómo se utilizará mi información durante y después del proyecto		
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	Y	
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	Y	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	Y	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	Y	
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	Y	
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores	Y	
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	X	

Nombre del participante [Impreso] *Oscar Alcides Sanabria* Firma *Oscar Alcides Sanabria* Fecha *30/09/199*

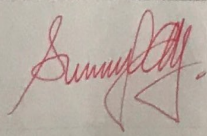


Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto		
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	X	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	X	
Acepto participar en el proyecto.	X	
Entiendo que participar en el proyecto incluirá ser entrevistado	X	
Entiendo que participar en el proyecto incluirá ser grabado en audio	X	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	X	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	X	
Cómo se utilizará mi información durante y después del proyecto		
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	X	
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	X	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	X	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	X	
Entiendo y acepto que otros investigadores autorizados pueden utilizar mis datos en publicaciones, informes, páginas web y otros resultados de investigación, siempre y cuando acepten preservar la confidencialidad de la información según lo solicitado en este formulario.	X	
Para que la información que proporcione pueda ser utilizada legalmente por los investigadores		
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	X	

Nombre del participante [impreso] Firma Fecha

Susana Fiorentino  1 Oct 2019



Acceso a los Recursos Genéticos e Innovación Sostenible en la Industria de la Salud y la Investigación en Salud: Una Perspectiva Jurídica Colombiana

Formulario de consentimiento

<i>Marque las casillas apropiadas</i>	Sí	No
Participar en el proyecto		
El proyecto me ha sido completamente explicado. (Si responde No a esta pregunta, por favor no proceda con este formulario de consentimiento hasta que sea plenamente consciente de lo que significará su participación en el proyecto.)	X	
Se me ha dado la oportunidad de hacer preguntas sobre el proyecto.	X	
Acepto participar en el proyecto.	X	
Entiendo que participar en el proyecto incluirá ser entrevistado	X	
Entiendo que participar en el proyecto incluirá ser grabado en audio	X	
Entiendo que participar en el proyecto incluirá tomar fotos de mi lugar de trabajo	X	
Entiendo que mi participación es voluntaria y que puedo retirarme del estudio en cualquier momento; No tengo que dar ninguna razón por la que ya no quiero participar y no habrá consecuencias adversas si elijo retirarme.	X	
Cómo se utilizará mi información durante y después del proyecto		
Entiendo que mis datos personales como nombre, teléfono number, dirección y dirección de correo electrónico, etc. no se revelará a personas ajenas al proyecto.	X	
Entiendo que la información sobre mi papel en la organización de la que formo parte se pondrá a disposición del público haciéndome identificable ante personas ajenas al proyecto.	X	
Entiendo y acepto que mis palabras pueden ser citadas en publicaciones, informes, páginas web y otros resultados de investigación. Entiendo que no se me nombrará en dichos resultados de investigación a menos que solicite específicamente esto.	X	
Entiendo y acepto que otros investigadores autorizados tendrán acceso a estos datos siempre y cuando acepten preservar la confidencialidad de la información tal como se solicita en este formulario.	X	
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Para que la información que proporcione pueda ser utilizada legalmente por los investigadores		
Acepto asignar los derechos de autor que poseo en cualquier material generado como parte de este proyecto a la Universidad de Sheffield.	X	

Nombre del participante [impreso]

JAVIER BARNIER

Firma

Fecha

1/20/19

Appendix III Information Sheet for Candidates

Participant Information Sheet September 2019 (Plant Sellers)

Access to Genetic Resources and Sustainable Innovation in the Health Industry and Health Research: A Colombian Legal Perspective

You are invited to take part in a research project investigating to explore Colombian law on health research and the biomedical industry regarding the use of the knowledge and practices of local, indigenous and Afro-Colombian communities. Before you decide to take part, please read the following information, and do not hesitate to request further information or explanation of anything that is not clear.

Project Purpose

The project seeks to explore the contribution of local, indigenous and Afro-Colombian communities in the use of medicinal plants and whether the law includes the ways in which health research and the health industry in Colombia use the knowledge and practices of those communities.

Why have I been chosen?

You have been chosen to participate due to your knowledge as a provider of medicinal plants in a market place. In the course of this research, another providers of medicinal plants in different market places will also be interviewed.

Do I have to take part?

No. It is up to you to decide whether or not to participate. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Once your data has been captured, it will be available to the PhD team, and once published it will be available generally. You can still withdraw from any on-going or future data collection in the project at any time, by emailing the PhD candidate Carlos Augusto Conde Gutierrez (c.conde@sheffield.ac.uk), and Supervisors Professor Tamara Hervey (t.hervey@sheffield.ac.uk) and Professor Emilie Cloatre (e.cloatre@kent.ac.uk) and do not have to give a reason. If you withdraw, the information you have given will be destroyed and will not be used in the project.

What will happen to me if I take part?

If you choose to take part in this research, you will be interviewed about your understandings of one or more aspects of the use of local, indigenous and Afro-Colombian communities' knowledge and practices related to medicinal plants in market places, and the ways that the law regulates the use of medicinal plants. The interview will seek to draw out aspects about which you, or those you represent, are concerned. Those aspects will be used to support an analysis of Colombian policies and law behind the use of communities' practices and knowledge related to medicinal plants for health research and the health industry. We will also use the interview data to understand how you acquire, employ and trade your

knowledge on the use of medicinal plant in urban markets, and whether the law regulates it. The interview will last approximately one hour, or longer if you wish, and will be recorded in note form and electronically. We may request one or two follow-up interviews.

What are the risks and benefits of taking part?

You are being included in the research in your legal capacity, so personal discomforts, disadvantages and risks are highly unlikely to arise.

Participating in this project as a member of plant traders' network in urban markets is intended to secure benefits for you and your organisation. You will feed into in-depth analysis of the context of the Colombian policies and law behind the use of local, indigenous and Afro-Colombian communities' practices and knowledge of medicinal plants', through helping to articulate specific legal questions which your organisation, or those it represents, would like to have answered. You will help illuminate the meanings of how your role as a plant trader contributes with the dissemination to the public of communities' practices and knowledge of communities related to medicinal plants, and their legal implications. You will assist in understandings of accountability for the health industry and health research in the use of Colombia's biodiversity and ethnic diversity, and its legitimacy, among local, indigenous and Afro-Colombian communities, as well as the public in general.

Will my taking part in this project be kept confidential?

No. You have been asked to participate because of your unique knowledge in the use of medicinal plants. Due to the small number of plant traders involved in this project, it will not be possible to keep your participation in the project confidential. Nor will it be necessary or desirable: your interview is designed to uncover those aspects of the use of medicinal plants, as well as the law that regulates it, that concern you as a stakeholder, in your official capacity. We will offer a bespoke analysis of a legal issue that is of concern to you, and we will publish that analysis as part of a PhD thesis. Thus, it is part of the project's design that who you are, as well as the information you provide, will be used in the dissemination or publication of this research. While it is being analysed and before dissemination, all data will be stored and analysed in a secure location to ensure proper security. During that time, you will have a chance to review the recording of your interview, to ensure you are happy with its contents.

Will I be recorded, and how will the recorded media be used?

Yes. To ensure accuracy, as well as handwritten notes being taken during and after the interview, this interview will be audio recorded and later transcribed. During and following transcription, the sound recording will be stored in a secure location for verification purposes. Since the recorded interviews will take place in an urban market, some background noise is expected, therefore, we will also take some photos of the surroundings to complement the interview. As noted above, and explained further below, parts of the data will be published.

What is the legal basis for processing my personal data? Who is the Data Controller?

According to the EU and UK data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)) of General Data Protection Regulation 2016/679. Further information can be found in the University's Privacy Notice <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

The University of Sheffield will act as the Data Controller for this study.

What will happen to the results of the research project?

The results of this research project will be disseminated in the following way. You and other stakeholders' interviews, including other researchers and plant traders, will provide the basis for analysis of whether the law includes the ways that researchers and the health industry use practices and knowledge of local, indigenous and Afro-Colombian communities related to medicinal plants. These will be published as part of a PhD Law thesis. In addition, the project will produce publications aimed at international academic conference papers, publications in peer-reviewed academic journals and reflective blogs.

Who has ethically reviewed the project?

This project has been ethically reviewed and formally approved through the University of Sheffield's Ethics Review Procedure, as administered by the Department of Politics, University of Sheffield.

What if something goes wrong and I wish to complain about the research?

Should you wish to raise a complaint about the research, please raise it with Professor Tamara Hervey, the main Supervisor of the PhD candidate in the first instance. If you feel your complaint has not been handled to your satisfaction, please contact the Head of the School of Law, Professor Graham Gee, who will then escalate the complaint through the appropriate channels. Information about how to raise a complaint about handling of personal data can be found in the University's Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

Contact for further information.

LEAD RESEARCHER:

Carlos Augusto Conde Gutiérrez,
Mobile: 0057350149817,
Email: c.conde@sheffield.ac.uk,
Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

SUPERVISOR

Professor Tamara Hervey
email: t.hervey@sheffield.ac.uk

Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

HEAD OF THE SCHOOL OF LAW,

Professor Graham Gee,

Email: g.gee@sheffield.ac.uk

Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

Thank you for taking part in this project and agreeing to become a co-producer of its results.

Participant Information Sheet September 2019 (Researchers)

Access to Genetic Resources and Sustainable Innovation in the Health Industry and Health Research: A Colombian Legal Perspective

You are invited to take part in a research project investigating to explore Colombian law on health research and the biomedical industry regarding the use of the knowledge and practices of local, indigenous and Afro-Colombian communities. Before you decide to take part, please read the following information, and do not hesitate to request further information or explanation of anything that is not clear.

Project Purpose

The project seeks to explore the contribution of local, indigenous and Afro-Colombian communities in the use of medicinal plants and whether the law includes the ways in which health research and the health industry in Colombia use the knowledge and practices of those communities.

Why have I been chosen?

You have been chosen to participate as an expert and leading researcher in Colombia in the field of the use of medicinal plants for health research. In the course of this research, other experts might also be consulted, as well as providers of medicinal plants whose place of trade are urban market places.

Do I have to take part?

No. It is up to you to decide whether or not to participate. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Once your data has been captured, it will be available to the PhD team, and once published it will be available generally. You can still withdraw from any on-going or future data collection in the project at any time, by emailing the PhD candidate Carlos Augusto Conde Gutierrez (c.conde@sheffield.ac.uk), and Supervisors Professor Tamara Hervey (t.hervey@sheffield.ac.uk) and Professor Emilie Cloatre (e.cloatre@kent.ac.uk) and do not

have to give a reason. If you withdraw, the information you have given will be destroyed and will not be used in the project.

What will happen to me if I take part?

If you choose to take part in this research, you will be interviewed about your understandings of one or more aspects of the use of local, indigenous and Afro-Colombian communities' knowledge and practices related to medicinal plants for health research, and the ways that the law regulates the use of medicinal plants. The interview will seek to draw out a specific scenario or scenarios about which you, or those you represent, are concerned. This scenario will be used to support an analysis of Colombian policies and law behind the use of communities' practices and knowledge related to medicinal plants for health research and the health industry. We will also use the interview data to understand how researchers approach towards the use of medicinal plants and communities' practices and knowledge, as it applies to health research regulation. The interview will last approximately one hour, or longer if you wish, and will be recorded in note form and electronically. We may request one or two follow-up interviews.

What are the risks and benefits of taking part?

You are being included in the research in your professional capacity, so personal discomforts, disadvantages and risks are highly unlikely to arise.

Participating in this project as one of a small number of experts in the use of medicinal plants for health is intended to secure benefits for you and your organisation. You will feed into in-depth analysis of the context of the Colombian policies and law behind the use of local, indigenous and Afro-Colombian communities' practices and knowledge medicinal plants', through helping to articulate specific legal questions which your organisation, or those it represents, would like to have answered. You will help illuminate the meanings of the use of medicinal plants and communities' practices and knowledge legal and policy texts, and their implications for health research. You will assist in understandings of accountability for researchers in the use of Colombia's biodiversity and ethnic diversity for health research, and its legitimacy, among local, indigenous and Afro-Colombian communities, as well as the public in general.

Will my taking part in this project be kept confidential?

No. You have been asked to participate because of your unique expertise in the use of medicinal plants for health research. Due to the small number of experts involved in this project, it will not be possible to keep your participation in the project confidential. Nor will it be necessary or desirable: your interview is designed to uncover those aspects of the use of medicinal plants and communities' practices and knowledge, as well as the law that regulates that concern you as a stakeholder, in your official capacity. We will offer a bespoke analysis of a legal issue that is of concern to you, and we will publish that analysis as part of an PhD thesis. Thus, it is part of the project's design that who you are, as well as the information you provide, will be used in the dissemination or publication of this research.

While it is being analysed and before dissemination, all data will be stored and analysed in a secure location to ensure proper security. During that time, you will have a chance to review the recording of your interview, to ensure you are happy with its contents.

Will I be recorded, and how will the recorded media be used?

Yes. To ensure accuracy, as well as handwritten notes being taken during and after the interview, this interview will be audio recorded and later transcribed. During and following transcription, the sound recording will be stored in a secure location for verification purposes. As noted above, and explained further below, parts of the data will be published.

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The University of Sheffield will act as the Data Controller for this study.

What will happen to the results of the research project?

The results of this research project will be disseminated in the following way. You and other stakeholders, including other researchers and plant traders, to be interviewed will provide the basis for analysis of whether the law includes the ways that researchers uses practices and knowledge of local, indigenous and Afro-Colombian communities related to medicinal plants. These will be published as part of a PhD Law thesis. In addition, the project will produce publications aimed at international academic conference papers, publications in peer-reviewed academic journals, reflective blogs.

Who has ethically reviewed the project?

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What if something goes wrong and I wish to complain about the research?

Should you wish to raise a complaint about the research, please raise it with Professor Tamara Hervey, the main Supervisor of the PhD candidate in the first instance. If you feel your complaint has not been handled to your satisfaction, please contact the Head of the School of Law, Professor Graham Gee, who will then escalate the complaint through the appropriate channels. Information about how to raise a complaint about handling of personal data can be found in the University’s Privacy Notice: <https://www.sheffield.ac.uk/govern/data-protection/privacy/general>.

Contact for further information.

LEAD RESEARCHER:

Carlos Augusto Conde Gutiérrez,
Mobile: 0057350149817,
Email: c.conde@sheffield.ac.uk,
Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

SUPERVISOR

Professor Tamara Hervey
email: t.hervey@sheffield.ac.uk
Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

HEAD OF THE SCHOOL OF LAW,

Professor Graham Gee,
Email: g.gee@sheffield.ac.uk
Address: School of Law, University of Sheffield
Bartolomé House, Winter Street
Sheffield S3 7ND, UK

Thank you for taking part in this project and agreeing to become a co-producer of its results.

Appendix IV Ethics Approval



Downloaded: 31/12/2019

Approved: 02/09/2019

Carlos Conde Gutierrez
Registration number: 90189537
School of Law
Programme: PhD

Dear Carlos

PROJECT TITLE: Access to Genetic Resources and Sustainable Innovation in the Health Industry and Health Research: A Colombian Legal Perspective

APPLICATION: Reference Number 030513

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 02/09/2019 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 030513 (form submission date: 22/08/2019); (expected project end date: 10/01/2020).
- Participant information sheet 1070003 version 2 (22/08/2019).
- Participant information sheet 1070002 version 2 (22/08/2019).
- Participant information sheet 1070001 version 2 (22/08/2019).
- Participant information sheet 1070000 version 2 (22/08/2019).
- Participant consent form 1070273 version 1 (22/08/2019).
- Participant consent form 1069711 version 3 (22/08/2019).

If during the course of the project you need to [deviate significantly from the above-approved documentation](#) please inform me since written approval will be required.

Your responsibilities in delivering this research project are set out at the end of this letter.

Yours sincerely

Penelope Russell
Ethics Administrator
School of Law

Please note the following responsibilities of the researcher in delivering the research project:

- The project must abide by the University's Research Ethics Policy: <https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure>
- The project must abide by the University's Good Research & Innovation Practices Policy: https://www.sheffield.ac.uk/polo/poly_fs/1.6710661/file/GRIPPolicy.pdf
- The researcher must inform their supervisor (in the case of a student) or Ethics Administrator (in the case of a member of staff) of any significant changes to the project or the approved documentation.
- The researcher must comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
- The researcher is responsible for effectively managing the data collected both during and after the end of the project in line with best practice, and any relevant legislative, regulatory or contractual requirements.

Appendix V: Decision 391 of 1996
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 SOVEREIGNTY 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 or 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 VI: Decision 486 of 2000 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 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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