THE EXCLUSION OF ANIMAL INVENTIONS FROM PATENT PROTECTION: ISSUES OF INTERPRETATION AND APPLICATION FOR A DEVELOPING COUNTRY - MALAYSIA

A THESIS SUBMITTED IN PARTIAL FULFILMENT
FOR THE REQUIREMENTS OF THE UNIVERSITY OF SHEFFIELD
FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

SYAHLIZA WARNOH
SCHOOL OF LAW
UNIVERSITY OF SHEFFIELD
2012

Abstract

Article 27.3(b) of the Agreement on Trade-related Aspects of Intellectual Property Rights 1994 allows its Signatories to exclude 'animals' from patent protection within national patent laws. While the exclusion of 'animal varieties' is contained in s13(1)(b) of the Malaysian Patents Act 1983, the meaning of the term which represents the exclusion, and, therefore, the excluded subject matter, is unclear. A question arises as to how the country should interpret the exclusionary provision in the context of the flexibility under Article 27.3(b). This thesis answers the question in the light of the growing demand for animal protein-based food from Malaysians, which proves difficult to meet from within existing production methods. Therefore, animal biotechnology has been identified by the Malaysian Government as a pertinent tool to reduce costly imports of livestock products. Underpinned by doctrinal approach, the thesis assesses two models of interpretation within the international patent law framework: the permissive and restrictive approaches. The former arises from narrowly construing the term 'animal varieties' under Article 53(b) of the European Patent Convention which results in permissively enabling patenting for animal inventions which would be excluded under a broad legislative construction arising from the interpretation of the term 'invention' under s2 of the Canadian Patent Act 1985. The implications of both approaches on the livestock industry are assessed so as to identify a suitable model which would promote the progression of the Malaysian animal biotechnology sector, and ultimately secure the supply of the livestock products for the population. Underpinned by the argument that patent protection is a pertinent factor in encouraging innovation and investment, this thesis argues that the permissive approach is the most practical approach for Malaysia to adopt for interpreting the exclusion of animal inventions under s13(1)(b). This thesis provides a test case for other developing countries which also exclude animal inventions within their national patent laws, and have a similar economic template to Malaysia, enabling them to appreciate how the exclusion can be construed in pursuing their economic priorities.

Acknowledgements

First and foremost, I would like to thank my first supervisor, Dr Amanda Warren-Jones for her constant support, invaluable advice and feedback, and commitment in guiding me since she took over the supervision role. Her expertise of the research area has helped me broaden my horizon of knowledge. I would also like to extend my thanks to Dr Mark Taylor (my second supervisor), Dr Gwen Robinson (the Director, Postgraduate Research Students, School of Law), all the support staff of the School of Law, and Ms Maria Mawson (the Librarian, Faculty of Social Sciences), for their assistance.

This research would never have commenced if it were not for my ex-supervisor, Professor Margaret Llewelyn who accepted the proposal. I would like to convey my appreciation for her invariable support, motivation and invaluable insight during the daunting period of the early stages of the research, and beyond. I will never forget her patience and commitment in guiding me.

I would like to thank the Attorney General of Malaysia and the Public Service Department of Malaysia for the research opportunity, and in particular the latter for funding the research.

I am indebted to the relevant officers and staff of the following organisations for their invaluable assistance: the World Intellectual Property Organization, the European Patent Office, the Canadian Intellectual Property Office, the British Library, the Library and Archive Canada, the Attorney General's Chambers of Malaysia, the Public Service Department of Malaysia, the Intellectual Property Organisation of Malaysia, the Ministry of Agriculture and Agro-Based Industry Malaysia, the Ministry of Natural Resources and Environment Malaysia, the Ministry of Domestic Trade, Co-operatives and Consumerism Malaysia, and the Department of Veterinary Services Malaysia.

My heartful thanks go to all my family, in particular my husband (Mr Wan Ahmad Dzaffran Wan Kamaruddin), daughters (Wan Irdhina Sofiah and Wan Izzah Sakinah), mother (Madam Madznah Taher), late father (Mr Warnoh Katiman, who passed away during the writing of this thesis) and sisters (Madam Kathrina and Rita Maria, and their families), for their love, support, forbearance and understanding throughout the research years.

Special thanks are due to Madam Husna Fauzi, Ms Audrey Pang, and Mr Graham Sedgley for their assistance, advice and encouragement.

Finally, I would never have been able to complete this thesis without the help, contribution (directly or indirectly) and motivation from my colleagues, friends and many others (in Sheffield, United Kingdom, Malaysia, and others) to whom I would like to express my appreciation. It would be impossible for me to mention each name in this limited space (without the risk of omitting any name). For this reason, I will thank them in a more personal way, when and wherever I meet them.

Table of contents

Chapter Two: The exclusion of animal inventions under Article 27.3(b) of the TRIPs Agreement 1994: the past, present and future

Chapter Three: The exclusion of animal varieties under section 13(1)(b) of the Malaysian Patents Act 1983: legal development and application

Discussion and conclusion: a way forward for Malaysia

Appendices

List of legislation, statutory instruments and guidelines

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

Argentina Invention Patents and Utility Models Act.

Australian Patents Act 1990.

Brazilian Industrial Property Code 1996.

Canadian Guidelines for the Safety Assessment of Novel Foods.

Canadian Manual of Patent Office Practice.

Canadian Patent Act 1826.

Canadian Patent Act 1869.

Canadian Patent Act 1985.

Canadian Plant Breeders' Rights Act 1990.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000.

China Patent Law of the People's Republic of China 1984.

China Regulation on Administration of Agriculturally Modified Organisms Safety 2001.

Convention on Biological Diversity 1992.

Convention on the Unification of Certain Points of Substantive Law on Patents for Invention 1963.

Czech Republic Law on the Legal Protection of New Varieties of Plants and Breeds of Animals.

Directive 98/44/EC of the European Parliament and of the Council of July 6, 1988 on the legal protection of biotechnology inventions.

European Patent Convention 2010.

Guidelines of Examination of the European Patent Office.

Implementing Regulations to the Convention on the Grant of European Patents.

Indian Guidelines for Registration of Livestock and Poultry Breeds.

Indian Patents Act 1970.

United States 35th Title Code.

Vienna Convention on the Law of Treaties 1969.

World Intellectual Property Organization Revised Model Law for Developing Countries on Inventions 1979.

List of cases

Ciba-Geigy/Propagating Material [1979-85] EPOR 758; [1984] OJ EPO 112.

Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] RPC 28; [2008] UKHL 49.

Continental Soya Co. Ltd. v J.R. Short Milling Co. (Canada) Ltd. [1942] SCR 187.

Datuk Seri Ahmad Said Hamdan, Ketua Suruhanjaya, Suruhanjaya Pencegahan Rasuah Malaysia & Ors v Tan Boon Wah [2010] 3 MLJ 193.

DG of Inland v Kulim Rubber Plantations Ltd [1981] 1 MLJ 214.

Diamond, Commissioner of Patents and Trademarks v Chakrabarty [1980] 447 US 303; 100 SCt 2204.

Edinburgh Patent case, European patent (EP) no 0695351, Opposition Division's interlocutory decision of 21 July 2003.

EISAI G5/83 (Second medical indication).

Essentially Biological Processes, G2/07 and G1/08 [2011] EPOR 27.

Ex Parte Latimer (1889) Dec. Com. Pat., 123.

Harvard College v Canada (Commissioner of Patents) [2003] 5 LRC 330; [2002] SCC 76; [2002] 4 SCR 45; [2000] 4 FC 528; [1998] 3 FC 510; Decision of the Commissioner of Patents dated 4 August 1995.

Human Genome Sciences Inc v Eli Lilly and Company Limited [2012] RPC 6; [2011] UKSC 51.

Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 9; [2004] UKHL 46.

Leland Stanford/Modified Animals [2002] EPOR 2.

Lubrizol/Hybrid Plants [1990] EPOR 173.

Novartis/Transgenic Plant G 01/98 [2000] EPOR 303; T 1054/96 [1999] EPOR 123.

Percy Schmeiser and Schmeiser Ltd v Monsanto Canada Inc. and Monsanto Company [2004] 1 SCR 902; [2004] SCC 34; [2003] 2 FC 165; [2002] FCA 309; [2001] FCT 256.

PGS/Glutamine Synthetase Inhibitors [1995] EPOR 357.

Pioneer Hi-Bred Ltd. v Canada (Commissioner of Patents) [1989] 1 SCR 1623; [1987] 3 FC 8.

Diagram and table

List of abbreviations

ADR	Alternative Dispute Resolution
AIA	Advanced Informed Agreement
AIPPI	Canadian Group of International Association for the Protection of Intellectual Property
AMLS	Animal Movement Licensing System
ASEAN	Association of Southeast Asian Nations
BBSRC	Biotechnology and Biological Sciences Research Council
BCH	Biosafety Clearing House
BRIIC	Brazil, Russia, India, Indonesia and China
BSE	Bovine Spongiform Encephalopathy
BST	Bovine somatotropin
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CFIA	Canadian Food Inspection Agency
CFP	Common Fisheries Policy
CIPO	Canadian Intellectual Property Office
COE	Council of Europe
DDA	Doha Development Agenda
DEFRA	Department for Environment, Food and Rural Affairs, UK
DFO	Fisheries and Oceans Canada
DNA	Deoxyribonucleic acid
EADGENE	European Animal Disease Genomics Network of Excellence for Animal Health and Food Safety
EBA	Enlarged Board of Appeal (of the EPO)
EBL	Enquiry-based learning

EC	Environment Canada
ED	Examining Division (of the EPO)
EEC	European Economic Community
EFSA	European Food Safety Authority
EGE	European Group on Ethics in Science and New Technologies
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDI	Foreign direct investment
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Production
GM	Genetically modified
GMOs	Genetically modified organisms
HC	Health Canada
HFA	Halal Food Authorities
ICJ	International Court of Justice
IMF	International Monetary Fund
INRA	French National Institute for Agricultural Research
IPRs	Intellectual property rights
ISA	Infectious salmon anaemia
JPO	Japan Patent Office
LDCs	Least-developed countries
LMOs	Living modified organisms

LMOs-FFP	Living modified organisms intended for direct use as food or feed, or for processing
MyIPO	Intellectual Property Organisation of Malaysia
NAFTA	North American Free Trade Agreement
NGOs	Non-governmental organisations
NICs	Newly industrialised countries
OD	Opposition Division (of the EPO)
OECD	Organisation for Economic Co-operation and Development
PCT	Patent Co-operation Treaty
PWP	Patents Working Party
R&D	Research and development
RSC	Royal Society of Canada
SABRE	Sustainable Animal Breeding
SCNT	Somatic cell nuclear (or nucleus) transfer
TACs	Total Allowable Catches
TBA	Technical Board of Appeal (of the EPO)
TNC	Trade Negotiations Committee
TWN	Third World Network
UK	United Kingdom
UKFSA	United Kingdom Food Standard Agency
UKIPO	United Kingdom Intellectual Property Office
UN	United Nations
US	United States
USDA	United States Department of Agriculture
USFDA	United States Food and Drug Administration
USPTO	United States Patent and Trademark Office

WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WWF	World Wide Fund

INTRODUCTION

This thesis focuses on the unpatentability of animal inventions. Under patent law, an invention is patentable if it is new, if it involves an inventive step, and if it is industrially applicable (the patentability criteria). In addition an invention must not fall under any excluded categories recognised by the patent system. Within the international patent law framework, Article 27.1 of the Agreement on Trade-related Aspects of Intellectual Property Rights 1994 (the TRIPs Agreement)[1] spells out the rule of patentability whereas Article 27.3 provides a list of subject matter which may not be patentable.[2] In particular, Article 27.3(b) allows Signatories to the TRIPS Agreement to exclude animal inventions under their national patent laws.[3] Nevertheless, the TRIPs Agreement does not define the term 'animals' which represents the exclusion. As a result, a Signatory has a wide discretion to determine the meaning of the term which is adopted in the exclusionary provision, and therefore, whether or not animal inventions are patentable under its patent system.

In particular, this thesis studies the exclusion of animal inventions from the Malaysian patent protection legislation, specifically s13(1)(b) of its Patents Act 1983 (Malaysian Patents Act 1983).[4] Malaysia is a Signatory to the TRIPs Agreement, hence its status as a Member State

---

1 Available at: WTO, http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs (Accessed: 8 April 2011).

2 See Appendix 4.

3 Other matters which may be excluded by Member States are diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and plants. While also being living matter, micro-organisms are patentable due to the recognition of their ability to fulfil the patentability criteria. Other subject matters mentioned here are, however, not covered by this thesis.

4 Act 291. Available at: World Intellectual Property Organization (WIPO), http://www.wipo.int/wipolex/en/text.jsp?file_id=128826 (Accessed: 28 March 2012). Section 13(1) states: 'Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable: (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes; Provided that this paragraph shall not apply to products used in any such methods.' In turn, s12 provides the meaning for an 'invention' as: 'an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.'

of the World Trade Organization (WTO), since 1 January 1995.[5] In this respect, the existence of the exclusion of animal inventions in s13(1)(b) of the Malaysian Patents Act 1983 corresponds with Article 27.3(b) of the TRIPs Agreement. This thesis is motivated by the fact that while 'animal varieties' are excluded from patent protection under s13(1)(b), but the term is not defined by the Malaysian Patents Act 1983. So far, the exclusion has yet to be interpreted by the Intellectual Property Organisation of Malaysia (MyIPO) or the Malaysian courts. Consequently, within the context of national patent law, it is not clear what subject matter is excluded by the exclusionary term, nor what implications arise from any intended construction.

Yet as far as Malaysia and other Signatories are concerned the flexibility under Article 27.3(b) necessitates an answer as to how to construe the exclusion while observing their international obligations under Article 27.1, which also requires that patents be made available to any inventions which fulfil the patentability criteria irrespective of the fields of technology. In the context of international patent law, a Signatory which is deemed to be failing to accord protection to animal inventions, may be considered in breach of its obligations under Article 27.1, notwithstanding that there is no definitive international standard of interpretation with regard to the exclusion of animal inventions. This implication is particularly relevant in view of potential bilateral agreements which maybe entered into between Signatories to the TRIPs Agreement where a country may impose a condition on the other contracting country that patent protection be made available to animal inventions irrespective of the flexibility under Article 27.3(b).[6] As a result, the 'failure' of the latter country may expose it to trade sanctions which arise from the dispute settlement mechanism, used by the WTO so as to promote international compliance with trade-related rules, including patent law principles such as

[5] WTO: Members and observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (Accessed: 1 April 2011).

[6] This point is elaborated further in sub-section 2.2.3 of chapter 2.

Article 27.1.[7] In view of this adverse consequence, it is pertinent that a Signatory such as Malaysia should be able to justify its decision on how the exclusion is to be interpreted within national patent law.

In this Introduction chapter the following aspects are identified, and justification for each is advanced: the research questions of the thesis, the methodological approach to answer the questions, the context of assessment of the questions, the two opposite legal approaches which are adopted and assessed to answer the questions, the relevance of the European and Canadian materials to the questions, the audience of the thesis, the contribution of the thesis, the limitations of the thesis, and potential future work. The chapter ends with an overview of the organisation of the thesis where pertinent points argued by each chapter of the thesis, so as to answer the research questions set forth, are highlighted.

Given the vague aspects identified in the context of the Malaysian patent law, and the importance of clarifying the issues, this thesis aims to answer the following two questions: firstly, how can the exclusion of animal varieties under s13(1)(b) of the Malaysian Patents Act 1983 be construed; and secondly, which of the existing approaches within the international patent law framework, either (1) the permissive approach; or (2) the restrictive approach, is the most practical for Malaysia to adopt in the light of the problems and needs of its livestock industry.

The research questions are answered by assessing two opposite legal approaches, which are identified as being relevant to Malaysia by their effect on the industry that they regulate. In essence, this thesis adopts a doctrinal approach (specifically, a comparative methodological

[7] WTO, Understanding the WTO – settling disputes, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (Accessed: 15 June 2012).

approach based in an industry impact analysis). Primary and secondary sources are engaged to analyse the benefits and disadvantages of the interpretations to existing legal provisions relating to the exclusion of animal inventions, and to identify their impact on the livestock industry.

Overall, the endeavour to answer the research questions of this thesis is underpinned by an enquiry-based learning (EBL) approach.[8] In essence, driven by a process of enquiry, the approach emphasises the gathering, understanding and evaluating of relevant information relating to an issue which is to be investigated. The knowledge obtained is then applied to the identified issue or problem in order to achieve a reasonable solution.[9] As there is no one solution to the problem, the EBL allows a researcher to present his or her conclusions based on a range of evidence which support his or her views.[10] These key features of the EBL are utilised by this thesis in reaching the conclusions at the end of the study.

The focus on the Malaysian livestock industry (agricultural) as the context of assessment of the law is for a number of reasons. In the light of the growing number of (and demand from) the population, developing countries place great emphasis on increasing production, and improving quality, of agricultural products (including livestock) for the purpose of feeding their inhabitants.[11] Agricultural research has, therefore, been one of the main tools to achieve these aims.[12] Being a developing country, Malaysia has a similar emphasis. In this respect,

---

8 For detailed information about the EBL approach, see for instance, T. Barrett, I.M. Labhrainn and H. Fallon (eds), *Handbook of enquiry and problem based learning*, http://www.aishe.org/readings/2005-2/contents.html (Accessed: 28 March 2012); T. Deignan, Enquiry-based learning: perspectives in practice (2009) 14 *Teaching in Higher Education*, 1, 13-28.

9 ibid.

10 ibid.

11 Food and Agriculture Organization of the United Nations (FAO), What should be the role and focus of biotechnology in the agricultural research agendas of developing countries? http://www.fao.org/biotech/C8doc.htm (Accessed: 28 March 2012).

12 ibid.

the Malaysian National Biotechnology Policy 2005[13] explicitly underlines agricultural biotechnology for development, as agriculture has been the backbone of the country's economy since long before its independence.[14] Livestock has itself been an important commodity which contributes to the country's income and is a source of protein for the population. In tandem with the National Biotechnology Policy, animal biotechnology applications have been widely utilised in research involving livestock animals in higher learning and public research institutions in the country. The research aims at increasing the output and enhancing the quality of the livestock. The effort is underpinned by the aspiration of the Malaysian Government to reduce the country's dependency on imports so as to meet the growing demand of the population due to the insufficiency of the main livestock products. Imports cost the government a substantial expense, and are increasing every year. For these reasons, any implications arising from the interpretation of s13(1)(b) which involve animal inventions (including livestock obtained from modern animal biotechnology) are particularly significant, given the need to: (1) adequately supply animal protein-based food to Malaysians; and (2) develop relevant technology and products.

While Malaysia has the liberty to formulate its own interpretation, this must be done in consequence of an understanding of the options available. This thesis engages two international models of interpretation for analysis: the permissive approach (which is adopted by the European patent system), and the restrictive approach (which is adopted by the Canadian patent system). According to Article 53(b) of the European Patent Convention 2010

[13] Available at: Malaysian Biotechnology Information Centre, http://www.bic.org.my/?action=localscenario&do=policy (Accessed: 3 December 2009). For full details of the Policy, see Appendix 1.

[14] Healthcare and bioremediation are two other sectors for development under the Policy. 'Bioremediation' means: 'the use of biological agents, such as bacteria or plants, to remove or neutralize contaminants, as in polluted soil or water'. See http://www.thefreedictionary.com/bioremediation (Accessed: 14 June 2012).

(EPC),[15] European patents shall not be granted to 'animal varieties or essentially biological processes for the production of animals'.[16] Nevertheless, 'microbiological processes and the products thereof' are not excluded from patentability.[17] Notwithstanding the prohibition against animal varieties, patent claims for animal inventions have been allowed by the European Patent Office (EPO) through the only 'animal variety' case to date, namely the *Harvard/Onco-mouse*.[18] Underpinning the decision is that Article 53(b) is an exception to the general rule of patentability[19] (that an invention is patentable if it fulfils the patentability criteria), which should be given a very narrow application.[20] Adopting this rule, the EPO decided in the case that the transgenic mice, which had been genetically engineered to make them susceptible to cancer, were not a 'variety' within the meaning of the exception, thus the invention was patentable. Conversely, the Canadian patent system chooses to take a different stand in dealing with the patentability of living things. In the case of *Harvard College v Canada (Commissioner of Patents) (Harvard Mouse)*[21] (similarly being the only case within the country's patent law jurisdiction where the patentability of animal inventions was at issue), the claim to patent the transgenic mouse was refused by the Canadian Supreme Court. The genetically engineered mouse was held not to be patentable because, unlike inanimate matter which can be invented by an inventor, higher life forms were deemed to be incapable

---

15 Available at: EPO, http://www.epo.org/law-practice/legal-texts/epc.html (Accessed: 3 June 2011).

16 ibid. See Appendix 5.

17 ibid.

18 *Transgenic Animals/Harvard*, T 315/03, Decision of Technical Board of Appeal, 6 July 2004; *Onco-mouse/Harvard*, Decision of the Opposition Division 7 November 2001, Official Journal of the EPO, October 2003, 473; *Harvard* V 0006/92, Examining and Opposition Divisions, Official Journal of the EPO 1992, 589; *Harvard* T 0019/90, Technical Board of Appeal, Official Journal of the EPO 1990, 476; *Harvard* V 0004/89, Examining and Opposition Division, Official Journal of the EPO 1989, 451.

19 Article 52(1) of the EPC.

20 This rule is elaborated further in sub-sections 3.2 and 3.3 of chapter 4.

21 [2003] 5 LRC 330; [2002] SCC 76; [2002] 4 SCR 45; [2000] 4 FC 528; [1998] 3 FC 510; Decision of the Commissioner of Patents dated 4 August 1995. Available at Canadian Intellectual Property Office (CIPO), http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/933/summary.html?query=933+%3cin%3e+comdecnumber&start=1&num=10 (Accessed: 4 May 2010).

of constituting an 'invention' within the meaning of the term 'invention' under s2 of the Canadian Patent Act 1985 (Canadian Patent Act 1985).[22]

In the context of Article 27.3(b) which allows Signatories to the TRIPs Agreement to exclude animal inventions under their national patent laws, the converse approach demonstrates how Signatories to the Agreement have, so far, decided on the implementation of the flexibility. Therefore, in essence, the term 'permissive approach' used throughout this thesis refers to the position adopted by the EPO. It denotes the ease with which an inventor may obtain patent protection for animal inventions (as products) in the EPC Member States, notwithstanding the explicit exclusion of animal varieties under Article 53(b) of the Convention. Conversely, the term 'restrictive approach' is exemplified in the context of the position adopted under the Canadian Patent Act 1985. It refers to the unpatentability of animal inventions under Canadian patent law, despite the absence of express statutory exclusion. The focus on the two approaches is because they represent the archetypal polar opposite approaches which has been explored both judicially and legislatively, providing invaluable guidance on how Malaysia could construe its s13(1)(b).

While it was mentioned earlier that this thesis focuses on the food industry, it is notable that the permissive and restrictive approaches arise from the decisions which pertain to a health-related invention. This thesis adopts the view that both of the approaches are extendable to livestock animals derived from modern biotechnology for two reasons: (1) Article 53(b) of the EPC and s2 of the Canadian Patent Act 1985 (within which the patentability of animal inventions is interpreted) are general patent law provisions;[23]and (2) the decisions of the

[22] Patent Act, R.S.C, 1985, c.P-4. Available at: Department of Justice Canada, http://laws-lois.justice.gc.ca/eng/acts/P-4/index.html (Accessed: 13 October 2011).

[23] M.W. Tvedt, Patent protection in the field of animal breeding (2007) 57 *Acta Agriculturae Scand Section A*, 106.

Harvard/Onco-mouse and *Harvard Mouse* were reached from an extensive consideration of patent law principles relating to animal patenting. Therefore, notwithstanding the specific subject matter which was at issue in the cases, arguably the two approaches derived from them are similarly applicable to farm animals.[24] In addition, it is worth noting that there is not so far any decision involving farm animals *per se*.

The relevance of the European and Canadian materials to the research questions requires some explanation. Malaysia is not a Member State of the EPC. However, its patent law originated from the UK's patent system. Being a Member State of the EPC, the UK courts are, in principle, constrained to adopt the decisions of the EPO in interpreting the unpatentability of 'variety of animal' in paragraph 3(f) of Schedule A2 of the UK Patents Act 1977.[25] Therefore, based on the principle of judicial precedence, the European materials become relevant to Malaysia through the adoption of the EPO decision by the UK courts. As regards the Canadian materials, similar to Malaysia, Canada is a commonwealth country whose system of law derived from English Law. Therefore, while not binding, the materials are also of highly persuasive value to the Malaysian courts in construing the exclusion of animal varieties in s13(1)(b).[26]

While the exclusion of animal inventions was adopted by Article 27.3(b) at the conclusion of the General Agreement on Tariffs and Trade (GATT) Uruguay Round Meeting (Uruguay Round Meeting),[27] it was the subject of review within the WTO four years after the TRIPs Agreement came into effect in 1995. Underpinning the review is the continuing contrasting

---

[24] ibid.

[25] Available at: UK Intellectual Property Office (UKIPO), http://www.ipo.gov.uk/patentsact1977.pdf (Accessed: 30 May 2011). For the provision see Appendix 9. Prior to the amendment in 2000, the provision was contained in s1(3) of the Act. The relationship between the jurisprudence of the UK and European Board is further discussed in sub-section 3.1.1 of chapter 5.

[26] This point is further elaborated in chapters 3, 4 and 5 of the thesis.

[27] The Meeting spans the period from 1986 to 1994.

perception of developed and developing countries as to the patentability of the invention.[28] So far, the review has not yet achieved any definite answer as to whether the exclusion of animal inventions should remain in, or otherwise be removed from, the TRIPs Agreement. This situation shows the importance of the issue, and also the complexities of the problem to be resolved. As already identified, while the issue of the unpatentability of animal inventions has been legally developed at the international patent law level, the implications of the existing interpretation to a given industry have not yet been explored in Malaysia. As such this thesis is also important in identifying the issues that Malaysia has to take into consideration in construing s13(1)(b) in the light of the minimum requirement to grant patent protection under Article 27.1. Therefore, its decision on how narrowly or broadly to construe the exclusionary provision is informed by current international legal developments, and thus can be firmly defended. For these reasons, the thesis also analyses pertinent issues debated during the review process of Article 27.3(b), namely the patentability of life forms (including animal inventions), access and transfer of technology, and the requirement to disclose the source, and country of origin of genetic material used in animal inventions. In the context of the research questions, the analysis allows an evaluation as to whether or not developing countries such as Malaysia should consider allowing patent protection to animal inventions based on at least three factors: (1) the country's technological development; (2) the nature of the country being a technology-user (rather than exporter); and (3) the socio-economic impact arising from the lack of protein-based animal products. The assessment also identifies the implications of the mandatory disclosure requirement to a patent applicant and, more broadly, the progress of the animal biotechnology and livestock industry.[29]

[28] Issues relating to the review process are dwelt upon in detail in chapter 2.
[29] ibid.

The central aspect of the thesis is that it analyses the implications of the permissive, and restrictive approaches to the development of animal biotechnology applications and the livestock industry so as to permit the identification of a suitable model which would promote the industrial development determined to be most appropriate in Malaysia. The assessment discloses that the political, economic and industrial perspective of the comparable regions (Europe and Canada) toward animal patenting conforms to the approach which each has adopted. In the context of the research questions, the approach which allows the progression of research and development (R&D) activities, animal biotechnology and livestock industry is proposed for adoption by Malaysia.

While the interpretation of the term 'animal varieties' under s13(1)(b) directly benefits Malaysian judicial authorities and patent examiners in deciding the patentability of animal inventions, the thesis aims at a broader audience. Firstly, Malaysian policy makers and drafters of the law need to know the implications of the legal term used and whether or not it carries the purpose of the exclusion intended by legislature. The thesis provides an appraisal if any amendment is necessary to the existing provision. Secondly, clarification of aspects relating to the term 'animal varieties' is also useful to legal practitioners in advising their clients who intend to file a patent application with the MyIPO. Finally, the creation of the inventions involves inventors and investors. As the process to develop inventions is time-consuming and requires huge investment, these parties would be interested to know if their inventions will be protected or their investment could be recouped under the Malaysian patent system.

It was identified earlier that this thesis builds on the existing construction of the permissive and restrictive approaches, rather than developing a novel interpretation to answer the

research questions. The EPO and some critics have argued their points on how the term 'animal varieties' under Article 53(b) of the EPC is to be construed. In turn, the Canadian Supreme Court has adopted a purely legal approach to decide on the unpatentability of animal inventions. However, so far no one has tested the existing construction within an exclusionary provision in national patent law and economic policy pertaining to the livestock industry of a particular country. This thesis fills this gap in two respects. By analysing the EPO and Canadian Supreme Court decisions, and the critics of the respective decisions, the thesis identifies the strengths and weaknesses of the previous arguments, so as to assess their defensibility and implications for the specific national and economic policies of a country. Practically, while the context of Malaysia is being studied, the thesis provides guidance for other developing countries which similarly exclude 'animal varieties' or 'animals' in their national patent laws, but have not decided how the exclusion is to be legally interpreted. [30] In particular, the thesis provides a test case for those countries which have a similar economic template to Malaysia with which to appreciate how the exclusionary provision can be construed in pursuing their economic priorities.

Of necessity, this thesis has certain limitations. Firstly, while the unpatentability of animal varieties in s13(1)(b) is being studied, the narrower focus of this thesis is on product patents rather than process patents. [31] This is because process patents are not an issue within patent

[30] For instance, see s62(b) of the Sri Lanka Intellectual Property Act No 36 of 2003; s3(j) of the Indian Patents Act 1970 (39 of 1970); Article 25 of the China Patent Law of the People's Republic of China 1984; and s22.4 of the Intellectual Property Code of the Philippines 1997 (Republic Act No 2893). All the statutes are available at: WIPO, http://www.wipo.int/wipolex/en/ (Accessed: 28 March 2012).

[31] A patent could be described in a number of ways depending on how it is perceived: (1) it may be described by authorities issuing the patent. For instance, in Europe, there are two types of patents namely the European patent which has a national patent effect (including in non-European Union (non-EU) countries) and the Community patent which will be effective only in all EU countries once it is implemented; (2) they may be classified based on the subject matter that they protect, such as a biotechnological patent (inventions related to the biotechnology sector) or a technological patent (which relates to mechanical inventions); and (3) by looking at the nature of the interest that is protected. In this way patents can be divided into three types namely a process patent, a product patent and a product-by-process patent. A process patent gives protection to activities or actions (methods, processes or uses). It can either be methods or processes involved in the

law in Malaysia or in most countries, since processes are explicitly recognised as patentable subject matter. As a result, patents are normally allowed by patent offices for their intrinsic ability to fulfil the patent qualification criteria.

Secondly, ethical issues which are highly debated when animal patenting is discussed are beyond the scope of the thesis. Intrinsically, this is because the unpatentability of animal inventions under s13(1)(b) relates to the question of whether or not animal inventions are patentable subject matter. These are different from the question of whether animal inventions ought to be patentable or not on ethical grounds. In support of this contention, s13(1)(b) is distinct from the moral-related legal provision contained in s31(1) of the Malaysian Patents Act 1983.[32]

Finally, this thesis confines its assessment to the implications of the two adopted approaches being analysed for the livestock industry's food production. The implications for other sectors where animal biotechnology is also involved (such as healthcare and bioremediation) are not considered. This limitation is based on the fact that each industry involves distinct and unique challenges, problems and issues to be solved. Consequently, it is beyond the scope of this work, which is directed to providing value for policy makers and the legislature to assess the most practical interpretation of the legal exclusion of animal inventions from patent protection in the context of the livestock industry (specifically as food). This aims to

---

production of an invention, or methods of using products. The latter is also known as a method of use patent (an example of this could be a claim to a new use using something which is already known). A product patent as the name suggests, gives protection to the product that is produced (and this includes 'selection patents' on chemicals). A product-by-process patent gives protection to a product which can only be described by its method of production. See the detailed account on this in L. Bently and B. Sherman, *Intellectual property law* (Oxford University Press, 2009) 365-368.

[32] Section 31(1) states: 'The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the performance of any act in respect of the claimed invention is prohibited by any law or regulation, except where the performance of that act would be contrary to public order or morality'. Similar moral-related provisions are provided in Article 27.2 of the TRIPs Agreement and Article 53(a) of the EPC. See Appendices 4 and 5, respectively, for the provisions. The Canadian Patent Act has no moral-related provision.

determine if it is necessary for the law to be amended, or for any provisions in the existing patent law related documentation or guidelines to be introduced, so as to clarify the law. In future work, empirical research to investigate (for instance): (1) the perceptions of Malaysian scientists and animal biotechnology companies on the importance of patenting animal inventions for the development of R&D activities; and (2) the views of industrial stakeholders on the implications of the exclusion for the interests of investors in the Malaysian animal biotechnology sector, are the aspects which would be useful for expanding the understanding of the law.

This thesis consists of six chapters. **Chapter One** reviews the industrial context of the thesis. It identifies the need to secure animal-protein based sources for the growing demand from Malaysians, but the long-term problem of self-sufficiency level for main livestock products. Modern animal biotechnology applications and animal biotechnology food have been identified as a pertinent tool to solve the problem. However, it is unclear how the technology and product are to be legally regulated in the context of the exclusion of animal varieties under s13(1)(b) of the Malaysian Patents Act 1983. **Chapter Two** assesses the flexibility to exclude animal inventions from national patent law within the international patent law framework as underlined by Article 27.3(b) of the TRIPs Agreement. Mainly, it identifies issues and implications which are pertinent for a Signatory (including Malaysia) to consider in interpreting the relevant national exclusionary provision. **Chapter Three** assesses s13(1)(b) of the Malaysian Patents 1983. It identifies the ambiguity, minimal development and application of the provision within the Malaysian patent law, and therefore, the justification for the research. **Chapter Four** analyses the first model of construing the exclusion of animal varieties namely the permissive approach and its implications on the livestock industry. **Chapter Five** analyses the second model of construing the exclusion of animal varieties

namely the restrictive approach and its implications on the livestock industry. In the light of the needs and problems faced by the Malaysian livestock industry (identified in chapter 1), the **Discussion and Conclusion chapter** evaluates the permissive and restrictive approach so as to identify the legal approach which would resolve the problem and permit the development of animal biotechnology and products. The approach is proposed to Malaysia for adoption so as to construe the exclusion of animal varieties under s13(1)(b). Pertinent points argued by each chapter toward answering the research questions are highlighted here.

Chapter One examines and assesses the global and Malaysia's livestock industries, and animal biotechnology applications to enhance the industry. The focus is on identifying the development, challenges and expectations that Malaysia has toward its animal biotechnology, and livestock sector. It is identified that animal biotechnology applications have a huge potential to increase production and high quality output which are the aims of developing countries, including Malaysia. While there are concerns from consumers pertaining to the safety of animal biotechnology food[33] for human health and the environment, the chapter demonstrates that there is ample scientific evidence to refute the concern. Most importantly, the chapter identifies that Malaysia is facing a long-term problem in achieving a self-sufficiency level for all main livestock commodities, notwithstanding the on-going efforts to meet the growing demand and specific needs of the population. Mainly, this is due to challenges which are beyond human control, such as livestock and aquatic diseases, and constraints of animal and fish feed. Notably, the Malaysian Government has made it explicit that animal biotechnology applications are to be fully utilised in order to develop the livestock industry, hence, fulfilling the relevant demand and need. The chapter argues that animal biotechnology and animal biotechnology food provide Malaysia with a solution to

[33] Throughout this thesis, the term 'animal biotechnology food' refers to animals which are intended to be used for food and produced through modern animal biotechnology techniques including genetic engineering and cloning.

resolve the problem identified here. Therefore, the question as to how the exclusion of animal inventions under s13(1)(b) of the Malaysian Patents Act 1983 is to be construed (either narrowly or broadly), is to be guided by this parameter.

Chapter Two examines Article 27.3(b) of the TRIPs Agreement with two aims. Firstly, to identify the rationale underpinning the flexibility for Signatories either to exclude animal inventions under the national patent system, or not. Secondly, to identify and assess the international issues relating to the exclusion under the review process of the provision. It is disclosed that the flexibility is the result of the different perspectives of the negotiating countries toward the patentability of animal inventions, due to their diverse technological and economic development. Developed countries such as the US, Japan and Australia have been of the view that patent protection is necessary for the dissemination of knowledge, for encouraging innovation and for increasing trade.[34] Conversely, developing countries consider animals as unpatentable on the grounds that they are discoveries rather than inventions. The chapter contends that the retention of the exclusion under Article 27.3(b) is necessary and important so as to allow developing countries to interpret the flexibility according to their national priorities which they wish to pursue. This includes a decision on how narrowly or broadly the exclusion is to be construed. Nevertheless, in the context of the thesis, the chapter asserts that patent protection for animal inventions should be considered by developing countries which intend to exploit animal biotechnology applications in enhancing their livestock industry for the purpose of securing the supply of livestock products for the population. This is provided that the countries have the technological ability to adapt the technology transfer from developed countries. In this respect, developing countries are

[34] See for instance GATT, 'Draft Agreement on the Trade-Related Aspects of IPRs: Communication from the US', Document MTN.GNG/NG11/W/70 (11 May 1990) Article 23, 9; WTO, 'Review of the provisions of Article 27.3(b): Summary of issues raised and points made', Document IP/C/W/369/Rev.1 (9 March 2006) 4.

contrasted with the least-developed countries (LDCs) which would struggle to benefit from strengthening their patent protection due to low technological development.

One of the pertinent arguments of developing countries during the review process was that the disclosure of the source and country of origin of genetic material used in animal inventions is to be made mandatory under Article 27.3(b). The chapter identifies the potential burden to patent applicants to fulfil the condition due to the difficulties in ascertaining the two aspects which are caused mainly by the prevalent practice of the trans-boundary movement of animal livestock. This would pose an unnecessary hurdle to obtain patent protection for animal inventions, discourage interest to innovate, and adversely affect the progression of technology. Finally, while there is no definitive rule as to how the exclusion of animal inventions under national patent laws is to be construed, the chapter argues that the examination and assessment of the permissive and restrictive approaches (in chapters 4 and 5, respectively) is the most appropriate way of dealing with the issue. Since the existing two models for interpreting the exclusion of animal inventions are within the international patent law framework, any choice of interpretation made by a Signatory (including Malaysia) cannot be easily challenged.

Chapter Three examines s13(1)(b) of the Malaysian Patents Act 1983 which contains the exclusion of animal varieties so as to identify the clarity and legal development of the provision. Examination of the legislative history of the provision discloses that the exclusion was included under the Malaysian Patents Act 1983 mainly to bring the country's patent law as close as possible to the provisions of international patent law text. This is important given the aim of the country being to participate in the international patent law arena (by becoming a signatory and a member state of patent law conventions and organizations, such as the Paris

Convention, and the World Intellectual Property Organization (WIPO), respectively. This aim is designed to ensure that the commercial interest of local inventors is secured globally, in view of the country's shift of economy from agriculture to industry between the 1980s and the mid-1990s. Nevertheless, the parliamentary proceedings of the Malaysian Patents Bill 1983 disclose that the exclusion was not extensively debated or thoroughly considered. The minimal deliberation leads to the conclusion that the meaning of 'animal varieties' was not at all weighed by the legislature in the light of scientific advancement to create animal inventions. This, together with the absence of application of the exclusion so far by the MyIPO or judicial authorities, renders the legal position of the exclusion in the country vague. Therefore, this research is justified. In the context of the thesis, the chapter contends that any interpretation to be given to s13(1)(b) is to be guided by the needs and problems of the country's livestock industry identified in chapter 1.

Chapter Four examines and assesses the first model of interpretation adopted by the thesis, namely the European-wide permissive approach. It exemplifies the narrow construction of an exclusionary provision which results in permissively enabling patenting for animal inventions that would be excluded under a broad legislative construction. The chapter shows that the exclusion of animal varieties under Article 53(b) of the EPC is largely influenced by the existence of the same exclusion in its predecessor; Article 2(b) of the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention 1963 (Strasbourg Convention).[35] In turn, the need for consistency between the two Conventions is underpinned by the aim of creating a unified patent system for the European Union (EU) Member States. Through this, the EU aspires to compete economically with the US and Japan, which are the two key players in the international patent law scene. Notwithstanding the long existence of

[35] Available at: Council of Europe (COE), http://conventions.coe.int/Treaty/en/Treaties/Html/047.htm (Accessed: 30 June 2011).

the exclusion of animal varieties in the European Patent Convention the intended meaning, purpose, and subject matter of the exclusion are all unclear. As Article 53(b) relates to the question of whether or not animal inventions fall under the term 'animal varieties' (unpatentable), its interpretation becomes pertinent. In the final decision on the case of the *Harvard/Onco-mouse* it was held that the exclusion is to be narrowly construed. In particular, only species are to be excluded. Genetically engineered animals, being classified as sub-species, are not barred from patent protection. The chapter asserts that underpinning the narrow construction is the recognition that animal inventions which could fulfil patent qualification criteria should be given the necessary patent protection. This is logical given the fact that, unlike plant varieties, which are similarly excluded from the patent system under Article 53(b), but which would be entitled to a *sui generis*[36] protection under the International Convention for the Protection of New Varieties of Plants (UPOV Convention),[37] animal inventions would be without any legal protection if a patent is not granted to them. Eventually, the development of the technology (and thereby the growth of the livestock industry) will be adversely affected as there would be a lack of incentive to inventors to innovate. In the context of the thesis, the chapter argues that the permissive approach develops animal biotechnology applications and the livestock industry. This is because, through patent protection for livestock animals derived from modern biotechnology, investors would be attracted to invest in the technology, and the relevant R&D activities. The regulatory framework to assess the pre-market safety of animal biotechnology food which are already in place in Europe support the advancement of the technology further through the potential marketability of the products in the region.

[36] Latin expression which means: 'of its own kind'. See http://www.thefreedictionary.com/sui+generis (Accessed: 17 August 2009).

[37] The Convention was adopted in Paris on 2 December 1961 and came into force on 10 August 1968. It has been revised on 10 November 1972, 23 October 1978 and 19 March 1991. Available at: International Union for the Protection of New Varieties of Plants, http://www.upov.int/index_en.html (Accessed: 11 April 2011). The Convention gives protection to plant varieties which are new, distinct, homogenous and stable.

Chapter Five examines and assesses the second model of interpretation adopted by the thesis namely the Canadian restrictive approach, in comparison with the permissive approach adopted in Europe. Contrary to the EU policy which aims to promote animal biotechnology applications to ensure the sustainable production of livestock production, Canada has adopted a more pessimistic view. This is evidenced by the country's negative political stance toward animal patenting as disclosed during the negotiations of the TRIPs Agreement and the reluctance of the government to regulate the marketability of animal biotechnology food. It has also been identified that while some animal biotechnology applications have been adopted in R&D activities involving livestock animals in Canada, none is directed toward the creation of transgenic livestock animals. Pessimistic consumers' opinion toward the product has been identified both in Europe and Canada. Nevertheless, unlike in Europe where the decision to utilise animal biotechnology in full is based on its importance to secure food production, the public view has been a pertinent impetus toward the Canadian Government's unenthusiastic policy. From the legal perspective, the chapter shows that the Canadian Supreme Court decision to refuse patent protection to the transgenic mouse in the case of *Harvard Mouse* (for its failure to qualify under any of the categories of invention under s2 of the Canadian Patent Act 1985), conforms to the government policy on the issue. Specifically, it is demonstrated that the Supreme Court decision shows a lack of legal reasoning because of the Court's own recognition that patent prerequisites are met, and that the transgenic mouse (or animal inventions generally) can be categorised under the term 'art', 'manufacture' or 'composition of matter' under s2. Underpinned by the argument that patent protection is a pertinent factor in encouraging innovation and investment, it is contended that the lack of patent protection for animal inventions *per se* in Canada adversely affects animal biotechnology, and consequently the livestock industry.

The **Discussion and Conclusion chapter** concludes the whole thesis. Bringing forward the analyses in the foregoing chapters, an evaluation is made of whether Malaysia should adopt the permissive or restrictive approach in construing the exclusion of animal varieties in s13(1)(b) of the Malaysian Patents Act 1985. The thesis argues that in order for Malaysia to resolve the problem of a self-sufficiency level of all main livestock products, and in the light of the aspirations and investment made by the government to develop the animal biotechnology sector, it should adopt the permissive approach. Through an evaluation of the restrictive approach, the chapter stresses certain points. Firstly, only the permissive approach can secure the investment and technology transfer which is required by Malaysia to develop its animal biotechnology and livestock industry. Secondly, Malaysia's national policies relating to the technology are in tandem with the EU policies which warrant the adoption of the latter's legal approach. Thirdly, the permissive approach corresponds with the international obligations imposed by Article 27.3(b) of the TRIPs Agreement on its Signatories where an invention which fulfils patent qualification criteria is to be patentable. Fourthly, the granting of patent to animal inventions does not prejudice Malaysia's interests under other international conventions such as the Convention on Biological Diversity 1992 (CBD)[38] which it ratified. Fifthly, the refusal to grant patents to animal inventions would leave such inventions without any legal protection, which would adversely affect the progress of the technology. Sixthly, patent protection to animal inventions *per se* is pertinent as other forms of protection would not adequately protect the commercial interests of an inventor. Finally, in the context of animal biotechnology relating to the livestock industry, an argument that the licensing of patents would hinder technology transfer to developing countries is determined to be premature for Malaysia to consider, as more advanced applications are still

[38] Available at: CBD, http://www.cbd.int/doc/legal/cbd-en.pdf (Accessed: 31 March 2012).

at the research stage. Conversely, the refusal to allow patents on animal inventions would cause a more crucial socio-economic problem as animal-protein based food for the population cannot be secured. The chapter ends by a proposal that there is no requirement that s13(1)(b) of the Malaysian Patents Act 1983 be amended. The exclusion of 'animal varieties' in the exclusionary provision is to be narrowly interpreted so as not to exclude transgenic or cloned animals for food purposes from patent protection. Section 12 of the Malaysian Patents Act 1983 on the meaning of the term 'invention' supports this construction. Nevertheless, it is suggested that the Guidelines for Patent Examination of MyIPO clarify the Malaysian legal position by introducing two provisions. Firstly, a provision which allows patent protection be granted, not only to the process of production of an animal invention, but also to the product itself. Secondly, a provision to the effect that an animal invention is patentable provided it meets the patentability criteria.

CHAPTER ONE

THE MALAYSIAN LIVESTOCK INDUSTRY AND ANIMAL BIOTECHNOLOGY APPLICATIONS: EXPECTATIONS AND CHALLENGES

1. Introduction

The world food-price crisis between 2007 and 2008 demonstrates the far-reaching implications of an inconsistency between production and demand for food by the world's population. The crisis has caused economic concerns at national level where costs of major crops such as rice, wheat, corn and soybean, increased drastically.[1] Socially, food-related riots and demonstrations took place in many countries across the globe such as Haiti, Egypt, Philippines, Cameroon and others.[2] Various factors accumulatively contributed to the crisis. Among others are the rapid increases of oil and energy prices, bad weather which caused low harvests[3] and the decrease of global grain stockpiles caused by growing demand for animal feed.[4] The last of these has been associated with the global growing consumption of livestock products such as beef, pork, poultry, eggs and dairy products, especially in developing countries.

Livestock and its products are closely related to human lives and have been contributing to human livelihood for decades as sources of food, income, employment and various other purposes. With the growth of the human population which is projected by the United Nations

---

1 Cereals prices rose 21% in the International Monetary Fund (IMF) market indices in 2006, 31% by 2007 and 49% by the first half of 2008. See World Food Programme, Food out of reach: pathway to the financial crisis, http://www.wfp.org/photos/gallery/food-crisis-timeline (Accessed: 22 November 2010).

2 Global crisis as food prices soar, *The Star*, 14 April 2008, http://thestar.com.my/news/story.asp?file=/2008/4/14/focus/20942898&sec=focus (Accessed: 22 November 2010).

3 In 2005, crops in Russia and Ukraine were reportedly struck by drought while Australia underwent its worst dry season in many years. See World Food Programme, n 1 above.

4 ibid.

(UN) to reach 9.2 billion by 2050,[5] the livestock sector worldwide is facing constant challenges to meet the increasing demand. For many countries in the world, especially developing and LDCs, the key challenge facing their national livestock industry is how to increase the livestock output to meet the population's needs. Conversely, the focus of industrialised countries has been moving toward producing quality livestock products[6] rather than meeting self-sufficiency levels.

Human intervention in the livestock industry has aimed to achieve two most important objectives, namely high production and quality yields. Commencing with traditional selection methods, advances in biotechnology have brought a new revolution to the industry. Modern breeding technologies such as artificial insemination,[7] multiple ovulations followed by embryo transfer,[8] deoxyribonucleic acid (DNA)-based marker-assisted selection[9] and synchronisation of oestrus[10] have allowed the production of larger numbers of offspring and a greater rate of precision in fertilisation.[11] Apart from these breeding techniques, there is

---

5 Food and Agriculture Organization of the United Nations (FAO), The state of food and agriculture: livestock in the balance, 2009, http://www.fao.org/docrep/012/i0680e/i0680e.pdf (Accessed: 26 November 2010) vi. The world's population in 2010 is 6.9 billion. See UN, World population prospects: the 2008 revision population database, http://esa.un.org/unpp/p2k0data.asp (Accessed: 26 November 2010).

6 M. Mazzocchi, C. Brasili and E. Sandri, Trends in dietary patterns and compliance with World Health Organization recommendations: a cross-country analysis (2007) 11 *Public Health Nutrition*, 5, 539.

7 Means: 'introduction of semen into the uterus or oviduct by other than natural means'. See http://www.merriam-webster.com/dictionary/artificial%20insemination (Accessed: 25 March 2011).

8 The process involves: (1) treating female livestock animals with hormones to increase the number of eggs at ovulation; (2) artificial insemination of the cow; (3) the flushing of the embryos (non-surgically, using a catherer placed into the uterus); and (4) the implantation of the embryos in recipient livestock animals. See http://www.biotopics.co.uk/edexcel/biotechnol/supovu.html (Accessed: 25 March 2011).

9 DNA is an abbreviation for Deoxyribonucleic acid. It means 'a nucleic acid which carries the genetic information in the cell of all organisms'. See http://www.thefreedictionary.com/DNA (Accessed: 15 March 2011).

10 Means: the synchronisation of mating interest in livestock animals by methods such as injection of hormones. See http://medical-dictionary.thefreedictionary.com/Estrus+synchronization (Accessed: 25 March 2011).

11 M.B. Wheeler, Agricultural applications for transgenic livestock (2007) 25 *Trends in biotechnology*, 5, 204-210; J.F. Garcia, M.R.S. Fortes, L.R. Porto-Neto and P.J. Boettcher, Achievement of research in the field of molecular genetics: recent molecular genetics achievements and unfolding applications to livestock, 53-62 in A. Rosati, A. Tewolde and C. Mosconi (eds), *WAAP Book of the year 2007: a review on developments and research in livestock systems* (Wageningen Academic Publishers, 2009); R.H. Phipps and A. Cockburn, GM technology: a tool to benefit livestock production, 247-257 in E. Owen, T. Smith, M.A. Steele, S. Anderson, A.J. Duncan, M. Herrero, J.D. Leaver, C.K. Reynolds, J.I. Richards, J.C. Ku-Vera (eds), *Responding to the livestock revolution* (Nottingham University Press, 2004).

considerable research and practical evidence which have shown the potential of genetic engineering[12] and somatic cell nuclear transfer (SCNT) (cloning)[13] techniques in producing yields of intended traits involving animals of different species. This is a fundamental achievement which was not possible before from the use of traditional breeding. As a result, modern biotechnology is one of the tools which, has been identified[14] as able to play an important role in assisting the livestock industry, not only to increase production, but also to improve genetic traits to produce livestock of high quality. The dual ability of modern biotechnology could fulfil the objectives of the livestock industry in countries worldwide.

The difference between traditional and modern breeding lies in the techniques involved. In traditional breeding, livestock animals are 'genetically altered' through crossbreeding and selection techniques.[15] Crossbreeding involves the mating of animals which belong to different breeds, whereas selection technique entails the selection of superior parents to produce generations of similar or even better quality, such as livestock with superior fertility and better adaptation to environmental changes. While both methods involve natural breeding processes, they differ from the fact that human intervention is involved in the latter. Comparing the selection technique with genetic engineering methods, while humans play a

[12] Modern biotechnology began in 1970s with the two basic techniques of recombinant DNA technology (genetic engineering) and hybridoma technology. In genetic engineering technology, also referred to as gene splicing, genetic material from an external source is inserted into a cell in such a way that it causes the production of desired protein by the cell. In hybridoma technology, different type of immune cell are fused together to form a hybrid cell line producing monoclonal antibodies. See P. Grubb, *Patents for chemicals, pharmaceuticals and biotechnology: fundamentals of global law, practice and strateg*y (Oxford: Oxford University Press, 1999) 225.

[13] Cloning in livestock animals was introduced in livestock breeding programmes in the 1980s. The SCNT process has been successfully performed in livestock species such as cattle, sheep, pigs and goats. The most well-known livestock animal produced using this method is perhaps 'Dolly the sheep'. See A.L. van Eenennaam, What is the future of animal biotechnology (2006) 60 *California Agriculture*, 3, 133.

[14] ibid. The promises of modern biotechnology for food security have also been recognised by many critics from developing countries. See for instance, N.J. Tonukari and D.G. Omotor, Biotechnology and food security in developing countries (2010) 5 *Biotechnology and Molecular Biology Reviews*, 1, 13-23; N. Ozor and E.M. Igbokwe, Roles of agricultural biotechnology in ensuring food security in developing societies (2007) 6 *African Journal of Biotechnology*, 14, 1597-1602.

[15] A. Christie and N. Peace, Intellectual property protection for the products of animal breeding (1996) 18 *European Intellectual Property Review*, 4, 214.

significant role in both, the manipulation of genetic traits at molecular level in the latter technique signifies a more fundamental involvement of humans in determining the output of the process. Notwithstanding the underlying promises, biotechnology has raised various concerns. It is interesting to note that scientists, being practitioners of the technology, are not all agreed about the advantages of biotechnology. Due to the 'invasive' procedures which are involved, products of the technology have been associated with various issues, which call for regulatory frameworks at national and international level. Of particular importance are the potential environmental hazards and risks to human health. At the international level, these aspects have been regulated by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000 (Cartagena Protocol).[16]

This chapter identifies the expectations of the Malaysian livestock industry and highlights the challenges that have been limiting the industry in meeting the population's demand. Based on the analyses of the two aspects, a solution to resolve the on-going problem of self-sufficiency levels for the main livestock products, within the country, will be proposed. While Malaysia's context is the one that is being examined, the global dimension will be considered in giving a comparative situation for relevant aspects under discussion.

Towards this end, this chapter is divided into seven sections. Section 2 explains the importance of the livestock industry to Malaysia and the aspiration of the government to maximise the use of animal biotechnology applications to develop the industry. In addition, biotechnological applications which have so far been adopted by the industry will be examined in order to identify whether all methods, or only certain ones, have been applied. The section gives the background to the country's expectations of the industry and

[16] Available at: Convention on Biological Diversity (CBD), http://bch.cbd.int/protocol/text/ (Accessed: 3 June 2011).

technology. The extent of the technological application further demonstrates the level of knowledge and expertise currently available in the country. Notwithstanding the application of animal biotechnology, there have been various concerns arising from it. Therefore, since the success of any technology would ultimately depend on consumers' willingness to invest their money, public concerns about the products of biotechnology at international level, and in Malaysia, will be examined in section 3. As regards Malaysia, it will be seen if the concerns have led to opposition to the technology and its products. Apart from that, as livestock animals (including those genetically altered) are subject to trans-boundary movement for various purposes, the problems and benefits of the Cartagena Protocol which governs issues relating to the movement will be assessed. Despite the concerns that consumers may have, similar to the global trend, the Malaysian livestock industry has to meet the growing and specific demands from its population. Therefore, section 4 examines the trends in consumption and production, and the changing trend of consumers' and nations' preference for livestock products. This is followed by section 5 which investigates some of the challenges faced by the livestock industry and the implications which they have caused to Malaysia. Based on the information contained in the preceding sections, section 6 will identify the potential of animal biotechnology applications to resolve the problem (faced by Malaysia) as identified in section 5. Section 7 concludes the chapter.

This chapter sets the context to the thesis. An understanding of how animal biotechnology applications could assist Malaysia to meet the demands of its consumers and resolve the problems of its livestock industry is important. It functions as a guiding parameter for the country (and also other developing countries with similar economic interests) in deciding how the law on the patenting of animal inventions should be regulated. Since the application

of animal biotechnology in the Malaysian livestock industry is pertinent to this thesis, its development should be first understood.

2. The Malaysian animal biotechnology industry: aspirations and development

Agriculture has been the backbone of Malaysia's economy since long before its independence on the 31st August 1957. Although between the 1980s and the mid-1990s, the country's economy experienced a shift from an agricultural to an industrial basis, agriculture remains one of the key economic drivers. There are various national policies which have been in place to support the industry. Of particular importance is the Third National Agricultural Policy (Malaysian Agricultural Policy) which broadly aims to maximise the country's income by optimal usage of resources in the sector.[17] A specific objective of the Policy includes the increase of food production (in view of the growth in demand), reduction of imports and increase of exports. To this end, numerous efforts have been planned and adopted by the government to develop the livestock and fisheries industries.

While the initial decision to develop the biotechnology field in Malaysia was announced in 1991, the earnest intention to develop the sector could be said to be fairly new. The Malaysian National Biotechnology Policy[18] evidenced the government's commitment to promote the technology as a key new economic sector. In this regard, three areas of development have been identified: (1) agricultural biotechnology; (2) healthcare biotechnology; and (3) industrial biotechnology.[19] The importance of the first of these is explicable by the fact that the agricultural sector has been one of the main sources of income

[17] Ministry of Agriculture and Agro-Based Industry Malaysia, Third National Agricultural Policy (1992-2010), http://moa.gov.my/web/guest/dpn3 (Accessed: 3 December 2010).
[18] See Appendix 1.
[19] ibid.

for the country for a long time. Within this, 'Thrust 1' of the Policy aims at 'total utilisation of biotechnology to transform and enhance the value creation of the agricultural sector'.[20]

Animal biotechnology research in Malaysia has been undertaken by various research and higher learning institutions for decades. In tandem with the aspiration to harness biotechnology for the development of the agricultural sector (including the livestock and fisheries industries), the Malaysian animal biotechnology industry is working towards this end. The progress of animal biotechnology in Malaysia can be divided into two stages: (1) the application stage; and (2) the research stage. The application of animal biotechnology in Malaysia's livestock sector is limited. The country has not yet produced any transgenic livestock or fisheries products, as developed countries have. This is not surprising given that research in animal science in developed countries started more than 200 years ago, compared to only a few decades ago in developing countries.[21] As regards modern breeding techniques, unlike most North American and western European countries which have widely applied technologies such as embryo transfer and molecular genetics technologies, the only technique which has been widely applied in Malaysia is artificial insemination.[22] The method is particularly important in increasing the usefulness of superior sires, hence, a greater number of offspring can be produced within the same period, compared to natural breeding methods. Nevertheless, the use of other reproductive biotechnological techniques such as gamete and

[20] ibid.

[21] A. Waters-Bayer and W. Bayer, Research to alleviate poverty in the face of industrialisation of livestock production, in E. Owen et al, n 11 above, 191.

[22] This practice corresponds with the practice by other developing countries due to the affordability of the technology compared to other modern breeding techniques. In fact, the technique has been the most popularly used in all regions in the world: Africa, Asia, Europe, Latin America and the Caribbean, Near and Middle East, North America and Southwest Pacific (55% to 100% usage), compared to two other biotechnologies namely embryo transfer (10% to 100%) and molecular genetics technologies (11% to 100%). See D. Pilling, R. Cardellino, M. Zjalic, B. Rischkowsky, K.A. Tempelman and I. Hoffmann, The use of reproductive and molecular biotechnology in animal genetic resource management – a global overview (2007) *Animal Genetic Resources Information*, 40, 3; FAO, The state of capacities in animal genetic resources management: reproductive and molecular biotechnology, 2007, ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (Accessed: 17 December 2010) 265-266.

gene manipulation for the production of sexed embryos,[23] embryo transfer and embryo cryopreservation are already at the research stage.[24] Other focuses include molecular markers for identification of important traits such as disease resistance and heat stress tolerance, production of cheaper livestock feed and seed production techniques for the aquaculture industry.[25]

In Malaysia, the application of animal biotechnology and its commercialisation is most notable in the production of several vaccines against livestock diseases such as Newcastle and Fowl Pox diseases for the poultry industry.[26] In order to promote innovation, the government has been encouraging research institutions and individual scientists to apply for patent protection for newly developed biotechnological inventions.[27] It is pertinent to note that some higher learning institutions and public research institutes have been filing patent applications, locally and internationally, (for example) for DNA sequences encoding for various proteins and vaccines, and animal feed. Some of the applications have been granted while others are awaiting examination.[28]

---

[23] Means: 'the determination of the sex of an embryo before birth'. FAO, http://www.fao.org/glossary/spec-term-n.asp?id_glo=4151&id_lang=TERMS_E (Accessed: 14 April 2012).

[24] K. Yusoff, Biotech R&D scenario in Malaysia, http://www.eumbio.org/papers/BFS/R&D%20Scenario.pdf (Accessed: 17 December 2010); Malaysian Biotechnology Corporation, Overview: Malaysian agricultural biotechnology, http://biotechcorp.inventgw.com/wp-content/uploads/2011/11/publications/White_Paper_Agricultural.pdf (Accessed: 17 December 2010); Malaysian Biotechnology Information Centre, Biotechnology in Malaysia, http://www.bic.org.my/?action=localscenario&do=biotechnology (Accessed: 17 December 2010).

[25] ibid.

[26] Putra University of Malaysia, Commercialized products, http://www.vet.upm.edu.my/eresearch5.html (Accessed: 17 December 2010).

[27] More local inventions: scientists and researchers to get good payouts from Government, *The Star*, 23 June 2009, http://thestar.com.my/news/story.asp?file=/2009/6/23/nation/4175423&sec=nation (Accessed: 17 December 2010).

[28] Science University of Malaysia, http://cserver.cs.usm.my/patent/Search_Patent.aspx (Accessed: 17 December 2010); Putra University of Malaysia, Faculty of Agriculture: Facts and figures, http://www.rmc.upm.edu.my/upmip/index.php?content=faculty&fac=1 (Accessed: 9 January 2012); Malaysian Agricultural Research and Development Institute, IP status, http://www.mardi.my/web/guest/ip-status (Accessed: 9 January 2012).

It can be concluded from this section that Malaysia has the technological knowledge and ability to utilise modern animal biotechnology. For this reason, it has been actively encouraging and embarking upon various biotechnology techniques in diverse areas of animal research. While the production of transgenic[29] livestock animals, as already achieved by international animal biotechnology research, is still a long way off, the country's expectations from its animal biotechnology sector are at least clear; they should contribute toward the enhancement of food production so as to reduce the country's dependence on imports of food.

Notwithstanding this aim, consumers' acceptance of genetically modified (GM) livestock and their products is paramount for the products to reach the market. Owing to this, the following section identifies concerns of consumers in order to appreciate the challenges embracing the technology and products. Similar to livestock animals derived from traditional breeding, their GM counterparts are subject to trans-boundary movement. Internationally, the implications of the movement for the environment and human health are regulated by the Cartagena Protocol. Therefore, the next section will also analyse the problems and benefits of the Protocol in regulating the subject matter. It will be shown that the various concerns of consumers are refutable by evidence of the safe use of animal biotechnology food. If any, the concern is adequately addressed by the Cartagena Protocol. The discussion is important to the research questions so as to show the position of animal biotechnology food within the society and to appreciate whether or not concern arising from its potential use is justifiable.

[29] Means: 'an organism which has had genes from another organism in its genome through genetic engineering techniques'. See http://www.biology-online.org/dictionary/Transgenic (Accessed: 25 March 2011).

3. Animal biotechnology food: consumers' concerns and protection of interest

3.1 Concern about animal biotechnology food: the opposing views

Consumers' concerns about animal biotechnology food are two-fold: their effects on health and the environment. As regards the former, the safety for consumption of products of cloned livestock products has been the focus of many studies. For instance, in a study[30] on perceptions of consumers toward cloned cows' milk, it was discovered that in the first instance, consumers showed similar interest for the branded full-priced product and the 25-percent-discount product which used a biotechnology process. However, the purchase interest dropped for the latter when consumers were informed that the product came from cloned cows. However, the study also made an important conclusion that consumers' scepticism could be improved by education and information as to its benefit.[31] In a recent collaborative study by a group of scientists,[32] it has been concluded that cloned cattle show no biological or biochemical differences in their meat and milk composition compared to non-cloned cattle. Notably, the US Food and Administration (USFDA)[33] had also recently published that meat and milk from cloned cattle, pigs and goats, and the offspring of all clones are as safe to eat as food from conventionally bred animals. The conclusion is achieved based on data obtained from rigorous risk assessment pertaining to implication of the food to human health.[34]

---

30 L.J. Butler, M.M. Wolf and S. Bandoni, Consumer attitudes toward milk products produced from cloned cows (2008) 39 *Journal of Food Distribution Research*, 1, 35.

31 ibid.

32 X. Yang, X.C. Tian, C. Kubota, R. Page, J. Xu, J. Cibelili and G. Suidal Jr, Risk assessment of meat and milk from cloned animals (2007) 25 *Nature Biotechnology*, 1, 82.

33 US Department of Health and Human Services, FDA issues documents on the safety of food from animal clones, 15 January 2008, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116836.htm (Accessed: 12 March 2012).

34 ibid. The USFDA had earlier called for a voluntary prohibition on the marketing of milk or meat from cloned livestock animals and their offspring, despite the report from the Food and Drug Administration (FDA) Centre for Veterinary Medicine which indicated their safety for consumption. It had been reported that further data relating to the composition of meat and milk from clones and their progeny and also the

One of the potential uses of genetic engineering is the alteration of animals' growth rate. In the aquaculture sector, the technology has been applied to the production of Atlantic salmon. The growth hormone from Chinook salmon and eel-like ocean pout which was inserted into an Atlantic salmon enabled it to grow the whole year. The modification means the transgenic fish can grow faster than its non-transgenic counterpart of the same age, which normally stops growing in the winter. So it needs a shorter time to reach the market. While concerns over their safety for human health are also relevant for this product, opposition has been mainly on the threat that they could pose to the survival of native salmon due to the high possibility that they would escape from farms and pens. The concern is not without basis as studies have pointed in this direction. For example, a study by Purdue University, on the fast-growing of Japanese Medaka, a fish species which is used as a research model, has reported three important findings:[35] (1) the four-fold higher mating rate from its smaller-sized competitors could result to rapid domination of the altered genes in place of the wild stocks; (2) the 30% non-surviving potential of the transgenic fish before reaching sexual maturity; and (3) due to production of non-surviving offspring, it only requires 0.001% of the transgenic fish to eradicate the population of 60,000 wild fish.[36] In view of possible risks of these nature, Aqua Bounty Farms, the applicant in the case of transgenic Atlantic Salmon, has given repeated assurances that the risks could be overcome by farming the transgenic fish in inland pools, and that only sterile females would be sold,[37] hence avoiding cross-breeding.

---

health status of the progeny has been required, in order to convince consumers. See A.L.van Eenennaam, n 13 above, 132.

35 W.M. Muir and R.D. Howard, Fitness components and ecological risks of transgenic release: a model using Japanese Medaka *(Oryzias latipes)* (2001) 158 *The American Naturalist*, 1, 11-13.

36 ibid.

37 ibid.

Similar concern involving transgenic Atlantic salmon has been observed in the UK, where Scotland is the largest producer of farmed Atlantic salmon in the EU.[38] In 1995, a pilot scale growth trial project for breeding transgenic Atlantic salmon[39] was held at Loch Fyne. This trial caused considerable controversy. In a debate concerning the potential and risks of GM crops in the UK's Parliament in 1999, concern over the probable risks that the transgenic Salmon would cause to the wild populations was highlighted.[40] Due to the concerns, all the transgenic fish at Loch Fyne were destroyed at the end of the trial period, with no further trials since then. Subsequently, the use of transgenic fish in Scotland's aquaculture industry was forbidden by the Code of Good Practice for Scottish Finfish Aquaculture 2006.[41] A similar rejection of its production has been voiced by the Scottish Salmon Producers' Organization and the International Salmon Farmers' Association.[42] In relation to this, opposition in the US to the marketing of transgenic fish from restaurant owners, consumers' associations, and environmentalists have also been reported.[43]

Notwithstanding the concerns and opposition demonstrated here, salmon has notably been cited as one of the favourite fish in developed countries, apart from tuna and striped bass.[44] Unfortunately, according to the World Wide Fund (WWF),[45] the number of salmon has significantly reduced from 800,000 to 80,000 over the last 25 years. Over-fishing has been identified as one of the factors which have been contributing to the decrease in the supply of

[38] North Atlantic Salmon Conservation Organization (NASCO), 'Focus area report: aquaculture, introductions and transfers, and transgenics, United Kingdom (Scotland)', 2010, 4.
[39] ibid. 8.
[40] UK Parliament: Lords Hansard, 'Genetic Modification in Agriculture: ECC Report', http://www.publications.parliament.uk/pa/ld199899/ldhansrd/vo990527/text/90527-08.htm (Accessed: 19 November 2010).
[41] ibid.
[42] NASCO, n 38 above, 8.
[43] R. Black, Push to have GM salmon approved, *BBC News*, 24 March 2004, http://news.bbc.co.uk/1/hi/sci/tech/3565041.stm (Accessed: 18 November 2010).
[44] D. Cressey, Future fish, *Nature*, 2009, 458, 399.
[45] A. Kirby, Atlantic salmon in short supply, *BBC News*, 31 May 2000, http://news.bbc.co.uk/1/hi/sci/tech/769646.stm (Accessed: 20 December 2010).

fisheries worldwide.[46] Improvements to many aspects of fisheries production have long been practised worldwide; these include the use of modern equipment for finding fish and sophisticated trawls and fishing nets.[47] While these methods are effective in increasing fisheries production, each would require considerable cost, and if ineffectively managed may cause substantial damage to the environment. In the context of these potential issues, increasing the growth rate of the fish appears to be a viable option.

Concerns for human health through consumption of GM fish include the potential production of toxins or allergens due to the insertion of foreign genes and transfer of pathogens. Nevertheless, there is not yet any conclusive evidence in terms of the potential risks of the transgenic salmon to human health.[48] Notably, the risk of biotechnological aquaculture to human health has been described by the Food and Agriculture Organization of the United Nations (FAO)[49] as 'circumscribed and minor' because, in the fisheries sector, the most common gene construct involves a growth hormone gene derived from fish, hence avoiding allergic problems caused by a foreign gene.[50] Many other studies have concluded that the consumption of transgenic fish shows no adverse implications for health.[51] For instance, a study[52] has reported that mice which were feed with transgenic fish, demonstrated no negative implications for growth performance, reproduction capacity and biochemical analysis of blood.

---

[46] FAO, Overfishing on the increase in Asia-Pacific seas, 2004, http://www.fao.org/newsroom/en/news/2004/49367/index.html (Accessed: 22 March 2011).

[47] ibid.

[48] See for instance observation in R.S. Rasmussen and M.T. Morrissey, Biotechnology in aquaculture: transgenics and polyploidy (2007) 6 *Comprehensive Reviews in Food Science and Food Safety*, 12; P. Aerni, Risk, regulation and innovation: the case of aquaculture and transgenic fish (2004) 66 *Aquatic Science*, 335.

[49] FAO, The state of world fisheries and aquaculture, 2000, http://www.fao.org/DOCREP/003/X8002E/x8002e05.htm#P30 (Accessed: 22 March 2011) 74.

[50] ibid.

[51] See for instance G. Wu, Y. Sun and Z. Zhu, Growth hormone gene transfer in common carp (2003) 16 *Aquatic Living Resources*, 418-419; R.S. Rasmussen et al, n 48 above, ibid.

[52] G. Wu et al, ibid. 419.

It has been widely accepted that environmental stewardship is pertinent to maintain the world's biodiversity. However, the contention that GM fish would adversely affect the ecology should not be generalised given that there has been evidence to the contrary.[53] The minimal risks to ecology are supported by the observation that transgenic Atlantic salmon are less careful in avoiding predators.[54] As a result, they are less likely to survive in the wild.[55] It has been concluded in a study[56] that the risks to ecology brought about by transgenic coho salmon would depend on the availability of food in the wild environment. The study shows that, only when there is an abundance in food due to the low density of the population could the transgenic fish, which is stronger, affect its wild counterpart.[57] Nevertheless, in case of low availability of food, it is their inability to stand long periods of starvation caused by the growth hormone which could result in their elimination. For these reasons, the potential harm caused by GM fish should not be exaggerated, and their potential should not be rejected outright. The two most important concerns relating to the transgenic fish, namely its possible escape to the open sea and mating with its wild counterparts can be addressed by the approving authority. They include imposing mandatory compliance with the relevant conditions such as requiring the breeding process to be made onshore and the sterilization of the GM fish, as already undertaken by Aquabounty. Logically, compliance with the inland breeding requirement would automatically address the mating issue. If these conditions could be fulfilled by an applicant, there is no reason why the potential of animal biotechnology should be wasted in assisting the growing demand of livestock and aquaculture products from the world's population.

---

53 See for instance T. Reichhardt, Will souped salmon sink or swim? (2000) 406 *Nature*, 12; R.H. Devlin, M. D'Andrade, M. Uh and C.A. Biagi, Population effects of growth hormone transgenic coho salmon depending on food availability and genotype by environment interactions (2004) 101 *Proceedings of the National Academy of Sciences of the United States of America*, 25, 9303.

54 T. Reichhardt, ibid.

55 ibid.

56 R.H. Devlin et al, n 53 above, ibid.

57 ibid.

In the case of Malaysia, one might argue that it is premature to anticipate the Malaysian perceptions of animal biotechnology food when efforts to produce them are not yet on the Malaysian animal biotechnology agenda. Nevertheless, in the light of the country's serious commitment to exploit animal biotechnology applications, and the approval already granted to transgenic crops[58] the possibility of producing animal biotechnology food in the future would make the discussion relevant.

In the absence of any animal biotechnology food produced in the country so far, some responses from the public to the use of biotechnology involving plants and hormone could shed some light as to their attitude toward this increasingly important field of science. Malaysians' perceptions of three biotechnology applications have been assessed in a study.[59] They are GM soy beans,[60] GM insulin,[61] and GM palm oil.[62] In terms of perceived benefit and risks, the study found that the last of these was regarded as the most beneficial and the least risky, followed by GM insulin and GM soybean. While all applications clearly involve human manipulation, the study suggested that GM palm oil was regarded as having the least impact since there was no intra- or inter-species gene transfer.[63] When comparing GM palm oil with GM soybean (where both relate to human consumption) the higher acceptance of the former could be based on the perception of a product's direct benefit to their health. The disease-resistant feature of GM soybean appears not to fall into this category. Nevertheless,

---

58 In Malaysia, there are five approved transgenic products namely Roundup Ready soybean, MON 810 maize, MON 863 maize and NK 603 maize for use in food, feed and processing, as well as ice structuring protein derived from a GM yeast, for use in ice-cream. See Malaysia Biosafety Clearing House, Country's decision, http://www.biosafety.nre.gov.my/country_decision.shtml (Accessed: 21 December 2010).

59 L. Amin, J. Md Jahi, A.R. Md Nor, M. Osman and N.M. Mahadi, Malaysian public attitude towards several modern biotechnology applications, Proceedings of the 6th WSEAS International Conference on Environment, Ecosystems and Development, 2008, 60-61.

60 Which involve the transfer of bacterial genes into soy beans to make them resistant to herbicide.

61 Which involve the transfer of human genes into the bacteria.

62 Which involve the modification of oil palm genes to reduce its saturated content.

63 L. Amin et al, n 59 above, 60.

in another study,[64] it was reported that respondents who generally accept the promises of modern biotechnology perceive GM soybean as 'more familiar, of low risks, beneficial and to be encouraged.' As far as Malaysians are concerned, the studies demonstrate two important points: (1) the public are not totally against modern biotechnology and its products; and (2) their acceptance would increase with their familiarity of the technology. In the context of the thesis, therefore, the Malaysian Government and industrial stakeholders should take advantage of these facts, by effectively educating the consumers of the benefits of animal biotechnology food.

Malaysians perceptions to biotechnological products can also be inferred from the recent decision by the government to approve the trial release of genetically engineered sterile male *Aedes aegypti* mosquitoes in two areas in the country. The transgenic mosquitoes are meant to combat dengue disease by carrying a 'fatal' gene, which, when they mate with female mosquitoes, would lead to unviable offspring. Notwithstanding the potential of this innovation, the public remains sceptical of this new proposed method of tackling the disease. Notably, criticisms have come from consumers' associations and environment-based non-governmental organisations (NGOs). Most of the concerns relate to the efficiency of the control measures adopted by the applicant (the Institute for Medical Research Malaysia)[65] in order to ensure complete removal of all the released mosquitoes and larvae at the end of the trial period. The opposition argued that failure to control this would mean adverse health and safety implications for humans.[66] The concern could be understood, as bad handling of GM organism could have disastrous implications. For example, in the 1950s, researchers in Brazil imported African bees in their effort to create a hybrid population of bees which could

[64] L. Amin, J. Md Jahi, A.R. Md Nor, M. Osman and N.M. Mahadi, Uncovering factors influencing Malaysian public attitude towards modern biotechnology (2006) 14 *Asia-Pacific Journal of Molecular Biology and Biotechnology*, 2, 36.

[65] A research institute under the Ministry of Health Malaysia.

[66] ibid.

improve honey production and better adapt to tropical conditions.[67] Unfortunately, some of the African bees were accidentally released from their confined environment and mated with European (local) bees, producing Africanized honey bees which are more aggressive than their local counterparts. The hybrid bees have spread since then from Brazil to many regions in the US, displacing European honey bees which have been bred for many years. As a result of their aggressiveness, they have been posing risks to the populations' health and safety.[68]

Focussing back on the case of genetically altered mosquitoes in Malaysia, notwithstanding the concerns which arise, the potential of the technology involved is evidenced by the fact that similar experiments are currently on-going in many countries worldwide such as Colorado (the US), Thailand, Brazil and India, albeit all still at the stage of contained use experiments.[69] It has been reported that Singapore and Vietnam are reviewing the same technology.[70] The use of transgenic mosquitoes in Malaysia points to a pertinent direction. It indicates the seriousness of the issue at hand, and the less effective methods adopted so far.[71] According to the Malaysian Department of Biosafety, current efforts[72] only manage to control 80% of dengue fever. [73] In evidence, between January and October 2010, 38,330

---

67 G. Cambray, African bees – a solution to North America's bee problems? http://www.scienceinafrica.co.za/2007/april/africanbees.htm (Accessed 16 March 2011); M.J. Donovan, Genetically modified insects: why do we need them and how they will be regulated? (2009) 17 *Missouri Environmental Law & Policy Review*, 86.

68 ibid.

69 Ministry of Natural Resources and Environment Malaysia, Wild type and aedes aegypti genetically modified mosquitoes OX513A(My1), http://www.biosafety.nre.gov.my/app_field/nbb_decision.shtml (Accessed: 21 March 2011). Article 3 of the Cartagena Protocol defines 'contained use' as: 'any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment'. The Protocol is available at: CBD, http://bch.cbd.int/protocol/text/ (Accessed: 9 March 2012).

70 ibid.

71 S. Param, GM mosquitoes could help save many lives, *The Star*, http://www.thestar.com.my (Accessed: 21 December 2010).

72 Such as maintaining sanitation of the environment and spraying affected areas with insecticides.

73 Ministry of Natural Resources and Environment Malaysia, Permohonan untuk kelulusan uji kaji lapangan untuk tanda-lepas-tangkap semula secara terhad (MRR) nyamuk Aedes aegypti jenis liar dan jenis transgenik OX513A(My1): Rumusan isu-isu dari konsultasi awam, 29 October 2010, http://www.biosafety.nre.gov.my/consultation/Isu-Isu%20Konsultasi%20Awam%20v2.pdf (Accessed: 21 March 2011).

people were infected with dengue and 117 deaths were reported.[74] This was an increase from 32,560 cases and 72 deaths over the same period in 2009.[75] In view of these alarming statistics, the decision of the Government of Malaysia to approve the field trials is reasonable, in particular since the approval for the field trials was made without compromising the safety issues. It is important to note the strict terms and conditions for the certificate of approval. They include the requirements for consent from the relevant local councils where the release is to take place, an isolated location for the release sites, strict sex sorting procedures for the genetically and non-GM mosquitoes to ensure only male mosquitoes were released.[76] Further, the Department of Biosafety was: (1) satisfied with the success of the laboratory trials and assurances of the safety of the trial by strict compliance with the committee's guidelines;[77] and that (2) the concerns (either scientific views or otherwise) voiced by all the NGOs[78] consulted prior to the field trial have been fully considered by the government before the decision to approve the same.

This brings the discussion to another aspect of GM livestock animals and fish (which also relates to consumers' concern) namely the implications for the environment and human health due to their trans-boundary movement. The following sub-section analyses the problems and benefits of the Cartagena Protocol in regulating the potential risk.

---

74 Buzz of GM mosquitoes still feared, http://www.asiaone.com (Accessed: 21 December 2010).

75 ibid.

76 See detailed terms and conditions of the approval in National Biosafety Malaysia Board Decision, Application for approval for limited mark-release-capture of Aedes aegypti wild type and aedes aegypti genetically modified mosquitoes OX513A(My1), http://www.biosafety.nre.gov.my/app_field/nbb_decision.shtml (Accessed: 21 March 2011). Male mosquitoes were chosen because they do not bite or carry and transmit the dengue virus, as do their female counterparts.

77 Aedes mosquito experiment: too many risks involved, *The New Straits Times*, 6 September 2010. Malaysia has in place the Biosafety Act 2007 (Act 678) and the Biosafety (Approval and Notification) Regulations 2010. Both the Act and Regulations have come into effect on 1st December 2009 and 1 November 2010, respectively, and are available at: Malaysian Biosafety Clearing House, http://www.biosafety.nre.gov.my/law_regulation.shtml (Accessed: 23 March 2012).

78 Out of nine groups of people which gave their views during the Public Consultation period, only the Third World Network (TWN) had come back with valid scientific views.

3.2 The Cartagena Protocol: problems and benefits in regulating any potential risk to the environment and human health

The Cartagena Protocol was negotiated with GM crops in mind.[79] However, due to the general definition of the term 'living modified organisms'(LMOs)[80] the Protocol covers genetically engineered animals[81] (including innovations[82] such as GM livestock animals and fish). In recognition that LMOs may have an adverse effect on the conservation and sustainable use of biological diversity, including human health,[83] the Protocol focuses on the trans-boundary movement of the LMOs. It aims to ensure that they are safely transferred, handled and used.[84] There are four categories of LMOs which are subject to the Protocol namely, LMOs: (1) intended for intentional introduction into the environment of the importing Party;[85] (2) intended for direct use as food or feed, or for processing (LMOs-FFP);[86] (3) in transit; and (4) destined for contained use. Notwithstanding its noble objective, the Protocol has been subject to criticism. Therefore, pertinent aspects of the Protocol will be discussed, and their relevance to animal biotechnology food will be analysed.

---

79 J.M. Marshall, The Cartagena Protocol and genetically modified mosquitoes (2010) 28 *Nature Biotechnology*, 9, 896.

80 Article 3(g) of the Protocol defines the term as: 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. The Protocol uses the term 'LMOs' rather than 'GMOs' which are more widely used. Therefore, for the purpose of this thesis, the term 'LMOs' is interchangeably used with the term 'genetically modified organisms' (GMOs).

81 G. Jaffe, Implementing the Cartagena Biosafety Protocol through national biosafety regulatory systems: an analysis of key unresolved issues (2005) 5 *Journal of Public Affairs*, 299.

82 A. Warren-Jones, *Patenting rDNA: human and animal biotechnology in the United Kingdom and Europe* (Oxford: Lawtext Publishing, 2001) 200.

83 Article 1 (Objective) of the Cartagena Protocol.

84 ibid. Other requirements provided by the CBD (under which the Cartagena Protocol is the subsidiary instrument), and issues relating thereto, such as the access and benefit-sharing of genetic resources (including animals) used in research, obtained from a particular country, which have been the subject of review of Article 27.3(b) of the TRIPs Agreement will be discussed in section 3 of chapter 2.

85 LMOs for intentional release to environment include seeds for planting, fish for release, and micro-organisms for soil treatment. See V.O. Sinohin and G.R. Diokno, The biosafety protocol: a complement to modern biotechnology, (2001) 27 *CANOPY International*, 5, 7.

86 LMOs-FFP includes corn, soybeans, wheat or other grains, and animals meant to feed humans or animals. See G. Jaffe, n 81 above, 301.

3.2.1 The Advanced Informed Agreement Procedure (AIA Procedure)

The AIA Procedure is the central feature of the Protocol. It is underpinned by the principle that the trans-boundary movement of LMOs from one country to another can take place only with the prior informed consent of the importing Party (to the Protocol). The principle reflects that the sovereign right of an individual Party over its territorial sea and land is recognised by the Protocol.[87] In essence, the AIA Procedure requires the Party of export to notify its intention by providing required minimum information relating to the relevant LMOs.[88] The importing Party has to acknowledge receipt of the notification in writing.[89] Failure to acknowledge should not be taken as consent.[90] Any decision of the importing Party shall be in accordance with risk assessment procedures prescribed by the Protocol.[91] The Party has options either to allow or refuse the import, or to request further information before making any decision.[92] Where any condition is attached to a decision, reasons should be given for this.[93] Again, failure of the importing Party to communicate its decision after evaluating the evidence of the potential risks of the LMOs does not constitute its consent to the intended trans-boundary movement.[94]

One of the issues which have been identified by critics[95] is the narrow application of the AIA Procedure as the Protocol seems to 'exclude rather than include'. This is because the Protocol prescribes different procedures for the four categories of LMOs identified earlier. The AIA

---

87 Article 2(3) of the Protocol.
88 Article 8(1) of the Protocol. The requirements under Annex I of the Protocol includes the details of the exporter or importer of the LMOs and the intended use of the LMOs and their products.
89 Article 9(1) of the Protocol.
90 Article 9(4) of the Protocol.
91 Article 10(1) of the Protocol.
92 Article 10(3) of the Protocol.
93 Article 10(4) of the Protocol.
94 Article 10(5) of the Protocol.
95 A. Warren-Jones, n 82 above, 201; H. Meyer, The Cartagena Protocol on Biosafety (2000) 43 *Biotechnology and Development Monitor*, 2; D.J. Schnier, Genetically modified organisms and the Cartagena Protocol (2001) 12 *The Fordham Environmental Law Journal*, 408-409.

Procedure discussed here is only applicable to LMOs intended for deliberate release into the environment of the importing Party. The other three categories of LMOs are not subject to the procedure. Based on the recognition by the Protocol itself that all LMOs have potential risks for the environment and human health, criticism on this ground is not surprising. As regards the LMOs-FFP, while not covered by the AIA Procedure, they are subject to the notification procedure of the Protocol[96] which is to be governed by a national regulatory framework.[97] Critics[98] have argued that the notification procedure prescribed by the Protocol is a weaker form of the AIA procedure as the requirement of prior informed consent is absent. Nevertheless, by comparing the AIA, with the notification procedure, it is equally possible to argue that the implications of the two procedures are the same. This is because while the requirement of prior written notification of intent to export is absent, import of LMOs-FFP remains impossible without explicit agreement from the importing Party.[99] As regards developing countries or a Party with an economy in transition (which has no domestic regulatory framework), the Protocol expressly provides that the countries may require the exporting Party to undertake the risk assessment procedure at its own expense,[100] before any decision to import is made.[101] Similarly, the failure of the importing Party to communicate its decision could not be taken as giving consent to the import.[102]

The exclusion of LMOs in transit[103] and for contained used[104] from the AIA Procedure appears to be based on the perception of reduced potential risk that they may cause compared

[96] Article 11 of the Protocol.
[97] Article 11(4) of the Protocol.
[98] H. Meyer, n 95 above, ibid.
[99] Article 11(7) of the Protocol.
[100] Articles 15(2) and (3) of the Protocol.
[101] Article 11(6) of the Protocol.
[102] Article 11(7) of the Protocol.
[103] Article 6(1) of the Protocol.
[104] Article 6(2) of the Protocol.

to the case where LMOs are introduced to the environment of the Party of import.[105] Their exclusion from the procedure has, however, led to the criticism[106] that exporters may easily evade the procedure by declaring that the LMOs fall under the category of contained use by postponing field releases.[107] It should be noted that the Cartagena Protocol only provides a minimum standard which needs to be included in national legislations. Parties would need to adapt the provisions of the Protocol which suit national biosafety policies provided that the objective of the Protocol is achieved.[108] In this respect, the Protocol explicitly underlines that a Party is not restricted from providing more protective provisions in national legislation than those provided by the Protocol,[109] including subjecting all LMOs to a risk assessment prior to a decision about import. This rule similarly applies to LMOs in transit and in contained use. As regards the former, a Party of transit may regulate the transport of LMOs through its territory,[110] whereas the latter may be regulated by the standards of the Party of import.[111] There have been countries which impose a more restrictive procedure for LMOs-FFP, LMOs in transit and for contained use, than the minimum requirements by the Protocol. For instance, according to the Malaysian Biosafety Act 2007,[112] the AIA procedure is applicable to all release activities and import activities involving LMOs. This includes the LMOs-FFP and LMOs for field trials, and products thereof (all of which are not covered by the AIA procedure of the Protocol).[113] More strict provisions (than the Protocol's) are also observed in

[105] G. Jaffe, n 81 above, 302.
[106] H. Meyer, n 95 above, 3.
[107] ibid.
[108] Articles 2(1) and (2) of the Protocol.
[109] Article 2(4) of the Protocol.
[110] Article 6(1) of the Protocol.
[111] Article 6(2) of the Protocol.
[112] Part III of the Act.
[113] The Act subjects the export, contained use and import for contained use, of LMOs, to the notification procedure under Part IV.

the biosafety laws and regulations of countries such as Norway[114] and China.[115]

While currently animal biotechnology food is largely at the research stage, trans-boundary movement of the animals at later stages is imminent as research collaboration and trading between Parties to the Protocol ensues.[116] In terms of consent for importation and risk assessment, it is argued that the Protocol adequately covers GM livestock animals and fish. This is because, depending on the stages of development, animal biotechnology food may fall under all categories of LMOs governed by the Protocol, and hence be subject to the AIA or the notification procedure, and the risk assessment requirement. Illustratively, inventions such as the Atlantic Salmon may constitute LMOs for contained use or intentional release to environment during the research stage, whereas the same would later constitute the LMOs-FFP when it is to be marketed for human consumption. The product could also constitute LMOs in transit in both stages of development. As argued earlier, Parties may also impose relevant conditions in national biosafety legal framework so as to address the concern that may arise from the movement of the LMOs.

As regards LMOs in transit and for contained use, it appears difficult to refute the fear that GM livestock animals and fish may escape notwithstanding the short period of transit or even where used in a controlled environment such as a laboratory or confined storage facilities.

[114] Section 7(c) of Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms (Gene Technology Act) requires that contained use of LMOs be approved if the production and use is for placing on the market or other commercial use. As regards deliberate release of LMOs to the environment, under s 10 of the Act, an applicant shall provide evidence that the release will be 'of benefit to society and likely to promote sustainable development'. The Act is available at: WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=245117 (Accessed: 23 March 2012).

[115] Under Article 35 of the China's Regulation on Administration of Agriculturally Modified Organisms Safety 2001, approval for LMOs intended to transit within the country's territory shall be obtained by the owner before such transit can take place. 'Agricultural genetically modified organisms' under the Article 3 of the Regulation means 'animals, plants micro-organisms and their products whose genomic structures have been modified by genetic engineering technologies for use in agricultural production or processing'. The Regulation is available at: WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=182624 (Accessed: 23 March 2012).

[116] As of 23 March 2012, there are 162 parties to the Protocol. See CBD: The Cartagena Protocol on Biosafety, http://bch.cbd.int/protocol/parties/ (Accessed: 23 March 2012).

This problem has been identified, at least, for seeds where GM corn has been discovered in a remote region of Mexico where its planting had not been approved.[117] Investigation showed that the source of the transgene was potentially from 'imported transgenic grain that is shipped to rural communities for planting by small-scale farmers.'[118] Nevertheless, it is argued that the problem is more crucial with seeds and micro-organisms where their proliferation with natural counterparts is difficult to control, thus the potential harm to the environment and human health may be disastrous. Conversely, similar risks are almost absent for genetically altered animals for food purpose,[119] or, at least the risks are easily managed and controlled. For example, as regards the Atlantic Salmon, the inland breeding method will address any concern about its potential risks to the environment. With respect to other GM livestock animals such as cows with, increased quantity of milk produce or, leaner meat, and poultry with disease-resistant traits, it is argued that the environmental risk is much less an issue and more manageable due the breeding practices which take place in controlled areas.[120] Even in the case of potential escape from confined enclosures, it is difficult to envisage any harm that GM farm animals (such as double-breasted chickens) could pose to human health. The only effect will be the creation of additional quantities of quality poultry meat which would eventually benefit consumers. In addition, due to the practice in international transfer where animals are normally placed in special carriers or storage, the potential for escape during transit in any country is arguably negligible.

[117] S. Bragdon, K. Garforth and J.E. Haapala Jr, Safeguarding biodiversity: the Convention on Biological Diversity (CBD), http://web.idrc.ca/en/ev-119955-201-1-DO_TOPIC.html (Accessed: 21 January 2012) 25.
[118] ibid.
[119] A. Warren-Jones, n 82 above, 205.
[120] It has also been argued that environmental risk assessment is also a much less relevant issue for cloned farm animals as there are no 'wild' populations of livestock which they can breed with. See A. Bruce, Regulation of cloned farm livestock, Economic and Social Research Council, 2007, http://www.genomicsnetwork.ac.uk/media/Regulation%20of%20Cloned%20Farm%20Livestock.pdf (Accessed: 13 March 2012).

3.2.2 Identification of LMOs, and documentation accompanying their shipment

Another key issue covered by the Protocol is the identification of LMOs which are subject to trans-boundary movement. Again, the Protocol prescribes different rules for distinct categories of LMOs. Documentation accompanying LMOs: (1) for contained use;[121] and (2) intended for intentional introduction into the environment of the importing Party,[122] should be clearly identified as LMOs. In addition, any requirements for their safe handling, storage, transport and use, and the relevant traits and/or characteristics of the LMOs should also be specified.[123] For the purpose of identification and documentation, no rule is provided for LMOs in transit. This can be expected given that they would be subject to the relevant provisions depending on the end purpose of the LMOs (under the respective categories of Article 18). Nevertheless, criticism has surrounded the identification of LMOs-FFP as the Protocol only requires that the documentation accompanying their shipment should identify that they: (1) may contain LMOs; and (2) are not intended for international introduction into the environment.[124] This particular issue is further elaborated here.

The distinction between LMOs for intentional release into the environment and those which are not has been described as 'a legal fiction'.[125] This is because the purpose of LMOs could easily change, irrespective of the intention of the exporter. For instance, it has been identified that developing countries normally import grain for food purposes, but the same are used as seeds during a food crisis.[126] This is among the reasons which led to further negotiations

[121] Article 18(2)(b) of the Protocol.
[122] Article 18(2)(c) of the Protocol.
[123] ibid.
[124] Article 18(2)(a) of the Protocol.
[125] S. Bragdon et al, n 117 above, ibid.
[126] ibid. On the other hand, based on the argument that the commodities posed a lower risk to the environment as they are not intended to be released to the environment, developed countries had insisted the LMOs-FFP should not be subject to the AIA Procedure.

among Parties to the Protocol to determine the 'detailed requirements' of Article 18(2)(a).[127] In the recent decision of the Conference of the Parties,[128] Parties to the Protocol are required to ensure that documentation accompanying the LMOs-FFP states: '(1) in cases where the identity of the LMOs is known through means such as identity preservation systems, that the shipment contains LMOs-FFP; and (2) in cases where the identity of the LMOs is not known through means such as identity preservation systems, that the shipment may contain one or more LMOs-FFP'. [129] Unfortunately, the decision has been the subject to a range of criticism.[130] Firstly, it has been argued that compliance with the decision will unnecessarily increase the cost of trade as it will require a large investment to monitor and test international shipments as they leave exporting Parties and enter importing Parties. [131] This would eventually increase the price of GM crops such as maize and soybeans.[132] Secondly, it has also been argued that it is impractical for exporters (being at the end of the export chain, who take ownership of the GM crops from farm to importing country) to know the LMOs content of their cargoes.[133] Thirdly, the possibility to identify LMOs in an export cargo through an identity preservation system is rather limited, and the system can only identify the absence of LMOs and not their presence.[134]

---

[127] The further negotiations are mandated by the Article itself where it states: 'The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol'.

[128] According to Article 29(4), one of the important functions of the Conference of the Parties Serving as the Meeting of the Parties to the Protocol (Conference of Parties) is to make recommendations on any matters necessary for the implementation of the Protocol.

[129] Third meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 3) – Meeting decision BS-III/10, 'Handling, transport, packaging and identification of living modified organisms : paragraph 2(a) of Article 18', http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11066 (Accessed : 21 March 2012).

[130] A. Bouët, G. Gruère and L. Leroy, From 'may contain' to 'does contain': the price and trade effects of strict information requirements for GM maize under the Cartagena Protocol on Biosafety, Selected paper prepared for presentation at the Agricultural and Applied Economics Association's, 2010, 1-26; J. Huang, D. Zhang, J. Yang, S. Rozelle and N. Kalaitzandonakes, Will the Biosafety Protocol hinder or protect the developing world: learning from China's experience, (2008) 33 *Food Policy*, 1-12.

[131] ibid.

[132] ibid.

[133] J. Huang et al, n 130 above, 4.

[134] ibid.

With respect to animal biotechnology food, notwithstanding the critique identified here, it is argued that the decision is reasonable and will not overly burden the stakeholders. This is because the options underlined by the Protocol demonstrate its recognition of the challenges that stakeholders may have to fully implement the LMOs-tracing-system. The options may be seen by critics as a discretion which would eventually impair the effectiveness of the Protocol. Nevertheless, it is further argued that being an internationally imposed obligation, the measure is an important milestone so as to enhance consumers' acceptance and confidence in consuming the products, hence the development of the technology.

3.2.3 Liability and redress for damage arising out of the trans-boundary movement of LMOs

Article 27 (on 'liability and redress') is another pertinent aspect of the Protocol which has been subject to much deliberation during the Conference of the Parties and the issue as to the type of liability that would be imposed to Parties has only recently been resolved. Within the negotiations, developed countries proposed an administrative approach which relies upon the competence of national authority to monitor and address cases of damage or threats of damage caused by LMOs.[135] Conversely, developing countries which lack capacity to implement the approach proposed by developed countries, had been in favour of an international regime based on civil liability, administered by the existing court system.[136] The adopted Article 12 of the Supplementary Protocol on Liability and Redress to the Cartagena

[135] S. Jungcurt and N. Schabus, Liability and redress in the context of the Cartagena Protocol on Biosafety, (2010) 19, *Review of the European Community and International Environmental Law*, 2, 201; G.S. Nijar, S. Lawson-Stopps and G.P. Fern, *liability and redress under the Cartagena Protocol on Biosafety: a record of the negotiation for developing international rules* (Centre of Excellence for Biodiversity Law, 2008) 15-25.

[136] ibid.

Protocol on Biosafety[137] appears to consider the claims of both categories of Parties where three options for implementation are given: '(1) to apply their existing domestic law, including, where applicable, general rules and procedures on liability; (2) to apply or develop civil liability rules and procedures specifically for this purpose; or (3) to apply or develop a combination of both.'[138]

While critics[139] have precisely identified that there is no international obligation to implement the civil liability system[140] (due to the operative wording of 'parties may as appropriate' preceding the options) the alternatives are important from some perspectives. Developing countries are satisfied that the enabling reference to civil liability was secured.[141] Intrinsically, where the Supplementary Protocol comes into force,[142] they are able to resort to the option without opposition from developed countries. Apart from that, the monitoring of potential hazards from LMOs can be pursued by the countries' existing judicial system without much additional cost compared to the development of a new or additional administrative framework. The options should also be able to alleviate the concerns of consumers concerning the use of animal biotechnology food.

3.2.4 Non-parties to the Protocol

Another significant feature of the Protocol is that, while the document only binds Parties which ratify it, the obligations of non-Parties are also given due weight by the negotiators.

[137] Available at: CBD, http://bch.cbd.int/protocol/supplementary/ (Accessed: 22 March 2012). The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was finalised and adopted in the Conference of the Parties in Nagoya on 15th October 2010.
[138] ibid.
[139] S. Jungcurt et al, n 135 above, 203.
[140] ibid.
[141] ibid.
[142] Under Article 18, the Supplementary Protocol is to enter into force on the ninetieth day after the date of deposit of the fortieth instrument ratification. As of 23 March 2012, there are fifty one Signatories and two ratifications.

Intrinsically, this is because LMOs have been developed in many countries worldwide as the promise of biotechnology is increasingly recognised. As a result, Article 24 of the Protocol explicitly spells out that 'trans-boundary movement of LMOs between Parties and non-Parties shall be consistent with the objective of the Protocol'. Further, the provision states that: 'the Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such movement'.[143] Notwithstanding this, critics may argue that Article 24 remains less influential due to the non-binding legal effect of the Protocol on non-Parties. Nevertheless, in terms of animal biotechnology food, the willingness of non-Parties to similarly observe the provisions of the Protocol can be expected. This is because any likely risk in one country can impact on another due to the possible trans-boundary movement of the animals. Consequently, the credence of the provision cannot be taken lightly.

The concerns of international and national consumers toward animal biotechnology food shown in this section illustrate the challenges experienced by the products in proving their potential contribution to society. Despite the concerns, evidence of their safety in the environment and human health should not be deemed trivial. Therefore, animal biotechnology food should be given an equal opportunity to prove its potential for the benefit of society. In Malaysia, it can be concluded that consumers' confidence in their use could be nurtured and enhanced provided that the benefits of the products are thoroughly explained. It has been further shown that, if any, the concerns of Malaysian (and international) consumers are adequately addressed by the Cartagena Protocol, and biosafety legislations and regulations which are already in place in many countries worldwide.

[143] More broadly, for instance, the US which is not a Party to the Protocol has agreed to ensure that its data including import or use of LMOs into the country be made available on the Biosafety Clearing House (BCH). See J. Kinderler, The Cartagena Protocol on Biosafety (2008) 4 *Collection of Biosafety Reviews*, 41. Article 20 of the Cartagena Protocol establishes a BCH in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs.

Irrespective of the concerns of consumers which have been identified in this section, an appreciation of the trends of the global livestock industry (and in Malaysia) in terms of demand and specific requirements from the populations is particularly important. This aspect will be the focus of the next section. The discussion will facilitate an appropriate understanding of the factual situation that needs to be dealt with by a particular country in deciding if modern animal biotechnology and its products are crucial for consideration in order to secure a food supply for its population.

4. Demands of consumers for livestock and fisheries products

4.1 The importance of the livestock industry and products to the economy

The livestock industry has been one of the main contributors to the world's agricultural economy. According to the World Bank,[144] as of 2009, livestock already constituted 40% of the global value of agricultural output, and 30% of the agricultural Gross Domestic Production (GDP) in developing countries. The FAO statistical data shows that the world's trade in livestock products[145] increased significantly between 1995 and 2006. Since the 1980s, the industry has been undergoing a process which is termed by Delgado[146] as 'livestock revolution', in particular, due to the increase in demand for livestock products from developing countries. In Malaysia, agriculture has been an important sector which contributes to the country's economy and continues to be given special attention under the Tenth

[144] World Bank, Minding the stock: bringing public policy to bear on livestock sector development, http://siteresources.worldbank.org/INTARD/Resources/FinalMindingtheStock.pdf (Accessed: 26 November 2010) xiii.

[145] Include meat, dairy and eggs.

[146] C.L. Delgado, Rising consumption of meat and milk in developing countries has created a new food revolution (2003) *The Journal of Nutrition*, 133, 3907S.

Malaysian Plan (2010-2015). The sector is expected to contribute 2% of the GDP by 2015, compared to its 1% contribution in 2009.[147] Since the First Malaysia Plan (1966-1970), livestock has been listed among the important commodities which represent the backbone of Malaysia's agricultural industry apart from rubber, palm oil, rice, pepper and other crops. The following sub-sections will discuss three aspects which relate to the industry: (1) trends of production and consumption of livestock products; (2) changing trends of consumers' preference for livestock products; and (3) preference of some nations based on geographical location and religious obligation.

4.2 Trends in the consumption and production of livestock products

Notwithstanding the fact that the livestock revolution is due to the increase in demand from developing countries, per capita consumption of livestock products in developed countries is still significantly higher than in developing countries and is also increasing, albeit at a more modest rate.[148] For the period between 1980 and 2005, there was an increase in per capita consumption of livestock products of meat and milk, respectively, from 76.3kg to 82.1kg and 197.6kg to 207.7kg in developed countries. Nevertheless, a higher rate of growth was experienced by developing countries for the same period. Meat consumption increased from 14.1kg to 30.9kg, whereas milk consumption increased from 33.9kg to 50.5kg. With regard to the per capita consumption of eggs, developed countries recorded a decrease from 14.3kg to 13.0kg, whereas per capita consumption of eggs for developing countries grew threefold from 2.5kg to 8.0kg for the same period.[149] Regionally, among developing countries, East and Southeast Asia was reported to have experienced the greatest increase in livestock

[147] Economic Planning Unit Malaysia, Tenth Malaysia Plan (2011-2015), http://www.epu.gov.my/html/themes/epu/html/RMKE10/rmke10_english.html (Accessed: 26 October 2010) 134.
[148] FAO, n 5 above, 10.
[149] ibid.

consumption. Malaysia is one of the countries which have shown a significant increase in the Southeast Asia region, apart from the Democratic People's Republic of Korea and Vietnam.[150] Per capita consumption of poultry meat in Malaysia has been the highest. In evidence, for the ten year period from 2000 to 2010, there was an increase from 27.3kg to 35.04kg compared to beef, mutton and pork which rose only from 4.75kg to 7.96kg.[151]

Economists associate the rapid growth of the consumption of livestock products in developing countries with two factors: (1) urbanisation; and (2) increasing income. Recently, the influence of prices and income on demand for agriculture in the five largest developing and emerging economies: Brazil, Russia, India, Indonesia and China (the so-called 'BRIIC') was studied by the Organisation for Economic Co-operation and Development (OECD).[152] One of the findings revealed in the report was that, whereas demand for most agricultural products namely cereals, fruits and vegetables, sugar, fats and oil has been declining despite an increase in income, there was an exception with regard to the demand for meat and dairy products.[153]

In the Malaysian context, the findings of researchers who studied the patterns of urbanisation, nutrition and health transition, and demand systems for foods, have supported the economists' view. The percentage of urban population in Malaysia was increasing at a greater rate from 1980 to 2000 (35.8% to 61.8%), compared to the period between 1957 and 1970 (26.8% in 1970).[154] At least two reasons contributed to this trend: (1) between 1957 and 1970, the

[150] ibid.
[151] Personal communication with an official of the Ministry of Agriculture and Agro-Based Industry Malaysia dated 11 November 2010.
[152] D. Abler, *Demand growth in developing countries*, OECD Food, Agriculture and Fisheries Working Papers, No 29 (United States: OECD Publishing, 2010).
[153] ibid. 22.
[154] J. Jaafar, Emerging trends of urbanisation in Malaysia (2004) 1 *Journal of the Department of Statistics Malaysia*, 44.

country was undergoing an 'adjustment period' after gaining its independence from the British; and (2) starting from 1980, there was a shift in the government's economic policy from agriculture to industry, which meant more opportunities for employment were offered in urban areas.[155] In this regard, research[156] has shown that the increase in the income of Malaysians corresponds with the demand for meat, fish, vegetables and fruits which was higher than for other energy-source foods such as rice, bread and other cereals.

The output of livestock products, worldwide and in Malaysia, is responding to this consumption pattern. At an international level, the production of livestock products has been championed by countries such as China, Brazil and India.[157] They emerged as new key players for livestock production, replacing developed countries such as the US and the EU Member States which were the main producers before 1995.[158] The production of pigs, poultry, cattle and sheep and goats either doubled or tripled in developing countries for the ten year period from 1987 to 1997. Comparatively, in developed countries, only the production of pigs and poultry was increasing for the same period, whereas the production of cattle, sheep and goats was declining.[159] Production of livestock products was similarly increasing in Malaysia. For the period from 1985 to 2005, the increase in production of livestock products was: beef (from 17,000 tonnes to 40,000 tonnes), mutton (from 6,000 tonnes to 8,000 tonnes), pork (from 164,000 tonnes to 183,000 tonnes), poultry (from 251,000 tonnes to 1.3 million tonnes), eggs (from 3.4 million units to 10 million units) and

[155] ibid, 46.
[156] T.Y. Sheng, M.N. Shamsudin, Z. Mohamed, A.M. Abdullah and A. Radam, Complete demand systems of food in Malaysia (2008) *Agricultural Economics*, 10, 467-475; M.I. Noor, The nutrition and health transition in Malaysia (2002) 5 *Public Health Nutrition*, 1A, 191-195.
[157] H. Steinfield and P. Chilonda, Old players, new players in FAO, Livestock Report, 2006, ftp://ftp.fao.org/docrep/fao/009/a0255e/a0255e.pdf (Accessed: 26 October 2010) 3.
[158] ibid.
[159] FAO, n 5 above, 16.

milk (from 24 million litres to 65 million litres).[160]

The consumption of livestock products will continue to increase in future as the size, and income, of the population increase. While the latter implies a better quality of life for a greater number of people in the population, the livestock industry, globally and in Malaysia, needs to be able to cope with the increasing demand. In tandem with the increasing pattern in consumption, and, as consumers become more knowledgeable, their awareness of health issues are developing. The implications of this will be appreciated in the following sub-section. It is important that the specific requirements of consumers from livestock products are understood as they could pose a new challenge to the livestock industry.

4.3 Changing trend of consumers' preference for livestock products

In developed countries, where incomes are generally high and basic dietary needs have long been more than satisfied, consumers often look for more variety in their diets.[161] In this context, demand for livestock products corresponding to income growth, is less responsive in high-income countries compared to lower-income countries.[162] Consumers in developed countries such as within Europe, Japan and the US are increasingly demanding food with specific features.[163] These include healthy and good quality food[164] for consumption, and

[160] Economic Planning Unit Malaysia, Fifth Malaysia Plan (1986-1990), Sixth Malaysia Plan (1990-1995), Seventh Malaysia Plan (1996-2000), Eighth Malaysia Plan (2001-2005, http://www.epu.gov.my/previousplan (Accessed: 26 October 2010).

[161] FAO, The state of world fisheries and aquaculture, 2008, http://www.fao.org/docrep/011/i0250e/i0250e00.htm (Accessed: 26 October 2010) 64.

[162] FAO, n 5 above, 23.

[163] FAO, n 161 above, 64.

[164] The term 'healthy food' has been defined by a medical dictionary as 'a food that is low in fat and saturated fat and that which contains limited cholesterol and sodium'. See http://www.medterms.com/script/main/art.asp?articlekey=40307 (Accessed: 17 March 2011). The FAO Committee on World Food Security in its 1999 Rome Meeting has described the term 'food quality' to include safety and quality attributes. The latter includes nutritional value, appearance, colour, texture and taste. See FAO, The importance of food quality and safety for developing countries, 1999,

food that is safe for the environment.[165]

Non-communicable diseases mainly cardiovascular disease, cancers, diabetes and chronic respiratory disease, have been presenting a major challenge to global public health.[166] While matters such as nutrition and diet have long been one of the important health agenda items for the World Health Organization (WHO), it is worth noting the ever-increasing growth of cases of non-communicable diseases. The diseases constitute the world's largest killers, causing an estimated 35 million deaths each year (60% of all deaths globally).[167] The trend, which, in the past, has been commonly associated with affluent societies in developed countries, is currently being experienced by developing countries and LDCs. In Malaysia, in 2009 for instance, heart and lung disease have been recorded as the main cause of death in government hospitals which amounted to 16.9%.[168] The WHO has acknowledged two leading causes which led to this phenomenon: (1) an unhealthy diet; and (2) lack of physical activity.[169] As regards the former, high consumption of energy-dense foods that are high in fat has been specifically identified as one of the factors which increase the health risks for all consumers.[170]

---

http://www.fao.org/docrep/meeting/x1845e.htm (Accessed: 17 March 2011). Therefore, quality food includes leaner meat and nutraceutical (also termed as 'medical food' or 'pharmfood') which means: 'a food product with a pharmacological additive meant to improve health, for example, to lower cholesterol'. See http://www.medterms.com/script/main/art.asp?articlekey=40716 (Accessed: 17 March 2011). Products of modern biotechnology have the potential to display only healthy characteristics or both healthy and quality characteristics. For example, milk which is produced through genetic engineering techniques that have increased casein for better-tasting cheese encompasses quality features, whereas leaner meat denotes a healthy and high quality product.

165 FAO, n 161 above, ibid.

166 WHO, Global strategy on diet, physical activity and health, http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf (Accessed: 29 November 2010) 2.

167 WHO, 2008-2013: action plan for the global strategy for the prevention and control of non-communicable diseases, http://www.who.int/nmh/Actionplan-PC-NCD-2008.pdf (Accessed: 29 November 2010) iii.

168 Ministry of Health Malaysia, Health facts 2009, http://moh.gov.my/images/gallery/stats/heal_fact/healthfact-P_2009.pdf (Accessed: 29 November 2010).

169 WHO, n 167 above, ibid.

170 ibid.

Notwithstanding the similar health problems troubling countries worldwide, developed countries have made notable improvements toward adhering to the WHO recommended dietary pattern.[171] The recommendations indicated certain lower and upper limits for calorie intake from seven categories of sources of energy: fats, proteins, carbohydrates, saturated fats, trans-fats, raw sugar, and fruit and vegetables.[172] Using the WHO recommendation as the basis of their study, research[173] has concluded that developed countries were regularly improving their dietary habits towards the 'ideal diet' and were the closest to the recommendations. A similar trend was observed among developing countries, albeit at a marginal rate. Almost no improvement was found for LDCs.[174] This study supports the contention that consumers in developed countries choose quality of food as their main consideration.

An important sector which has been specifically identified by the WHO as being able to play a fundamental role is the manufacturing industry.[175] Responding to the global dietary strategy as advocated by the WHO, the market health services and nutritionists in five European countries which make up 80% of the processed meat market in Western Europe have been putting pressure on the meat and food industry to reduce the amount of saturated fats in their products.[176] Nevertheless, with taste being the most decisive factor for the success of processed meat products,[177] the challenge facing the meat industry is how to produce

[171] WHO, 'Diet, nutrition and the prevention of chronic diseases: report of a Joint WHO/FAO Expert Consultation (2003)', http://www.who.int/dietphysicalactivity/publications/trs916/en/ (Accessed: 17 March 2011) 56.
[172] Fats (lower: 15%, upper: 30%), proteins (lower: 10%, upper: 15%), carbohydrates (lower: 55%, upper: 75%), saturated fats (lower: none, upper: 10%), trans-fats (lower: none, upper: 1%) raw sugar (lower: none, upper: 10%), fruit and vegetables (lower: 400g, upper: none).
[173] M. Mazzocchi et al, n 6 above, 539.
[174] ibid.
[175] WHO, n 167 above, 8.
[176] S. Lander, Low in fat – high in taste: fat replacement technology (2010) *Food Marketing and Technology*, 16-18.
[177] ibid.

reduced-fat products and maintain the taste. Modern animal biotechnology has the potential to address this challenge and will be discussed further in the final section of this chapter.

In line with the WHO's recommendation to maintain a healthy diet in order to reduce the risk of heart attack and stroke, the consumption of lean meat and fish has been specifically mentioned and encouraged.[178] In this regard, consumers' preference for lean meat in western countries has been studied. In a study involving participating consumers of four European countries namely, Germany, Spain, France and the UK, their perception of the healthy qualities of beef was explored.[179] The study revealed that, while generally the participating consumers consider beef as a healthy food product, fresh lean beef is perceived as more healthy compared to processed and packaged beef. Notably, the study also found that consumers prefer improvement to produce leaner beef during the production phase (for instance by adjusting the feed to influence the fatty acids composition of beef), rather than the processing phase (for instance marinating to reduce the formation of carcinogenic compounds during grilling).[180] This shows that consumers are prompting a change in animal physiology, rather than in the meat processing industry, which can be more effectively achieved through modern biotechnology. The preference of Malaysian consumers for meat has also been studied[181] where it was concluded that while demand from domestic consumers is for a greater quantity of beef products, demand for the quality of beef (higher-value hybrid or imported beef) is notable among people with higher incomes.

[178] WHO, What can I do to avoid a heart attack or a stroke?, http://www.who.int/features/qa/27/en/ (Accessed: 30 November 2010).

[179] L. van Wezemael, W. Verkebe, M.D. de Barcellos, J. Scholderer and F.J.A. Pérez-Cueto, Consumer perceptions of beef healthiness: results from a qualitative study in four European countries (2010) 10 *BMC Public Health*, 342, 8.

[180] ibid.

[181] T.Y. Sheng, M.N. Shamsudin, R. Alias, M. Zainalabidin and M.A. Amin, Demand for beef in Malaysia: preference for quantity, quality or lean? (2008) 15 *International Food Research Journal*, 3, 347-353. Leanness is a sub-set of quality for the purpose of the study.

This sub-section has shown that the healthy quality in beef has become an increasingly important factor to consumers worldwide. The awareness of the benefits of leaner meat is more prevalent within developed countries. Nevertheless, people from developing countries are catching up by consuming better quality meat. Therefore, while currently, requiring leaner meat seems to be a very specific feature for the purpose of developed countries, arguably the trend will develop in the near future in developing countries as the level of income and education of the population increases. Another pertinent aspect for consideration is the specific preference for livestock products among some of the nations, which is discussed in the next sub-section. This has become a factor which contributes to the focus on the consumption of some types of animal-protein based products.

4.4 Preferences for livestock and fisheries products among nations: geographical location and religious obligations

Geographical location is an aspect which has influenced consumption patterns across countries around the globe.[182] In South Asia, including India for example, per capita consumption of livestock products has increased progressively, except for meat.[183] This is due to the fact that the majority of the population continues to practise a vegetarian diet, even though the younger generation has been more open to a western meat-based diet.[184] In Japan, higher levels of fish consumption replace lower levels of livestock products consumption.[185] As regards Malaysia, the country's population comprises many ethnic groups. Malays (who profess the Muslim religion) constitute the majority of the population, while others include

[182] FAO, n 5 above, 10.
[183] ibid.
[184] ibid. 12.
[185] ibid.

Chinese, Indian and various indigenous ethnics, such as the natives of Sabah (Kadazans and Bajaus) and Sarawak (Ibans). Due to religious obligations, Muslim consumers in Malaysia can only consume 'halal' (permissible) products.[186] Muslims are forbidden to consume pork and animals which are not slaughtered in accordance with Islamic principles. Therefore, pork is consumed only by non-Muslim consumers. Other livestock products such as beef, mutton, poultry, milk and eggs are generally consumed by all other ethnic groups, including Malays.

Where Malaysians' choice of animal-protein intake is discussed, the consumption of fish must be mentioned, as fish is a popular part of the Malaysian (and broadly, Asian) daily diet. It is not suggested that fish is consumed less by populations in developed countries. In fact, according to the FAO, [187] the per capita consumption of fish in developing countries is only half than that of developed countries. In evidence, in 2005, per capita consumption of fish in developed countries was 29.3kg whereas per capita consumption in Asia was 17.9kg.[188] Nevertheless, similar to the trend in consumption for livestock products, the rate of growth in per capita consumption of fish is higher in developing countries than in developed countries. [189] The generally accepted lower health risk implications resulting from consumption of fish may have contributed to the popularity of fish among consumers where Omega-3 essential fatty acids found in fish have been known for various health benefits in helping to reduce inflammation, to heal dry skin, to control high cholesterol level and others.[190] The consumption of fish among Malaysians has been much higher than that of meat. For the period from 1985 to 2003 per capita consumption of fish increased from 45.44kg to

[186] For further explanation about 'halal' definition, see for instance, The United Kingdom Halal Food Authorities (HFA), http://www.halalfoodauthority.co.uk/definitionhalal.html (Accessed: 30 November 2010).
[187] FAO, n 161 above, 61.
[188] ibid.
[189] ibid.
[190] Nutrition online, Nutrition from meat, poultry and fish, http://www.nutritiononline.net/nutrition-from-meat.html (Accessed: 3 December 2010). Note similar recommendation from the WHO for fish consumption to reduce risk of heart attack and stroke.

56.39kg, whereas, meat consumption increased from 29.4kg to 48.5kg.[191] Further, in a cross-country study involving nine countries in Asia, it was revealed that for the period from 2001 to 2004, Malaysian's allocation of consumption expenditure for fish (from total budget) was the highest among the participating countries.[192]

This section has shown the increasing trends in consumption and the myriad needs of consumers pertaining to livestock and fisheries products. A country should be able to cope with the relevant aspects in order to ensure adequate supplies to, and meet specific demand of, the population. Geographical location and religious obligations are some of the factors which distinguish the preference for livestock and fisheries products among nations. They also explain the different challenges that a country has, compared to others, in terms of requirements for certain types of protein-based products. The appreciation of the aspects are key in assisting a particular country to make an informed assessment of whether or not current national practice of the animal livestock and fisheries industry could meet the trends. The next section will look at the specific challenges of the industry and implications arising from them. As regards Malaysia, it aims to identify the on-going and crucial problems which require solution.

[191] T.Y. Sheng et al, n 156 above, 468.

[192] Bangladesh, China, India, Indonesia, Malaysia, Phillipines, Sri Lanka, Thailand and Vietnam. See M.M. Dey, Y.T. Garcia, P. Kumar, S. Piumsombun, M.S. Haque, L. Li, A. Radam, A. Senaratne, N.T. Khiem and S. Koeshendrajana, Demand for fish in Asia: a cross-country analysis (2008) 52 *The Australian Journal of Agricultural and Resource Economics*, 326-328.

5. Challenges facing livestock and fisheries production, and, its implications for Malaysia

5.1 Constraints confronting the livestock and fisheries industries

There are many issues, which hinder attempts by the livestock and fisheries industries to achieve production targets set at a global or national level. The lack of financial capacity to build basic or extended infrastructure facilities, weaknesses in management and marketing strategy and lack of legal or regulatory framework are some of them. Nevertheless, for the purpose of this section, three factors will be examined. They are: (1) a shortage of breeding stock and fish seed; (2) the risk of livestock and aquatic diseases; and (3) constraints of feed. They are specifically chosen as they are 'beyond human control', and relevant in the context of this thesis, being factors to which the application of modern animal biotechnologies has mainly been directed.

5.1.1 Shortage of productive breeding stock and fish seed

The importance of animal genetic resources for the sustainability of the world's food security, agriculture, and nutritional and rural development, is recognised and evidenced by the adoption of the Interlaken Declaration of Animal Genetic Resources 2007 (Interlaken Declaration') by 109 countries worldwide.[193] Having adequate animal genetic resources is a significant requirement for the livestock industry in order to ensure continuing supply. Not surprisingly livestock has been described as 'farmers' most essential input'.[194]

[193] FAO, Global plan of action for animal genetic resources and the Interlaken Declaration, ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (Accessed: 8 December 2010).
[194] ibid.

Unfortunately for Malaysia's ruminant industry (which includes livestock such as cattle, buffalo, goat and sheep), the shortage of productive breeding stock has long been identified as a major problem.[195] In contrast, the poultry and pig industry does not experience the same problem. Two reasons contribute to this distinction: (1) the nature of poultry and pigs which have high reproductive rates; and (2) the short generation interval of poultry and pigs compared to ruminants.[196] Lack of breeding stock will put the Malaysian livestock industry in a challenging situation especially when the existing stock is facing increasing demand from consumers and also due to the risk of livestock diseases. Slow progress in generating indigenous breeds and breeding stocks [197] has resulted in the Malaysian Government importing high quality cattle for breeding purposes and applying artificial insemination procedures[198] to generate increased production. Many quality breeds have been brought into the country for commercial purposes, namely Anglo Nubian (from England), Boer (South Africa) and Jamnapari (India and Pakistan) for goat breeds; Brahman (India), Charollais (France), Droughtmaster (Australia) and Jersey (England) for cattle breeds; and Damara (East Asia and Egypt) and Dorper (South Africa) for sheep breeds.[199]

On a similar note, constraints of fish seed for the aquaculture sector remain a problem worldwide. In particular, aquaculturists who rely on wild-caught fry to be cultured, such as yellowtail, grouper, or yellow fin tuna face more problems than those who breed species such as carp, shrimp and salmon. This is because the latter groups can already be produced using artificial reproduction. [200] For the Malaysian fisheries industry, one would assume that

[195] Economic Planning Unit Malaysia, Fifth Malaysia Plan, http://www.epu.gov.my/previousplan (Accessed: 26 October 2010).
[196] FAO, n 5 above, 20.
[197] Economic Planning Unit Malaysia, Sixth Malaysia Plan, http://www.epu.gov.my/previousplan (Accessed: 26 October 2010) 97.
[198] Economic Planning Unit Malaysia, n 195 above, ibid.
[199] Department of Veterinary Services Malaysia, http://www.dvs.gov.my/web/guest/penerbitan (Accessed: 23 April 2012).
[200] FAO, n 161 above, 159.

constraints of seed causes fewer problems to the country's fisheries industry since the industry focuses heavily on capture fisheries rather than aquaculture. In evidence, in 2010, 26% of the country's fish production was contributed by capture fisheries (from coastal and deep sea fisheries), while only 7.93% comes from aquaculture.[201] Nevertheless, as its aquaculture sector also includes finfish species such as tilapia, and grouper[202] (which have not been able to use artificial reproduction techniques) similar problems would apply to the country.

5.1.2 Risk of livestock and aquatic diseases

Livestock diseases have caused global concerns for at least two main reasons: (1) implications for food security and the economy; and (2) implications for human health. It is useful to look at the timeline of some livestock diseases which have affected the globe. For instance, Newcastle disease was discovered in 1926, Bovine Spongiform Encephalopathy (BSE, or Mad Cow disease) in 1984, the Henipavirus (Nipah virus) in 1998 and the Influenza A (H1N1) virus, the strain which is better known as 'swine flu' in 2009. This timeline evidences the long repeatable threats which have affected livestock animals and caused economic loss to industry and farmers.

The economic implications of these diseases for developing and developed countries are massive. It was estimated that the total costs caused by the disease in the UK amounted to US$18 to US$25 billion between 1999 and 2002.[203] The 2009 Pandemic H1N1 Influenza,

[201] Department of Fisheries Malaysia, Performance and achievements of the fisheries sector, http://www.dof.gov.my/18?p_p_id=56_INSTANCE_3Fyn&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&page=1 (Accessed: 10 January 2012).

[202] Department of Fisheries Malaysia, Status of the fisheries sector in Malaysia, 2009, http://www.dof.gov.my/c/document_library/get_file?uuid=4e69ed3d-f8c5-4b68-87be-d904b95ec011&groupId=172176 (Accessed: 10 January 2012).

[203] P.K. Thornton, Livestock production: recent trends, future prospects (2010) 365 *Philosophical Transactions of the Royal Society B*, 2860.

caused Mexico an estimated economic cost of over US$2 billion.[204] In the case of developing countries, the Avian Influenza (H5N1) disease which affected poultry industries has caused adverse implication on prices and the amount of poultry meat sold in the major markets of affected developing countries.[205] It was shown that prices fell by 8% to 75% in countries such as Cambodia, Indonesia, Vietnam, Egypt and Bangladesh. The drop in the volume of poultry meat traded was in the range of 33% to 90%. These drops were mainly due to consumer apprehension about the risk of contracting the Avian Influenza disease by consuming the poultry meat.[206]

Malaysia is not exempt from the livestock diseases mentioned above. The following discussion highlights the economic implications of the Nipah virus outbreak to the country.[207] Economically, the outbreak caused excessive economic trade loss to the country's pig industry and the farmers. Approximately 1.1 million pigs were destroyed during the outbreak period, causing an estimated loss of US$97 million.[208] The number destroyed accounted for nearly half of the country's pig population (2.4 million) prior to the outbreak. This caused a drastic decrease of pig meat production from 283,000 tonnes in 1995 to only 150,000 tonnes in 2000.[209] Prior to the outbreak, Malaysia exported pigs to Singapore and Hong Kong. In 1999, the ban on imports due to the outbreak caused an estimated trade loss of US$120 million.[210] Other indicators pointed in the same direction. For instance, self-sufficiency levels

[204] S. Burgos and J. Otte, 'Global public health and transboundary animal diseases: issues and options, approaches and concerns', FAO-UN Research Report, 2010, 3.
[205] S.M.L Kabir, Avian flu (H5N1): threat of 'global pandemic' is growing and it's impact on the developing countries' economy (2010) 4 *African Journal of Microbiology Research*, 12, 1193.
[206] ibid.
[207] The virus of which was first discovered in the country.
[208] FAO, The emergence of Nipah virus, http://www.fao.org/docrep/005/AC449E/ac449e04.htm (Accessed: 9 December 2010).
[209] Economic Planning Unit Malaysia, Eighth Malaysia Plan, http://www.epu.gov.my/previousplan (Accessed: 26 October 2010) 210.
[210] FAO, n 208 above.

for pig meat decreased drastically from 104% in 1995 to 80% in 2000.[211] In the context of the domestic market, the outbreak caused a drop of 80% in consumption, causing an estimated loss of US$124 million to local farmers during the outbreak period. In terms of management costs, the country spent an estimated US$136 million to bring the outbreak under control.[212]

Moving on to the fisheries industry, aquatic diseases has been described by aquaculture experts as a very significant threat to sustainable production and trade.[213] Generally, they are caused by an imbalance of the ecological environment due to factors such as increased urbanisation, growth of new industries and changes in industrial practices. The practices in aquaculture which include the removing of live aquatic animals from their natural environment (such as freshwater and offshore) to high density captivity and also the trans-boundary movement from one country to another have been widely recognised as the main factors which cause the spread of aquatic pathogens.[214] The economic implications of aquatic diseases are a major problem for countries around the world. Of all aquaculture sectors, prawn farming has been the most remarkably affected. Since more than 90% of prawn farming is based in Asia and Latin America, it means major losses have been experienced by most developing countries. To illustrate this point, in 1993 China reported a loss of US$20 million in a single season, and in 2002 India's estimated loss was more than US$250 million, that is 60% of the national production.[215] Fisheries industries in industrialised countries have been similarly affected. For instance, salmon-farming industries in Europe and North America experienced serious losses due to infectious salmon anaemia (ISA) in 1984. By 1999, the

[211] Economic Planning Unit Malaysia, n 209 above, 212.
[212] FAO, n 208 above.
[213] See for instance P.J. Walker, Disease emergence and food security: global impact of pathogens on sustainable aquaculture production in A.G. Brown (ed), Fish, aquaculture and food security: sustaining fish as a food supply, Record of a conference conducted by the ATSE Crawford Fund Parliament House, Canberra, 2004, 44.
[214] ibid.
[215] ibid. 46.

fisheries industries in Norway, Scotland and Canada were estimated to have lost US$60 million due to the same disease.[216]

5.1.3 Constraints of animal and fish feed

Animal feed is one of the determining factors for the amount of production and quality of livestock and fisheries products. According to the OECD-FAO[217] projections, from 2009 to 2018, the demand for feed such as wheat, coarse grain and oilseed meal, mainly from developing countries, will be increasing. Demand for these resources for livestock feed has to compete with at least two other factors: (1) increasing human consumption; and (2) production of bioproducts such as biofuel, bioethanol, biodiesel and biogas, which have been encouraged due to their environmental friendly and energy saving features. This competition would inevitably mean high costs for the inputs. In this regard, the OECD-FAO projected (for instance) an increase of 3% for wheat prices by 2019 from the average price in 2007-2009 (during the world food-price crisis) and also an increase for coarse grain rice.[218]

In order to meet the increasing local demand for animal feed, efforts have been continuously undertaken by the Malaysian Government to improve the supply and quality of foodstuffs for ruminant and non-ruminant animals. Locally available feed ingredients such as tapioca waste and rice bran are encouraged to be utilised either as compound feed for feeding livestock together with ground maize and soybean meal, or as a single feed. Of particular importance is the use of local palm kernel cake[219] which has proved to be of nutritional value for dairy

[216] ibid. 47.
[217] OECD-FAO, Agricultural Outlook 2010-2019: Highlights, 2010, http://www.agri-outlook.org/dataoecd/13/13/45438527.pdf (Accessed: 26 October 2010).
[218] ibid. 28.
[219] Palm kernel cake is a solid residue left behind after the extraction of oil kernels of the palm fruits. Oil palm has been Malaysia's major export commodity for years.

cattle[220] and fish such as tilapia and catfish[221] in Malaysia. Notwithstanding all these efforts, crucially, a large amount of animal feed is still imported. The high cost of feed ingredients means Malaysia has to spend a huge amount of money for the importation of soybean meal, corn flour and wheat flour for this purpose. According to the Ministry of Agriculture and Agro-Based Industry Malaysia, [222] the value of imports of animal feed has been gradually increasing from RM2.1 billion in 2003 to RM3.8 billion in 2007. The Ninth Malaysia Plan projected a further increase of imports to RM4.3 billion in 2010.[223]

The FAO has identified that feed perhaps is the best-known constraint for the aquaculture industry. [224] In the sector, fish has a dual function: (1) as a source of food for human consumption; and (2) as a source of food for fish itself. As regards the latter, fish feed consists of fishmeal, fish oil and trash fish[225] which themselves originate from a few fish species (called 'bait fish' or 'industrialised fish') which are less suitable for human consumption. Some critics[226] have argued that claims that increasing demand for aquafeeds will destroy the stocks of 'bait fish' were not supported by evidence, since catches for the last two decades have been stable. Nevertheless, as it is doubtful that the catch would increase,

---

[220] F.Y. Chin, Palm Kernel Cake (PKC) as a supplement for fattening and dairy cattle in Malaysia, http://www.jpvpk.gov.my (Accessed: 13 December 2010).

[221] N.W. Keong, Researching the use of Palm Kernel Cake in aquaculture feeds (2004) *Malaysian Palm Oil Board*, 19-21.

[222] Ministry of Agriculture and Agro-Based Industry Malaysia, Imports of agriculture sector, http://www.moa.gov.my (Accessed: 25 October 2010).

[223] Economic Planning Unit Malaysia, Ninth Malaysia Plan (2006-2010), http://www.epu.gov.my/previousplan (Accessed: 26 October 2010) 92.

[224] FAO, n 161 above, 159.

[225] Fishmeal means: 'ground dried fish used as fertiliser and as feed for domestic livestock'. Fish oil means: 'a fatty oil obtained from the livers of various fish'. See http://www.thefreedictionary.com/fish+meal (Accessed: 13 December 2010). Species used to produce fishmeal and fish oil include anchovies, sardines, anchovetta, herring, capelin, sand eels and other generally small, short-lived species. While consumed by humans in small quantities, these species, which are generally small, oily and bony, are used mainly for aquaculture feed. This is partly due to the damaging methods that are used to capture and store these species, making them more suitable for industrial processing rather than processing for human consumption. See G. Allan, Fish for feed vs fish for food, 21-22 in A.G. Brown n 213 above. Trash fish means: 'a usually marine fish having little or no market value as human food but used sometimes in the production of fish meal'. Trash fish is also called 'rough fish' in the aquaculture industry. See: http://www.merriam-webster.com/dictionary/trash+fish (Accessed: 13 December 2010).

[226] G. Allan, ibid. 25.

the need for substitute feed has been recognised.[227] This precautionary measure is the reason why research into substitute fish feed has become increasingly focussed worldwide.

The complete substitution of fishmeal has been achieved mainly for herbivorous and omnivorous fish (such as silver perch), and it has also been possible for very small species of carnivorous fish (such as barramundi).[228] Two-thirds substitution is already possible for prawns. Replacement proteins include grains (such as soybean meal, peas and beans and wheat products) and terrestrial animal meals (such as meat meal and poultry meal).[229] Unfortunately, there has been less success with substitution for most carnivorous fish which cannot survive without fish as a major component of their diet. Of particular importance are salmonids which significantly rely on fish oil.[230] The problems include aspects such as digestibility, acceptance and changes in the fatty acid profiles of fish.[231] In the light of the intensification of aquaculture, the continuing supply of fishmeal and fish oil for aquaculture feed (which in turn is based on the bait fish catch) is risky and might become critical in the near future. The situation may be exacerbated, for instance, by competition for the use of fish oil from other sectors such as the pharmaceutical industry.[232]

This sub-section has shown pertinent continuing challenges facing the Malaysian livestock and fisheries industries. As already shown, the problems identified are similarly experienced by other developing and developed countries. However, for developing countries, each of these problems would pose a greater challenge in the light of the growth of demand for livestock products, as compared to developed countries in which demand has become

[227] ibid.
[228] ibid. 24.
[229] ibid.
[230] FAO, n 161 above, 159.
[231] G. Allan, n 225 above, 25.
[232] ibid.

stagnant. The following sub-section highlights the implication arising from the challenges to Malaysia so as to assess whether or not the problem can be resolved in near future, without any support from new technologies.

5.2 The on-going efforts adopted in the Malaysian livestock and fisheries industries, and the problem of the self-sufficiency level

The Malaysian Government has handled the challenges facing the livestock and fisheries industries by developing infrastructure and research activities.[233] A huge amount of money has been allocated to research ways of improving livestock and fisheries production, both in terms of quantity and quality. Educational programmes have also been arranged and implemented in order to expose the farmers and fishermen to all aspects of good husbandry practices including farm or fisheries management and marketing strategies. As far as livestock animals are concerned, grazing reserves are continuously being developed in many parts of the country. Improvement has also been made to abattoirs, aiming to produce a better quality of products that comply with various health regulations, and hence an increase in production. With regard to the prevention of animal diseases, research into the production of vaccines for specific livestock diseases such as foot and mouth, Newcastle disease[234] and avian influenza has been undertaken. Ways have also been adopted to improve animal health through veterinary services. In addition to these, specific efforts for the fisheries industry include improvement of fishing equipment, the establishment of cold rooms and processing

[233] See Economic Planning Unit Malaysia, First Malaysia Plan (1966-1970) to Tenth Malaysia Plan (2011-2015), http://www.epu.gov.my/previousplan (Accessed: 26 October 2010).

[234] Newcastle disease is a contagious bird disease affecting many domestic and wild avian species which was first found in Newcastle-upon-Tyne, United Kingdom, in 1927, hence its name. See http://dictionary.reference.com/browse/newcastle+disease (Accessed: 9 December 2010).

facilities, training for the extensive use of modern fishing and conservation of fisheries stocks in marine parks.[235]

Unfortunately, notwithstanding these and years of efforts by the government to develop the industry, stories relating to the rising price of livestock products are still common. Headings of articles such as 'No reason to increase meat prices',[236] 'Conspiracy to raise price of chicken'[237] and 'Government to check on festive price hikes'[238] have become common annual phenomena in local newspapers particularly when festive seasons are approaching. Whereas these 'one-off' scenarios could not be taken as suggesting inadequate local supplies of livestock products, statistical evidence will show that Malaysia is in fact facing problems in meeting local demand in both livestock and fisheries products.

In Malaysia, similar to other major food commodities such as rice, fruit and vegetables, the self-sufficiency level of livestock products has been increasing for the past ten years (2000-2010) due to the various efforts by the government. The increase of percentage levels for livestock products are: beef (from 15% to 28%), mutton (6% to 10%), pork (100% to 132%), poultry (113% to 122%) and milk (3% to 5%).[239] Self-sufficiency levels for eggs have similarly increased (110.3% to 152.5%, from 1995 to 2005).[240] These statistics show that Malaysia is self-sufficient only in some livestock products. Despite the low percentage levels for beef and mutton, the goal of achieving self-sufficiency is pursued. The Ministry of Agriculture and Agro-Based Industry Malaysia targeted a 40% self-sufficiency level for these

[235] ibid.
[236] *New Straits Times*, 26 February 1993.
[237] *Harian Metro*, 12 January 1998.
[238] *New Straits Times*, 14 August 2010.
[239] Economic Planning Unit Malaysia, n 223 above, 93.
[240] ibid.

two products by 2015.[241] Currently, in order to meet the population's demand, Malaysia depends on 80% imports from countries such as India, Australia, New Zealand, Uruguay, Argentina and Brazil.[242] A similar challenge has been encountered with Malaysia's fish supply. The production of fish has increased from 1.5 million tonnes in 2000,[243] to 1.7 million tonnes in 2009.[244] Yet Malaysia has been continuously dependent on imported fish from countries such as Thailand and Indonesia,[245] to fulfil local demand. The value of imports was RM1.1 billion in 2000, and it increased to RM 2.2 billion in 2007.[246]

This section has shown the specific challenges facing the livestock and fisheries industries, and its implication for Malaysia. The problems have continued to persist notwithstanding the numerous efforts which have been adopted by the government. The self-sufficiency levels for three main livestock products in Malaysia namely, beef, mutton and milk is very critical. A similar problem is burdening the fisheries industry. For these products, much more effort is needed to increase the self-sufficiency levels to at least 50%, hence, alleviating the heavy dependency on imported products. A shortage in the supply of livestock and fisheries products may eventually lead to some further problems such as increased prices and lack of protein-based sources. Therefore, it is timely for Malaysia to look for a new option to overcome the problems. This contention will be further discussed in the next section which identifies the potential of modern biotechnology to assist the country in meeting the demands and needs of its population.

---

241 Ministry of Agriculture and Agro-Based Industry, Malaysia, Kenyataan media: pengimportan daging kerbau dari India, http://www.moa.gov.my/web/guest/siaranakhbar_april3 (Accessed: 3 December 2010).
242 ibid.
243 Economic Planning Unit Malaysia, n 223 above, 91.
244 Department of Fisheries Malaysia, food fish production, http://www.dof./gov.my (Accessed: 3 December 2010).
245 LKIM tambah import ikan sejuk beku dari 4 negara, *Berita Harian*, 1 March 2010.
246 Department of Fisheries Malaysia, Annual fisheries statistics 2007 – import/export, http://www.dof.gov.my/642 (Accessed: 3 December 2010).

6. Animal biotechnology applications and animal biotechnology food as a catalyst for Malaysia

It has been shown in section 5 that the needs of Malaysian consumers in terms of the quantity of livestock and fisheries products are not being met. Following on from the experience in developed countries, once the problems of quantity are resolved, consumers will concentrate more on problems of quality. Animal biotechnology is able to assist with both of these issues. Therefore, in addition to the potential of the genetic engineering technique identified in sub-section 3.1, other possible contributions of animal biotechnology applications are further assessed below.

Animal biotechnology can improve the physiological aspects of livestock animals and fish such as feed efficiency and disease resistance qualities, which results in higher yields. The introduction of certain enzymes using transgenic technology to the gut of livestock animals such as pigs and poultry can help to increase feed efficiency, and reduce the amount of feed required.[247] In the context of Malaysia, the decrease of the amount of feed required by the GM livestock would eventually mean less government expenditure on imported feed. As a result, relevant funds may be channelled to R&D activities in order to speed up the various animal biotechnology applications which are at the research stages. In a broader context, there is competing demand for feed resources, such as wheat and coarse grain rice for livestock animals, between human consumption and the production of bioproducts. The use of GM livestock can contribute to reduce the price of the crops, hence, ensuring the affordable consumption by consumers worldwide. Apart from this, the increased pressure caused to eco-systems and natural resources, such as land and water, due to intensive

[247] M.B. Wheeler n 11 above, 205; R.H. Phipps et al, n 11 above, 247.

production of livestock can, ultimately, be reduced. Increased feed efficiency has been further associated with potential improvements to the environmental condition, where it can decrease methane production which contributes to global warming and climate change.[248] In evidence, Enviropig (the genetically altered pig which has been developed in Canada) can better absorb phosphorus from its food, hence reducing environmental pollution caused by that substance.[249]

With respect to the alteration of genetic material to increase disease resistance, the production of mastitis-free cattle has been highlighted.[250] Mastitis is an infectious disease of the mammary gland that causes decreased milk production. By producing antibodies in the mammary glands, such a disease can be prevented. In addition, the ability of the technology to produce BSE-free livestock in the future has also been anticipated.[251] For the aquaculture industry, the quality of disease-resistance from bacterial infection has been specifically identified. For instance, research[252] has reported that transgenic Channel catfish shows improved disease resistance and survival rate compared to the non-transgenic individuals when challenged with pathogenic bacteria.[253] The production of disease-resistant livestock animals and fish provides an alternative to dependency on the use of vaccines in dealing with the continuous problems on livestock diseases. While vaccines have been effective in treating diseases, they are not without limit. Taking catfish as an example, it has been reported that common catfish disease, including enteric septicaemia, has no accurate effective treatment.[254]

---

[248] J.F. Garcia et al, n 11 above, 53.

[249] Transgenic fish go large, *Nature*, 16 September 2010, 259. The case for Enviropig is further discussed in section 4 of chapter 5.

[250] An example of this is Daisy, the GM cow developed by New Zealand scientists. See New Zealand's GM cattle under fire, *Nature*, 27 March 2010.

[251] ibid.

[252] R.A. Dunham, G.W. Warr, A. Nicholas, P.L. Duncan, B. Argue, D. Middleton and H. Kucuktas, Enhanced bacterial disease resistance of transgenic Channel catfish *Ictalurus punctatus* possessing cecropin genes (2002) 4 *Marine Biotechnology*, 342-343.

[253] ibid.

[254] ibid. 338.

In the long run, resistance to livestock and aquatic diseases means the increase of breeding stock which is fundamental for Malaysia.

In terms of quality of livestock and fisheries products, it has been anticipated[255] that genetic engineering could improve carcass composition by using certain knockout genes to increase the lean quality of meat. This is done by altering the metabolism or uptake of cholesterol and or the fatty acids to lower the fat and cholesterol content of meats, eggs and cheeses. In addition, the ability of genetic engineering in modifying milk composition and properties for several purposes has also been projected.[256] An example for this is the increase of casein[257] components in milk that could enhance the value of milk in manufacturing yogurt or cheese or producing better-tasting low-fat cheese.[258] Related to this, in 1993, the USFDA approved recombinant bovine somatotropin (BST) after satisfying itself over its safety for human health. [259] The hormone, which is derived from genetically engineered bacteria, is a product of genetic engineering that is currently being used throughout the US' dairy industry.[260] The protein increases milk production in lactating cows.[261] Leaner quality of meat, and reduced cholesterol rate in livestock and dairy products, are clear promise of modern biotechnology applications which could improve the health quality of Malaysians.

[255] ibid. 207.
[256] M.B. Wheeler, n 11 above, 206.
[257] Casein is 'a white, tasteless, odourless protein precipitated from milk by rennin. It is the basis of cheese and is used to make plastics, adhesives, paints, and foods'. See http://www.thefreedictionary.com/casein (Accessed: 19 December 2010).
[258] M.B. Wheeler, n 11 above, 206.
[259] A.L. van Eenennaam, n 13 above, 136.
[260] ibid.
[261] ibid.

7. Conclusion

The livestock and fisheries industries have contributed largely toward the world's and Malaysia's economy. In tandem with the growth of the population, demand for livestock and fisheries products has been increasing. While this trend can be observed in developed and developing countries, the rate of growth in the latter is more notable particularly because of the increasing income of the population, which helps them to purchase and consume the products. The two most important objectives of livestock and fisheries industry are high volume and quality of outputs. The focus of developing countries has been on increasing the production whereas the main consideration of developed countries is on the quality of the products, including their implications for human health and the environment.

The development of the livestock and fisheries industries in Malaysia and throughout the world is progressing rapidly in line with the explosion of demand. Nevertheless, the world food-price crisis between 2007 and 2008 made it explicit that the world's livestock and fisheries industries production is very vulnerable due to various factors which are beyond human control. Important challenges which have been identified include the shortage of productive breeding stock and fish seed, the risks of livestock and aquatic diseases and constraints of animal and fish feed. These are also the challenges that have been recognised worldwide as restricting the performance of the livestock and fisheries industries to produce optimal outputs.

Advances in molecular biology have brought a new dimension to the livestock industry. Scientific findings have proven that animal biotechnology applications are able to assist the industry in achieving the objectives of developing and developed countries. For developing

countries, the technology helps to develop livestock animals and fish which are disease-resistant, with improved digestive systems and growth rates. It therefore, produces increased yields. In the context of developed countries animal biotechnology has the potential to produce output which is richer in nutritional quality, has leaner meat, and is environmentally friendly. As it is anticipated that the healthy criterion of livestock products will become an important factor for the populations of developing countries as their income and knowledge is enhanced, modern animal biotechnology will similarly benefit them.

Notwithstanding the promises of the technology, animal biotechnology food is not without challenge. Notably, consumers are concern about the implications for their health and for the environment. As a result, many studies focus on these two aspects. Ample scientific evidence has been published as to the safety of animal biotechnology food for human health. In particular it has been shown that the meat and milk of cloned cattle is no different than the non-cloned variety, based on rigorous risk assessment of the potential risk of the products to human health. An important fact which has been identified is that consumer's scepticism toward animal biotechnology food could be improved by education and information about its benefits. This finding has been reported in several empirical research papers involving consumers globally and similar conclusions can be made for Malaysians who are not totally against modern biotechnology and its products. This is evidenced by the acceptance of products such as GM soybean, palm oil and insulin. Therefore, it is important for the Malaysian Government and industrial stakeholders to educate consumers about the benefits of animal biotechnology food.

At the international level, potential risks arising from the trans-boundary movement of LMOs (including GM livestock animals and fish) is addressed by the Cartagena Protocol. In addition

to the evidence for the safety of animal biotechnology food, this chapter has also argued that the concern of consumers, if any, relating to the potential risk to the environment and to human health, is adequately addressed by the Protocol. In particular this is achieved by four factors: (1) subjecting the transgenic animals to prior informed consent and notification procedures before the intended trans-boundary movement; (2) their compulsory identification in international shipments (if the identity of the LMOs is known); (3) the ability of Parties to the Protocol to claim damages caused by the LMOs using civil liability laws; and (4) the encouragement that non-Parties similarly observe the provisions of the Protocol.

Malaysia is self-sufficient in poultry, pork and eggs. However, the country is heavily dependent on imports for beef, mutton and fisheries products to meet the populations' growing demand. The import value of these products is very significant and increasing every year. In addition, the government is also spending a huge amount of money to import animal feeds. These problems are persistent notwithstanding the government's endeavours to enhance the livestock industry, including, increasing grazing reserves, exposing farmers and fishermen to good husbandry practice and improving marketing strategies. There are in hand two choices that can be considered; either continuing to rely on various efforts which have been adopted to develop the industry over recent years, or venturing into modern animal biotechnology which has the potential to assist the industries. As already identified, the first choice has not succeeded in generating a sufficiently increased food supply in all livestock commodities for the country. Therefore, Malaysia has made a pertinent decision by opting to utilise modern animal biotechnology to this end. So far the most notable application of the technology in the country is the modern breeding techniques of artificial insemination. Nevertheless, it has been shown that efforts to apply animal biotechnology in a wider area of research involving livestock animals and fish are already in place. This is made possible by

the clear vision of the government as contained in the country's National Biotechnology Policy which states that animal biotechnology is to be utilised in full in order to maximise the value of livestock and fisheries industries. In tandem with this are the explicit aims of the National Agricultural Policy to increase food (including livestock) production and exports, and reduce imports. This chapter argues that animal biotechnology applications can assist Malaysia to increase the self-sufficiency level in all main livestock and fisheries products, and improve the health quality of the population.

In order to promote innovation in biotechnological inventions the government has specifically encouraged local research institutions and individual scientists to apply for patent protection to protect their commercial interest. So far patents have been secured locally and internationally for products such as DNA sequence encoding for various proteins and vaccines and animal feed. Animal biotechnology food could constitute an invention within the patent law sense. However, the legal protection which is covered by s13(1)(b) of the Malaysian Patents Act 1983 (where 'animal varieties' are excluded from patent protection) is unclear. Article 27.3(b) of the TRIPs Agreement allows Signatories (such as Malaysia) to exclude 'animals' from national patent protection. Nevertheless, what is required in Malaysia is an answer as to how this flexibility could be construed. In the context of the thesis, the interpretation is to be assessed in the context of two pertinent points already identified in this chapter: (1) the long-term problem faced by Malaysia in achieving self-sufficiency in all main livestock products; and (2) the aspiration and commitment of the government to harness animal biotechnology applications to develop its livestock industry and increase its products in order to meet the various increasing requirements of consumers.

The next chapter will discuss the exclusion of animal inventions under Article 27.3(b) of the TRIPs Agreement. Central to the discussion is an examination of the rationale underpinning the flexibility for the exclusion and assessment of issues pertaining to the exclusion under the TRIPs Agreement. The chapter contributes to the research questions by highlighting to a Signatory to the TRIPs Agreement (including Malaysia), the rights which it has and obligations which are expected from it within the international patent law framework in interpreting its exclusionary provision.

CHAPTER TWO

THE EXCLUSION OF ANIMAL INVENTIONS UNDER ARTICLE 27.3(b) OF THE TRIPs AGREEMENT 1994: THE PAST, PRESENT AND FUTURE

1. Introduction

The TRIPs Agreement lays down an international minimum standard of patent protection which needs to be implemented by its Signatories. Article 27.1 of the TRIPs Agreement requires Signatories to grant patent protection for any inventions, whether products or processes, irrespective of their field, provided the patentability criteria are fulfilled. Notwithstanding this broad requirement for patentability, the treaty provides for some flexibility in the implementation of patent protection for living organisms. The flexibility is very important in view of such a complex multilateral agreement which involves negotiating countries with different levels of economic background and with diverse levels of technological development. Fundamentally, the flexibility seeks to ensure that all participating countries feel able to take on board various obligations that need to be included into their national patent laws, and ultimately implemented, should they decide to ratify the TRIPs Agreement.

As a result, irrespective of the obligation under Article 27.1 of the TRIPs Agreement, Signatories are allowed to exclude 'animals' from patent protection. Article 27.3(b) states:

> Members *may also exclude from patentability*:
> Plants and *animals* other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. (emphasis added)

Whereas the TRIPs Agreement came into force in 1995, the 'unsettled' nature of Article 27.3(b) (which is indicated by the last sentence in the provision) quickly becomes apparent. The provision, which is subject to review (also often referred to as the 'built-in' agenda) arose from, and is evidenced by, the complexities of reaching an agreement between the negotiating countries at the conclusion of the Uruguay Round Meeting. The crux of the problem lies within the different perspectives held by the negotiating countries on the purposes and implications of the exclusion. More than a decade has lapsed. The review, which started in December 1998, has not yet achieved any specific understanding among the negotiating parties including the basic issue of what 'review' should mean.[1] These divergences on basic points will be shown to be similarly relevant to the issue on patent protection for animal inventions. Consequently, while Signatories remain obliged to give effect to Article 27.1 and retain the flexibility to exclude 'animals' under Article 27.3(b), they are left with much uncertainty as to how the latter should be applied.

This chapter aims to understand the reason why different Signatories to the TRIPS Agreement have adopted diverse approaches to interpret the exclusion of animal inventions. It also intends to examine the development within the WTO of issues relating to the exclusion. In order to achieve these aims, this chapter is divided into five sections. Section 2 examines the past history of the exclusion. This contains an examination of the basis and purpose for having the exclusion in the TRIPs Agreement and the grounds underpinning the adoption of the final version of the exclusion. The negotiation process of the TRIPs Agreement will be examined to see if the reasons for the exclusion were made explicit, and to appreciate the

[1] On the one hand, developed countries hold the view that it means only a 'review of implementation'. On the other hand, developing countries argue that the revision of the content of the provision itself is crucial. See C.M. Correa, Review of the TRIPs Agreement: fostering the transfer of technology to developing countries, 946, http://www.twnside.org.sg/title/foster.htm (Accessed: 10 August 2010).

reasons leading to the flexibility to implement the exclusion. Section 3 discusses the present status of Article 27.3(b) arising from the review process of the provision during the Doha Development Agenda (DDA).[2] In this section issues relating to the patentability of life forms and the Convention on Biological Diversity 1992 (CBD)[3] will be analysed so as to understand the current debate between developed and developing countries on the issues. Grounds for favouring or opposing the elimination of the exclusion, under the review will also been assessed. In the absence of any specific resolution of the review of the exclusion, section 4 will discuss the future of the exclusion, in terms of its application in Malaysia, which has chosen to exclude animal varieties under its national patent law. Suggestions on how Malaysia can proceed to interpret the exclusion will be made. Section 5 concludes the chapter.

In relation to the previous chapter, this chapter will add emphasis to the fact that the needs of a developing country (such as Malaysia) and its national priorities play an important role in determining the interpretation of the exclusion. Having identified the needs of the livestock industry in Malaysia, this chapter places the debate in its international context, to identify factors which affect Signatories such as Malaysia in adopting a specific approach to construe the exclusion of animal inventions within national patent law. As this chapter will argue, due to the flexibility under Article 27.3(b), any interpretation for the exclusion of animal inventions would not undermine a Signatory's obligation under the TRIPs Agreement.

---

[2] The Doha Declaration is the WTO Ministerial Declaration which was adopted on 14 November 2001 at the Fourth Session of the Ministerial Conference. Through Article 19 of the Declaration (which underpins the Doha Development Agenda within the WTO), the Ministerial Declaration instructed the TRIPs Council 'to examine, under the review of Article 27.3(b), inter alia, the relationship between the TRIPs Agreement and the CBD.' The Declaration, together with other Declarations similarly adopted by the Ministerial Conference (including the Ministerial Declaration on the TRIPs Agreement and public health) are available at: http://www.wto.org/english/tratop_e/dda_e/texts_contents_e.htm (Accessed: 22 June 2012).

[3] Available at: CBD, http://www.cbd.int/doc/legal/cbd-en.pdf (Accessed: 31 March 2012).

Nevertheless, the issues debated within the review process are relevant to be considered by the Signatory in implementing the flexibility.

2. The Past: the historical overview of the exclusion of animal inventions under the negotiation of the TRIPs Agreement

2.1 The inclusion of intellectual property rights (IPRs) in the negotiations

IPRs which cover intangible objects as opposed to tangible goods have been under the exclusive territory and expertise of the WIPO.[4] Prior to the inclusion of IPRs under the trade regime (since the Uruguay Round Meeting), the WIPO had been functioning as standard-setter and decision-maker in the field of intellectual property protection.[5] As regards to patent rights, the function of the Organisation was implemented through one of its important administered Conventions, namely the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).[6] As far as the decision-making function is concerned, the WIPO does not have a formalised dispute settlement procedure, but only Alternative Dispute Resolution (ADR). Article 28 of the Paris Convention provides for the possibility of bringing

---

4 It is a specialised agency of the United Nations (UN) which has been mandated with the promotion of intellectual property throughout the world through co-operation among Member States and where appropriate, in collaboration with any other international organisation. The WIPO was established by the WIPO Convention in 1967. The Organisation administers the Paris Convention and the Berne Convention (for copyright protection). See WIPO, What is WIPO? http://www.wipo.int/about-wipo/en/what_is_wipo.html (Accessed: 9 February 2010).

5 D.D. Bièvre and L. Thomann, Forum shopping in the global intellectual property regime, Arbeitspapiere - Working Papers, Nr. 132, (Mannheimer Zentrum für Europäische Sozialforschung, 2010) 15.

6 The Act of Stockholm of 14 July 1967. The Convention provides for general guidelines for the protection of a range of subjects that are considered to be 'industrial property' under the Convention. The rights available for protecting this subject matter include patent, trademarks, trade names, industrial designs, and utility models. As far as the international patent framework is concerned, the Paris Convention plays an important role in the internationalisation of patent protection. Its difference with the TRIPs Agreement is that the latter is tied down to the international trade obligations of Member States of the World Trade Organisation (WTO). In order to be a WTO's Member State, a country must be a Signatory to the TRIPs Agreement.

disputes before the International Court of Justice (ICJ).[7] However, there is no specific reference to how disputes between party states are to be settled. [8]

The insertion of IPRs under trade regimes aptly raises a question: what led to the shift in regulatory regime for IPRs from WIPO to GATT, which has dealt mainly with trade in tangible goods since 1948?[9] One of the factors which led to the shift of the forum for regulating certain international issues from one regulatory institution to another is a concept known as 'forum or venue shopping'. Countries engage in forum shopping where there is an alternative and better venue to pursue and achieve their specific policy objectives.[10] In the context of international IPRs, it has been pointed out[11] that the main reason which leads states to forum shop is the 'differing degrees of judicialisation'.[12]

The inclusion of IPRs on the agenda of the Uruguay Round Meeting was mooted by the US[13] which has been known as the world's major trading power. However, in the 1970s and 1980s, the country's economic supremacy in manufacturing and technology was threatened by the catching up process from countries such as Japan and some other Asian newly industrialised

---

7 WIPO, n 4 above, ibid.

8 D.D. Bièvre et al, n 5 above, ibid.

9 WTO, Understanding the WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf (Accessed: 8 February 2010). The WTO replaced the GATT as an international organisation, but the GATT still exists as the WTO's umbrella treaty for trade in goods, updated as a result of the Uruguay Round Negotiations.

10 See for instance D.D. Bièvre et al, n 5 above; S.K. Sell, From forum-shifters to shape-shifters: rulemaking and enforcement in intellectual property, Paper presented at the annual meeting of the International Studies Association's (ISA) 50th Annual Convention 'Exploring the past, anticipating the future', New York City, 15 February 2009, http://www.allacademic.com//meta/p_mla_apa_research_citation/3/1/0/4/2/pages310424/p310424-1.php (Accessed: 29 March 2011).

11 Other reasons why states forum shop are: (1) diverging actor (country) preferences; (2) power and capabilities; and (3) government agency specialisation. D.D. Bièvre et al, n 5 above, 3.

12 ibid.

13 M. Blakeney, *Trade related aspects of intellectual property rights: a concise guide to the TRIPs Agreement* (London: Sweet and Maxwell, 1996) 2.

countries (NICs).[14] One of the factors which weakened the US competitive performance in the world's trading arena was the ineffective IPRs in developing countries.[15] This system enabled its economic competitors to take advantage of the innovations developed by US inventors by copying and trading counterfeit goods, causing the loss of substantial revenues to its domestic industries.[16] Illustratively, annual losses of the video industry were reported to be approximately US$6 billion in 1983 and the counterfeiting of spare parts was estimated to cause the automotive industry an approximate loss of US$12 billion.[17]

These adverse economic implications have been used by the affected key players in the industries such as computer software and microelectronics, chemicals, pharmaceuticals and biotechnology,[18] to convince the US Government of the need to restrict competition by connecting IPRs to trade.[19] It is in the pursuance of this economic interest that in 1982, during the preparatory work for the GATT ministerial meeting, the proposal to consider IPRs to be included in the agenda of the Meeting was submitted. The importance of having IPRs in the agenda of the Uruguay Round Meeting was due to the value of those rights, and this was evidenced by the strategy adopted by the US to assure that this aim was achieved. In the words of Edmund T. Pratt, chairman of Pfizer, who initiated the process in 1984:

> [w]e must also work to get more broadly based economic organizations such as the OECD [Organization for Economic Co-operation and Development] and the GATT, to develop intellectual property rules, because intellectual property protection is essential for the continued development of international trade and investment.[20]

---

14 C.M. Correa, *Implementing the TRIPs Agreement: general context and implications for developing countries* (Third World Network: 1998) 5-6.
15 M. Blakeney, n 13 above, ibid.
16 ibid.
17 ibid.
18 A.O. Adede, Origins and history of the TRIPS negotiations in C. Bellmann, G. Dutfield and R. Melendez-Ortiz (eds), *Trading in knowledge: development perspectives on TRIPS, trade and sustainability* (London: Earthscan, 2003) 24.
19 ibid.
20 A.O. Adede, n 18 above, 24.

The US' insistence for IPRs to be brought under the trade regime (GATT) was primarily due to its dissatisfaction with the performance of the WIPO in revising the Paris Convention for stronger standards of protection of international IPRs in view of the substantial losses caused to its industries.[21] The feature of the GATT forum that provided for effective enforcement of agreements through its dispute settlement mechanism was another reason for this. The mechanism is seen as an important enforcement tool with which the US can protect its highly technological industries' interests worldwide. This weapon is missing from the WIPO and the Paris Convention.[22]

The proposal to shift the regulatory regime received strong objections from developing countries led by Brazil and India, mainly due to the WIPO-World Trade Organization (WTO) expertise issue. Subsequent negotiations with regard to the issue of whether IPRs were to be shifted within GATT's jurisdiction were led by the Swiss and Colombian Ambassadors.[23] Their proposal argued that negotiations on IPRs issues within the GATT Meeting would not prejudice other complementary initiatives that might be taken in the WIPO and elsewhere.[24] As a result, IPRs were finally included in the Uruguay Round Meeting.

The decision by the GATT meeting to incorporate IPRs in the Uruguay Round Meeting in the light of the proposal championed by the US can be interpreted in two ways. On the one hand, it reflects the increasing recognition by the GATT Agreement of the relationship between IPRs, which themselves are underpinned by commercial elements, and international trade.

---

[21] See for instance A.O. Adede, n 18 above, 25; M. Matsushita, T.J. Schoenbaum and P.C. Mavroidis, *The World Trade Organization: law, practice and policy* (Oxford: The Oxford International Law Library, 2003) 398 and 677.

[22] ibid.

[23] T.P. Stewart (ed), *The GATT Uruguay Round: a negotiating history (1986-1992), Volume II: commentary* (Deventer: Kluwer Law and Taxation Publishers, 1993) 2263.

[24] ibid.

Bringing the rights under common international rules was seen as the best way to achieve the aim of introducing more consistency in trading regulations,[25] which is obviously part of the functions of the international Agreement such as GATT. On the other hand, since IPRs, in particular patent rights, depend heavily on the technological progress of a given country, it has been asserted[26] that the decision was only to fulfil the interests of the industrialised countries such as the US and Japan. With a strong economic ability, robust investments in scientific research and ultimately, technological advancement, the inclusion of IPRs into the realm of GATT has put these countries in a far better position to utilise the system to pursue their economic interests, compared to their developing counterparts.[27]

Two factors underpinned the divergence of views between developed and developing countries during the Uruguay Round Meeting: (1) a difference of objectives that each category of countries intended to achieve by participating in the negotiations; and (2) divergence of views as to the importance of IPRs in economic development. On the one hand, industrialised countries such as the US entered into the negotiations with a clear and strong objective to secure their economic interests worldwide.[28] One of the most important aspects being negotiated during the Uruguay Round Meeting was the scope and standard of IPRs protection to be adhered to by the negotiating countries. With strong demand for enforcing IPRs from the private sector, which is the key investor in R&D (compared to the public sector), it is important for developed countries to ensure that the aspect is agreed upon in accordance with the industries' interests. It has been widely emphasised[29] that IPRs, in

[25] WTO, n 9 above.
[26] See for instance observation in H. Adolf, Trade-related aspects of intellectual property rights and developing countries (2001) *The Developing Economies*, 76.
[27] ibid.
[28] For objectives set out by the US proposal for negotiation of the TRIPs Agreement, see P.K. Yu, The objectives and principles of the TRIPs Agreement (2009) 46 *Houston Law Review*, 4, 984.
[29] K.W. McCabe, The January 1999 review of Article 27 of the TRIPs Agreement: diverging views of developed and developing countries toward the patentability of biotechnology (1998) *Journal of Intellectual Property Law*, 47.

particular patent rights, are an important instrument for industrialised countries to recoup enormous amounts of investments involved in developing a particular product and bringing it to the market. In evidence, it was estimated by the Pharmaceutical Research and Manufacturers of America that it takes ten to twelve years and over US$350 million to bring a single pharmaceutical product to market.[30] Specifically on animal inventions, US$15 million was invested by Du Pont to finance the transgenic *onco-mouse* research which could assist in the detection of cancer.[31]

On the other hand, while the participation of developing countries in the Uruguay Round Meeting was also motivated by economic interests, their objectives and expectations from the process were different from their developed counterparts. The protection of innovation was at that time not yet on the economic agenda of developing countries.[32] In fact, IPRs had not been given much importance prior to the Uruguay Round Meeting, in particular due to the lack of technological progress and the existence of only small-scale industries in these countries, hence a lack of investment for research.[33] This state of affairs led to the absence of a legal framework at national level for IPRs since there was no need to protect the interest of inventors or to enforce their rights.[34] Notwithstanding this, it is not suggested that IPRs were not important to developing countries or that they were absolutely against their implementation. The point is that their protection was not the motivation for participating in the Meeting. Nevertheless, the awareness of developing countries of the importance of IPRs had been improved by participating in the Meeting. From that point onwards, developing

---

30 ibid. 48.

31 See *Harvard College v Canada (Commissioner of Patents)* [2003] 5 LRC 330, 344. For another instance, the regulatory costs to commercialise animal vaccine was estimated at US$242,000 to US$469,000. See OECD, The bioeconomy to 2030: designing a policy agenda, 2009, http://www.oecd.org/dataoecd/5/24/42837897.pdf (Accessed: 5 April 2011) 11.

32 H. Adolf, n 26 above, 49.

33 ibid.

34 ibid.

countries started to rationalise how the system could be utilised to their benefit, within their economic strength and technological development. This change of perception was particularly relevant during the 'second round of negotiations' that is during the review process of Article 27.3(b), as will be shown in section 3 of this chapter.

The main reason that prompted developing countries to negotiate in the Uruguay Round Meeting was their anticipation of gains from other trade areas which were concurrently being negotiated during the Meeting.[35] Developing countries are major producers of commodities such as agricultural goods, textiles and clothing. The negotiations were seen as a gateway to international market opportunities for these products which could assist the growth of their economies.[36] In this way, it can be concluded that the focus of developing countries during the Meeting was on the success of other Agreements attached to the WTO Agreement, rather than the TRIPs Agreement which was the focal point for developed countries. As regards the TRIPs Agreement, due to their lack of capital and technological expertise,[37] much hope was put by developing countries on the potential of technology transfer[38] (being the 'Objective' of the Agreement),[39] to obtain necessary technologies to develop their economies.

Since the negotiations involved the major economic players in the world where highly technological industries are mainly located, developing countries could already foresee the

---

35 The Agreement was an Annexe to the Agreement Establishing the World Trade Organisation (WTO Agreement) together with 13 Multilateral Agreements on Trade in Goods. The Multilateral Agreement on Trade are; General Agreement on Tariffs and Trade 1994 and Agreements on Agriculture, Application of Sanitary and Phytosanitary Measures, Textiles and Clothing, Technical Barriers to Trade, Trade-Related Investment Measures, Implementation of Articles VI and VII of the General Agreement on Tariffs and Trade, Preshipment Inspection, Rules of Origin, Import Licensing Procedures, Subsidies and Countervailing Measures and Safeguards. See M. Blakeney, n 13 above, 7. These other Agreements will however, not to be discussed further in this thesis.

36 A.O. Adede, n 18 above, 31.

37 A.M. Pacon, What will TRIPs do for developing countries? in F.K. Beier and G. Schricker (eds), *From GATT to TRIPS – the Agreement on Trade-related Aspects of IPRs* (New York: Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1996) 343.

38 A. Howard and J. Reinbothe, The state of play in the negotiations on TRIPs (GATT/Uruguay Round) (1991) 13 *European Intellectual Property Review*, 5, 158.

39 Article 7 of the TRIPs Agreement.

high standard of protection that would be required from them in order to protect the interests of developed countries. This led to their opposition to a prescribed scope and standard of protection for patent rights. Such a standard has been viewed by developing countries as creating an imbalance in benefits and a greater economic gap between them and developed countries.[40] Whereas they would be obliged to accord protection to innovations which are mostly developed by industrialised countries, they anticipated the unequal benefits that they could obtain from the imposed standard, due to their weaker capability in economic and technological development. In evidence, in the late 1980s developing countries held only about 1% of all patents in biotechnology, and by 2005 that figure has increased but to only 4%.[41] Consequently, it has been developing countries' consistent stance that the regulation of IPRs affects the 'sovereign rights of all countries'[42] and therefore, needs to be made on the basis of their own national standards and requirements.

The differences in objectives and expectations of developed and developing countries are also relevant in the context of the shift of regulatory regime discussed earlier. For developed countries which prefer strong enforcement for IPRs globally, the GATT is the most appropriate forum to achieve this aim. However, for developing countries, their lack of technological development was the basis for their argument that IPRs should remain under the WIPO, rather than being placed under the GATT. Allowing IPRs to be moved under the GATT, where strict enforcement mechanisms are available, would expose them to economic trade sanctions if they failed to accommodate the economic interests of developed countries. Notwithstanding the diverse views between developed and developing countries, the TRIPs

[40] C. Oh, IPRs and biological resources: implications for developing countries (2003) 8 *Journal of Intellectual Property Rights*, 405.

[41] G.K. Rosendal, Balancing access and benefit sharing and legal protection of innovations from bioprospecting: impacts on conservation of biodiversity (2006) 15 *The Journal of Environment and Development*, 4, 432.

[42] H. Adolf, n 26 above, 57.

Agreement was concluded in 1994 and came into effect a year later. On the one hand, for developed countries, this conclusion marked their achievement in getting developing countries to agree on the various IPRs rules prescribed by the TRIPs Agreement. Most importantly it was for securing the enforcement of the rights under the international trade regime. On the other hand, for developing countries, accepting the TRIPs Agreement as a package of the negotiations has been described by critics[43] as a 'price that they had to pay' in the exchange for concessions in issues salient to them such as market access in agricultural and textile trade.

After this review of the diverse expectations and interests of developed and developing countries on the general aspect of international IPRs, the next sub-section will focus on their views on patent protection involving biotechnological inventions, in particular animal inventions. As the discussion will demonstrate, the negotiators had different views as to the need to protect animal inventions under the patent regime. The final adopted version of Article 27.3(b) will be analysed to show how this divergence was 'reconciled' at the end of the Meeting. The analysis will reveal that, the solution has only aimed at the 'speedy' conclusion of the TRIPs Agreement, which eventually led to the review of Article 27.3(b) within the WTO.

[43] M. Matsushita et al, n 21 above, 697; A.O. Adede, n 18 above, 34.

2.2 Patent protection for animal inventions during the negotiation period

2.2.1 Proposals from the negotiators

Negotiating countries were divided in their proposals as far as the exclusion of animal inventions was concerned. The proposals could be broadly divided into two categories: (1) the countries which proposed their inclusion within the patent regime; and (2) the countries which suggested their exclusion. Proposals for the first category came from negotiating countries such as the US,[44] Switzerland,[45] Japan[46] and Australia.[47] These countries generally urged for broad patent coverage without any exclusion for inventions involving living matter.[48] Proposals for the second category came from three groups of negotiating countries. The first proposal came from the European Community (which later became the EU)[49] and the second was communicated by the Negotiating Group of the Nordic countries.[50] The final proposal came from fourteen countries from developing world, which comprised Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe.[51] These proposals reflected the adopted nature of the patent law and biotechnology policies already practised by the negotiating countries. In the context of

---

[44] GATT, 'Draft Agreement on the Trade-Related Aspects of IPRs: Communication from the US', Document MTN.GNG/NG11/W/70 (11 May 1990) Article 23, 9.

[45] GATT, 'Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Aspects of IPRs: Communication from the Switzerland', Document MTN.GNG/NG11/W/73 (14 May 1990) Article 229, 13.

[46] GATT, 'Main Elements of a Legal Text for TRIPS: Communication from Japan', Document MTN.GNG/NG11/W/74 (15 May 1990) 10.

[47] GATT, 'Standards and Norms for Negotiations on Trade-Related Aspects of IPRs: Communication from Australia', Document MTN.GNG/NG11/W/35 (10 July 1989) 3.

[48] T.P. Stewart, n 23 above, 2294.

[49] GATT, 'Guidelines and Objectives Proposed by the EU for the Negotiations on Trade Related Aspects of Substantive Standards of IPRs', Document MTN.GNG/NG11/W/26 (7 July 1988) 5-6. Similar position was later proposed in GATT, 'Draft Agreement on Trade-Related Aspects of IPRs', Document MTN.GNG/NG11/W/68 (29 March 1990) Article 23, 7-8.

[50] GATT, 'Proposal by the Nordic Countries for the Negotiations on Standards and Principles for Trade-Related Aspects of IPRs', Document MTN.GNG/NG11/W/36 (10 July 1989) 1-2.

[51] GATT, 'Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay', Document MTN.GNG/NG11/W/71 (14 May 1990) Article 4(1), 8.

international negotiations such as the Uruguay Round Meeting it would normally have been the intention of each negotiating country, to seek to ensure that that the Meeting would adopt the proposal that each had forwarded. This is because, assuming that the Meeting adopted a different principle from the one forwarded by a negotiating country, the relevant country would need to amend its national law to suit the requirement under the concluded agreement. It is beneficial that the development of patent protection involving living matter in some of the negotiating countries be discussed at this juncture so as to understand their laws, policies and practices relating to the subject matter.

It is pertinent to note that, traditionally, the grant of patent protection was limited to technical, mechanical and chemical inventions. §101 of the 35th Title US Code (§101 35 USC)[52] provides for a broad range of matter that could be patentable. Nevertheless, in practice, despite the granting of patent by the US Patent and Trademark Office (USPTO) to Louis Pasteur in 1873, the patent office consistently refused claims to life forms as not being patentable subject matter.[53] It has been observed[54] that the key precedent discouraging the patenting of life in the US was the decision given by the patent office in the case of *Ex Parte Latimer*,[55] which later formed the basis of the principle known as the 'product of nature' doctrine. In that case, the Commissioner of the USPTO in refusing a patent application which covered a fibre identified in the needles of a pine tree said that, 'it would be unreasonable and impossible to allow patents upon the trees of the forest and the plants of the earth.'[56] Based

[52] Available at: US Patent and Trademark Office (USPTO), http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf (Accessed: 31 March 2012). § 101 provides: Patentable inventions: 'Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title'.

[53] P. Grubb, *Patents for chemicals, pharmaceuticals and biotechnology: fundamentals of global law, practice and strategy* (Oxford: Oxford University Press, 1999) 227.

[54] D.J. Kevles, *A history of patenting life in the US with comparative attention to Europe and Canada* (Luxembourg: Office for Official Publications of the European Communities, 2002) 1.

[55] (1889) Dec. Com. Pat., 123.

[56] D.J. Kelves, n 54 above, ibid.

on this doctrine, life forms such as plants, animals and micro-organisms have been consistently held to be unpatentable.

As regards animals and micro-organisms, the long-held 'product of nature' doctrine was radically changed in 1980 due to the US Supreme Court's decision in the case of *Diamond v Chakrabarty* (the *Chakrabarty* case).[57] In the case, the patentability of a bacterium capable of breaking down multiple components of crude oil which was developed by the applicant was at issue. The USPTO refused the application in the first instance, since the claimed micro-organisms were a 'product of nature'.[58] However, the Supreme Court granted the patent sought for and made an important ruling where it was held that the patentability of an invention did not depend on the question whether it related to animate or inanimate matter, but rather whether or not the invention is made by man.[59] This finding has led to the evolution of the principle that 'anything under the sun manufactured by man is patentable', which allows patent examiners to consider the patentability of life forms, provided they meet the usual patentability criteria.[60]

While patent protection is territorial in nature, economic competition is key to the international patent law framework. In Japan, which is another major player of the world's economy, there has also been a consistent move toward enabling patent law to protect life forms. Starting with five categories originally excluded in the Patent Act 1959, the list became thinner with only products which are 'likely to disturb public order or morals or to be

[57] *Diamond, Commissioner of Patents and Trademarks v Chakrabarty* [1980] 447 US 303; 100 SCt 2204.
[58] ibid. 305.
[59] ibid. 312.
[60] Even though §101 35 USC allows wide scope for patentable inventions, it still has a limitation where the laws of nature, physical phenomena and abstract ideas have been held not patentable by the US courts. See observation by Burger CJ in *Diamond, Commissioner of Patents and Trademarks v Chakrabarty*, at 309.

injurious to public health' to be excluded.[61] While living organisms have never specifically been on the excluded list, micro-organisms and genetic materials became patentable in 1979 with the amendment to the patent examiners' guidelines by the Japan Patent Office (JPO).[62]

Moving on to Australia, under the Australian Patents Act 1990,[63] genetically modified organisms (GMOs) are patentable unless the use of the claimed invention is contrary to law under s51(1) or where it falls under the 'general inconvenience' exception under s18(1).[64] The phrase 'contrary to law' is limited to the instance where the use of the invention will be a criminal offence and, as far as the 'general inconvenience' exception is concerned, it has been used in Australia to deny patent claims only for subject matter to which the public expects free access, such as a method of operating a computer.[65]

Principally, the above developed countries' stance as to the patentability of life forms is that the policy of not excluding anything from being the subject matter of a patent or from patent protection is necessary in order to encourage innovation, help disseminate ideas and increase trade. Furthermore, since they are the nations which are already the most advanced in technology, these countries have the most to gain in terms of finance and power from the broad protection of biotechnological inventions.

---

61 The Patent Act is available at: Japan Patent Office, http://www.cas.go.jp/jp/seisaku/hourei/data/PA.pdf (Accessed: 31 March 2012). The original list comprised of foods and additives, drugs and methods to combine two or more drugs, substances produced chemically, substances produced by a method of transforming atomic nuclei, products which are likely to disturb public order or morals or to be injurious to public health. See G. Dutfield, *IPRs and the life science industry: past, present and future* (World Scientific, 2009) 211.

62 ibid. Plants became patentable in 1985 and animals in 1993. In 1979, the JPO issued standards for the patenting of biotechnological inventions under the following categories: Micro-organisms, processes for producing micro-organisms, processes using micro-organisms, products obtained from micro-biological sources, DNA and RNA molecules or sub-cellular units.

63 Available at WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=203130 (Accessed: 31 March 2012).

64 K. Ludlow, Genetically modified organisms and their products as patentable subject-matter in Australia, (1999) 21 *European Intellectual Property Review*, 6, 298-312.

65 ibid.

The proposals to exclude animal inventions by the EU and the Nordic countries can be understood by looking at the historical background and perceptions of their own patent laws. Their proposals were fundamentally influenced by the existence of a similar provision which had been included long before in Article 2(b) of the Strasbourg Convention and Article 53(b). This was further evidenced by an admission to this effect made by the representative of this group when the reason for proposing this exclusion was requested by other negotiators during the Uruguay Round Meeting.[66] Having the exclusion in the two European Patent Conventions, it was therefore, to be expected that the EU would forward a proposal which contained a similar exclusion.

The patentability of an invention involving living matter started to become relevant in the EU Member States as early as 1969, where in the case of *Rote Taube*,[67] the German Federal Supreme Court held that a method for breeding better quality doves was patentable, provided that it fulfilled the repeatability requirement. In the course of its judgement, the court made an important ruling when it stated that, in principle, the possibility of patenting is not excluded by the fact that living matter is involved. [68] This decision seems to suggest that the door to allowing patent protection for inventions involving living matter in Europe is permitted provided the patent qualification criteria are met. However, it will be shown in chapter 4 that the rule is not that straight forward, when Article 53(b) which excludes animal varieties is analysed.

---

66 GATT, 'Meeting of Negotiating Group of 12-14 July 1989', Document MTN.GNG/NG11/14 (12 September 1989) 3.

67 [1970] 1 IIC 136.

68 ibid. Nevertheless, in this case, the application to patent the breeding method was refused because of the failure of the applicant to repeat the method and to enable a person skilled in the art to produce the same result.

The basis of the proposal from developing countries was that potential Signatories should be given the freedom to exclude certain subject matter from patentability. The built-in flexibility was averred[69] to be necessary in view of various issues that required due consideration. This includes differences in the economic level of the negotiating countries and the need to take into account particular national interests[70] such as socio-economic needs, technological advancement,[71] ethical, and environmental issues. The uncertainty with regard to the economic consequences that could be caused by research activities in biotechnology[72] were also among the concerns of developing countries. As will be shown in sub-section 2.2.2 below, the drafts of the provision relating to the protection for animal inventions during the Uruguay Round Meeting similarly reflect the diverse views and national practice among the negotiating countries.

2.2.2 The drafts of the exclusionary provisions

As the negotiations developed, the drafts containing the exclusion of animal inventions during the Uruguay Round Meeting were contained in three documents: (1) the Anell Draft; (2) the Dunkel Draft; and (3) the Brussels Draft. The prepared drafts were essentially a compilation of the options for the various legal commitments as they had emerged from the process of informal consultations.

---

[69] GATT, 'Standards and Principles Concerning the Availability, Scope and Use of Trade-related Aspects of IPRs: Communication from India', Document MTN.GNG/NG11/W/37 (10 July 1989) 7-9; GATT, 'Communication from Brazil', Document MTN.GNG.NG11/W/57 (11 December 1989) 4.

[70] GATT, 'Meeting of Negotiating Group of 30 October-2 November 1989', Document MTN.GNG/NG11/16 (4 December 1989) 20.

[71] GATT, 'Standards and Principles Concerning the Availability, Scope and Use of Trade-related Aspects of IPRs: Communication from India', n 69 above, 9.

[72] GATT, 'Submission from Canada', Document MTN.GNG/NG11/W/47 (25 October 1989) 7.

The Anell Draft [73] was the first draft of the TRIPs Agreement which was prepared by the Ambassador Lars E. R. Anell (Chairman of the Negotiation Group) in his administrative capacity, with the aim of expediting the business of the meeting toward the conclusion of the TRIPs Agreement. Under this Draft, as far as animal inventions were concerned, the options of exactly what was to be excluded were still left open. Two questions which then became an issue were: (1) whether the exclusion of the invention was to be made mandatory or permissive; and (2) whether the term 'animals' or 'animal varieties' was to be adopted to represent the exclusion of animal inventions from patent protection. There is however, no documented evidence in the Negotiating Group's papers to show that the wording of the provision (relating to animal inventions) was debated.

The Anell Draft remained under discussion by the Negotiation Groups for four months until the emergence of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations [74] that was submitted to the Ministerial Meeting in Brussels (Brussels Draft) in December 1990. In the Brussels Draft, the relevant exclusionary provision was expanded to provide a number of other versions to be considered. Whereas there was still no conclusive decision with regard to the term that should represent the exclusion, at this stage, an agreement had been obtained for the exclusion to be made optional rather than mandatory.

The Brussels Ministerial Meeting was supposed to conclude the Uruguay Round Meeting,[75] including the provision which contained the exclusion of animal inventions. However, due to

[73] GATT, 'Status of Work in the Negotiation Group: Chairman's Report to the GNG', Document MTN.GNG/NG11/W/76 (23 July1990) 17.
[74] GATT, 'Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', Document MTN.TNC/W/35/Rev. 1 (3 December 1990) 208.
[75] GATT, 'Meeting at Ministerial Level, Brussels, 3-7 December 1990', Document MTN.TNC/18 (MIN) (18 December 1990) 9-10.

the ‘undecided’ position (as demonstrated by the availability of the options for the term to represent the exclusion) this provision (together with many other key areas of negotiations)[76] was sent back to the Trade Negotiations Committee (TNC) for further consideration. The Brussels Draft became the working text for the TNC (under the chairmanship of Mr Arthur Dunkel)[77] until the finalisation of the document prepared for the purpose of concluding the Uruguay Round.[78] The exclusionary provision contained in the final document (Dunkel Draft), which formed the final text of the TRIPs Agreement, showed that a decision had finally been made that the term ‘animals’ should be adopted by the Agreement. However, there was again no information available as to why the final text was chosen by the TNC.

2.2.3 The ‘compromise solution’

The developments of the exclusion of animal inventions as discussed in sub-sections 2.2.1 and 2.2.2 above pointed in the direction of a ‘compromise solution’. Whereas the original proposals by the three groups of the negotiating countries to exclude animal varieties and the broad protection sought by developed countries had both been compromised, the exclusion of animal inventions was principally accepted by the negotiating countries. Nevertheless, the proposal by the EU and developing countries to secure the exclusion seems to have prevailed over the proposal of their developed counterparts which required broad protection to be explicitly recognised by the TRIPs Agreement.

---

[76] Including issues on most-favoured-nation treatment, copyrights and related rights, trademarks, patent, and layout-designs of integrated circuits. See GATT, n 74 above, 193-195.

[77] At this stage, a new structure of the Group of Negotiations on Goods had been re-established to conduct further negotiations. Six groups were established to cover areas including market access, textiles and clothing, agriculture, rule-making, TRIPs and institutions. Ambassador Lars E.R. Anell was appointed as chairman to moderate negotiations on TRIPs. See GATT, ‘Trade Negotiations Committee 16th Meeting on 25 April 1991’, Document MTN.TNC/20 (7 May 1991) 2.

[78] GATT, ‘Draft Final Act Embodying the Results of the Uruguay Round on Multilateral Trade Negotiations’, Document MTN.TNC/W/FA (20 December 1991).

The biggest compromise must have come from the US. As noted by Straus:[79] 'the US was originally categorically opposed to an exclusion for plants and animals. It finally concurred because the provision only provides for an optional exclusion which need not be implemented by the US'. Notably, one of the principles agreed upon by all the negotiating countries in the Ministerial Declaration on the Uruguay Round[80] was that developed contracting parties should not seek, nor should developing contracting parties be required to make, concessions which were inconsistent with, their development, and financial and trading needs.[81] This general principle governing the negotiations seems to have been the basis for the flexibility granted to the negotiating countries which have different levels of economic and technological growth.

The decision to allow the negotiating countries to exclude animal inventions was indeed an inevitable step. It was meant to ensure that the countries which have divergent views on the patentability of biotechnological inventions came together, to agree to become Signatories to such a complex multilateral Agreement. Consequently, any provision which was included in the TRIPs Agreement must be seen as having considered the interests of developed and developing countries. In this context, the WTO could be seen as a 'moderator' which balances the interests of negotiating countries. Conversely, it can equally be concluded that such flexibility does not necessarily mean a balance of interests. In this respect, critics[82] have urged that developing countries should maximise the use of the flexibility under Article 27.3(b) in view of their progress in economy and technology. However, the practical

---

79 See A. Heinemann, Trade-related aspects of IPRs: report on the 9th Ringberg Symposium from July 6 to 8, 1995 in F.K. Beier et al, n 37 above, 416.

80 GATT, 'Ministerial Declaration on the Uruguay Round', Document GATT/1396 (25 September 1986) 4.

81 GATT, 'Mid Term Meeting', Document MTN.TNC/11 (21 April 1989) 21.

82 C.M. Correa, Implementing the TRIPs Agreement in the patents field: options for developing countries (1998) 1 *Journal of World Intellectual Property*, 1, 85-87; J. Watal, Implementing the TRIPs Agreement on patents: optimal legislative strategies for developing countries in O. Lippert (ed), *Competitive strategies for the protection of intellectual property* (Canada: Fraser Institute, 1999) 109.

application may not be without problems. The subjectivity of what is meant by 'minimum standard' of protection could inevitably put developing countries under pressure to strengthen the IPRs protection as intended by developed countries. Evidentially, bilateral agreements have been used by the US for this purpose.[83] Moreover, the general rule of patentability under Article 27.1 could also be used by industrialised countries to press for broad patent protection[84] because this very general principle is capable of narrowing down or overriding the flexibility given by Article 27.3(b). The situation may be different altogether if there were a specific provision in the TRIPs Agreement, stating that the option by any Signatory to exercise such flexibility is conclusive.

While having broad protection for living matter is important for developed countries, getting as many countries as possible to agree to become Signatories to such an international trade-based Agreement is arguably of greater achievement to their economy. Through the TRIPs Agreement, various other aspects of patenting such as terms of protection and licensing of patent products and processes are able to be internationally regulated and any non-compliance with these other issues could be effectively enforced.[85] Intrinsically, an important area which was left undecided by the negotiation process of the Uruguay Round Meeting is the subject matter excluded under Article 27.3(b). The decision to adopt the term 'animals', rather than the term 'animal varieties', as proposed by a small group of countries to represent the exclusion remains unclear. The minutes of the various proceedings, either in the documents forwarded by those countries proposing the exclusion or by the representatives in

[83] H. Adolf, n 26 above, 53-54. For instance, the 2000 bilateral agreement between the US and Jordan requires patents to be available for any invention in all fields of technology without including the exceptions contained in Article 27.3(b) of the TRIPs Agreement. See G. Dutfield, Sharing the benefits of biodiversity: is there a role for the patent system? (2002) *The Journal of World Intellectual Property Law*, 929, at footnote 85.

[84] C.M. Correa, Patent rights in C.M. Correa and A.A. Yusuf (eds), *Intellectual property and international trade: the TRIPS Agreement* (Wolters Kluwer, 2008) 229.

[85] H. Adolf, n 26 above, ibid.

discussing the form of the exclusion, show that no attempt was made to define what these terms mean. Therefore, as the term 'animals' has not been defined anywhere in the TRIPs Agreement, Signatories can exercise their discretion to determine the subject matter of the exclusion.

This section has shown how the exclusion of animal inventions was included in the TRIPs Agreement. It arose from the differences in national practice and perspectives of the negotiating countries toward the patentability of inventions involving living matter, which each country has tried to pursue at the international level. Notably, this is underpinned by different technological and economic development of the negotiating countries. The conclusion of the Uruguay Round Meeting in view of various international trade regulations contained therein was a paramount objective of GATT. As regards the exclusion under Article 27.3(b), assuming any decision was made in favour of any particular negotiating country, the success of concluding the TRIPs Agreement would be seriously prejudiced. The outcome of the Uruguay Round Meeting, by providing the negotiating countries with flexibility to exclude animal inventions from patent protection is therefore expected. Nevertheless, the achievement of the 'compromised solution' as contained in Article 27.3(b) marked the beginning of another episode of debate under the international IPRs regime.

In this respect, as explained by critics,[86] whereas an international agreement was concluded, the forum shopping does not necessarily end. During the review process of an agreement, countries would utilise the given regulatory regime to either argue in favour of adding a new issue to, or removing an existing issue from, the concluded agreement.[87] This rule precisely explains the current development in the review process of Article 27.3(b) which is the focus

[86] D.D. Bièvre et al, n 5 above, 3.
[87] ibid.

of the following section. The discussion will show that the flexibility granted to the Signatories to exclude animal inventions, has subjected Article 27.3(b) to greater complexities during the review process. Central to the discussion is an assessment of the issues which have been debated between developed and developing countries, and suggestions as to how the latter countries could advance their technology and economy by allowing patent protection to animal inventions while observing their rights and interests under the CBD. The discussion is relevant to the research question so as to inform a Signatory (including Malaysia) of international patent law issues pertaining to the exclusion of animal inventions which requires consideration in construing the relevant exclusionary provision within its national patent law.

3. The Present: the on-going review process of Article 27.3(b)

At the commencement of the review, the focus was mainly on issues pertaining to the subject matter of the exclusion under Article 27.3(b). This includes the question of whether or not the exclusion of animal inventions should remain in, or be deleted from the Article, and the clarification of some terms adopted by the Article: animals, micro-organisms, and patentable and non-patentable processes. While this agenda is still relevant, the review of Article 27.3(b) has, since 2001, included broader policy issues, which relate the implications of patenting living matter to the national interests of the negotiating parties. The inclusion of the new agenda depicts the increasing recognition within the WTO of the challenges faced by developing countries in implementing the provisions of the TRIPs Agreement.

3.1 The general perspectives of the negotiating countries

The term 'biotechnological invention', including animal inventions, in the context of patent rights triggers different perspectives 'in the mind' of developed and developing countries. For developed countries, the focus is primarily on commercial value and hence the question of how investments devoted to develop them could be recouped. This view can be easily appreciated if one looks into the amount of investments (in term of financial and technological expertise) spent in developing an invention.[88] Therefore, it is not surprising that developed countries are reluctant to enter into R&D, technology transfer, or licensing agreements in respect of their biotechnological inventions unless they are guaranteed exclusive rights.[89]

In contrast, for developing countries, the term 'biotechnological invention' has far reaching implications, and should not be purely assessed on its economic value. Developing countries have been known as important providers of biological resources[90] which are required for the development of research by life-science industries in developed world. As a result, they have claimed that their contribution should be equally recognised within the international IPRs framework. Patent protection for biotechnological inventions has been perceived by developing countries as a powerful tool that would allow developed countries to manipulate their genetic resources without appropriate economic return. In the long term, they argue that this practice would hinder technological development in their countries where the protection will be used to block access and the transfer of technology. Consequently, they require the term 'biotechnological invention' to be associated with other aspects including the value and sustainable development of biological resources, recognition of traditional knowledge which

88 K.W. McCabe, n 29 above, 48.
89 ibid. 50.
90 UNCTAD-ICTSD, *Resource book on TRIPS and development* (Cambridge University Press, 2005), 410.

has been developed for generations by their populations, and equal sharing of commercial profits arising from the manipulation of the genetic resources.[91] These divergences of perspective have created considerable tensions hence complicate the interpretation and application of the exclusion of animal inventions under Article 27.3(b). The following discussion will assess pertinent aspects which have been debated during the review process. They can be broadly categorised under: (1) patentability of life forms; and (2) issues relating to the CBD.

3.2 Pertinent issues debated between developed and developing countries

3.2.1 Patentability of life forms

3.2.1.1 Progress of the review

So far, there are mixed views as to whether the exclusion of animals under Article 27.3(b) should be retained or deleted.[92] Specifically, the views can be assigned to four categories: (1) that the exclusion is unnecessary and animal inventions should be patentable; (2) that the exclusion should be maintained as it is, with no lowering of the level of protection; (3) that the exclusion should be retained, but clarification or definitions of certain terms used are to be provided; and (4) that the exclusion should be amended or clarified to the effect that it should prohibit the patenting of all life forms, including their parts and natural processes which produce them.[93] The proponents to the first and second views are technologically-

[91] See for instance R.V. Anuradha, IPRs: implications for biodiversity and local and indigenous communities (2001) 10 *Review of European Community and International Environmental Law*, 1, 27-36; G. Dutfield, n 83 above, 899- 931; G.K. Rosendal, n 41 above, 428-447.

[92] See WTO, 'Review of the provisions of Article 27.3(b): Summary of issues raised and points made', Document IP/C/W/369/Rev.1 (9 March 2006) 4.

[93] ibid.

developed countries such as the US, Singapore, Australia, Canada, China, Korea, the EU, Japan, Singapore and Switzerland. Underpinning their views is that life forms can constitute inventions and their exclusion would hinder R&D activities, hence affecting economic advancement. [94] Conversely, countries which fall under the two latter categories are developing countries such as Brazil, India, Peru, Thailand, Kenya (on behalf of the African Group), Zimbabwe and Bangladesh.[95] This latter group of countries are primarily of the view that life forms are discoveries rather than inventions.[96] The main issues relating to these opposing views are elaborated further in sub-sections 3.2.1.2, 3.2.1.3 and 3.2.1.4 below.

3.2.1.2 Meaning of the terms adopted in Article 27.3(b)

There have been varying interpretations among critics as what could be excluded under Article 27.3(b). For instance, it has been contended[97] that the exclusion of 'animals' suggests the exclusion of even genetically altered animals. This construction appears to demonstrate the 'exclude all' rule. A question which may arise is: what is the difference between the term 'animals' under Article 27.3(b) of the TRIPs Agreement and the term 'animal varieties' under Article 53(b) of the EPC, with respect to the subject matter excluded under both provisions? While at a brief glance, they both seem to be linguistically similar, it has been suggested that the subject matter of exclusion carried by the terms is different, due to the construction of the provision. Some critics[98] have asserted that the term 'animals' has a broader meaning than 'animal varieties'. In the context of Article 53(b),[99] the contention is based on an analogy with the term 'plants' (which means plants in general) and 'plant varieties' (which means a

94 ibid.
95 ibid.
96 ibid.
97 M. Matsushita et al, n 21 above, 727.
98 J. Straus, Implications of the TRIPs Agreement in the field of patent law in F.K. Beier et al, n 37 above, 183; C.M. Correa, in C.M. Correa et al, n 84 above, 232.
99 See Appendix 5.

particular classification of plant in the plant kingdom), when they are contained in the same provision.[100] A few cases decided by the EPO such as *Ciba-Geigy/Propagating Material*[101] and *Lubrizol/Hybrid Plants*[102] have established this principle.[103] As such, it has been argued[104] that, on the one hand, Article 27.3(b) is to be interpreted broadly, and with regard to 'animals', the exclusion may cover transgenic animals and animal races.[105] On the other hand, based on the non-definitive flexibility suggested by Article 27.3(b), it has also been argued[106] that Signatories may also opt to exclude from patentability only certain categories of plant and animal inventions. A justification for construing the term 'animals' narrowly arises from the fact that Article 27.3(b) is an exception to the general rule of patentability under Article 27.1.[107] As a matter of fact, this narrow interpretation has been adopted by the EPO in construing term 'animal varieties' to mean only certain categories of animals and not animals *per se*.

For Signatories, most of which are developed countries,[108] which choose not to exclude animal inventions from their national patent law, intricacies as to the meaning, and therefore the subject matter of the exclusion as illustrated above, will not arise. Nevertheless, for countries which adopt the exclusion in their national patent laws (many of which are developing countries),[109] Article 27.3(b) would inevitably invite various possible interpretations. It may amount to 'all animal inventions are unpatentable' or 'only certain

[100] See UNCTAD-ICTSD, n 90 above, 392. According to Linnaean hierarchy (as developed by Linnaeus in 1758), living organisms are scientifically classified into seven categories: Kingdom, Phylum, Class, Order, Family, Genus and Species. See G.G. Simpson, *Principles of animal taxonomy* (London: Oxford University Press, 1961) 16. This classification for the animal Kingdom will be dealt with in detail in sub-section 3.2 of chapter 4.
[101] [1979-85] EPOR 758; [1984] OJ EPO 112.
[102] [1990] EPOR 173.
[103] This is further discussed in sub-section 3.2 of chapter 4.
[104] C.M. Correa, n 82 above, ibid.
[105] UNCTAD-ICTSD, n 90 above, ibid.
[106] ibid.
[107] D. Gervais, *The TRIPS Agreement: drafting history and analysis* (London: Sweet and Maxwell, 2008), 351.
[108] OECD, 'Intellectual property practices in the field of biotechnology', Document TD/TC/WP (98) 15/Final (2 February 1999).
[109] UNCTAD-ICTSD, n 90 above, 405.

animal inventions are unpatentable'. The latter seems to invite more potential arguments than the former, since there will be a need for a clear guideline within the national patent laws or the patent examiners' guidelines of a list of what could constitute patentable animal inventions and what could not. Yet the existence of the list could not be said to resolve the matter. As science and technologies progress rapidly, the list would need constant revision. A definition which is relevant this year might not be relevant in five years time. Bearing in mind that patent applications may take nearly five years to be granted,[110] a specific definition is likely to prejudice an applicant in various aspects. An applicant may need to amend the specification attached to an application in order to ensure that the claim falls within the patentable subject matter. Consequently, this would cause additional costs to the applicant. The matter is exacerbated if translations to documentation are required by the relevant patent office.[111] On the administrative aspect of a national patent system, this could lead to endless amendments to the national patent laws or patent offices' guidelines which would burden the legislature and patent offices.

[110] Depending on the additional procedures that may be involved, patent applications in the UK may take up to four and a half years to be granted. However, a typical patent application takes two to three years to be granted. See United Kingdom Intellectual Property Office (UKIPO), http://www.ipo.gov.uk/types/patent/p-applying/p- after.htm (Accessed: 22 February 2011).

[111] For instance, Article 1(3) of the London Agreement allows Member States of the EPC, which do not have English, French or German as their official languages to require that, for a patent to be valid, the claims must be translated into the local language. Article 65 of the EPC allows Member States to require the patent to be translated into the national language as a prerequisite for validity. This translation requirement increased the cost of European patents, taking into consideration that there are twenty three different languages for thirty four Member States of the EPC. The London Agreement aims to reduce this translation cost where Articles 1(1) and 1(2), respectively, provide that both Signatory parties that share the official language of the EPO and those that do not have the three official languages as their official language must dispense with the translation requirement. Nevertheless, the Netherlands, Sweden and Denmark for instance, require that the claims be translated into their official languages and also that the description be published in English. See L. Bentley and B. Sherman, *Intellectual property law* (Oxford University Press, 2009) 345.

3.2.1.3 Should the terms under Article 27.3(b) be defined?

The absence of an exact meaning for the terms has been a concern which was raised by a group of developing countries in international forums.[112] This can be surmised since it relates to their international obligation to provide a 'minimum standard' of protection required by the TRIPs Agreement. So far, there is no hard evidence to show that the deviation in terms of interpretation from the standard set out by the main granting office could cause a particular country which chooses to depart from such a standard, to be subject to any international enforcement procedures such as the WTO's.[113] Nevertheless, when international patent law with regard to the exclusion of animal inventions is evaluated, the interpretation given by a particular main granting office (in particular in developed countries) could become relevant to the case. The narrow interpretation of the term 'animal varieties' under Article 53(b), is an illustration. Since the excluded subject matter is determined by the EPO, which is the main patent-granting office for a significant number of developed countries[114] and which was one of the driving forces behind the introduction of the WTO,[115] it cannot easily be ignored by other Signatories to the TRIPs Agreement which have a similar exclusion. It has been highlighted[116] that where a provision has an existing jurisprudence (such as that applied by the EPO in respect of Article 53(b)) and this was known at the time the TRIPs Agreement came into being, then this should, at least, be taken into account when determining if a

[112] M. Khor, ASEAN raises concerns on life patenting at the WTO (1995) *Third World Economics*, 6. The Association of Southeast Asian Nations (ASEAN) comprises ten countries; Malaysia, Singapore, Indonesia, the Philippines, Brunei, Cambodia, Laos, Myanmar, Thailand and Vietnam.

[113] Observation based on the nature of cases which are subject to the WTO dispute settlement procedures. See WTO, Dispute settlement: the disputes, http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#selected_subject (Accessed: 10 July 2010).

[114] There are thirty seven current Member States of the EPC plus three extension states. EPO, Member States of the European Patent Organisation, http://www.epo.org/about-us/epo/member-states.html (Accessed: 8 June 2010).

[115] Which plays a powerful role in the development of national intellectual property laws, not least because it oversees the administration of the TRIPs Agreement.

[116] M. Adcock and M. Llewelyn, Micro-organisms, definitions and options under TRIPS, Paper prepared for a discussion meeting hosted by the Quaker UN Office (Geneva) and the International Centre for Trade and Sustainable Development, 2000, 11.

Signatory has reached that minimum standard. In this respect, the subject matter which other countries might wish to exclude would require careful consideration as any 'deviation' from the decided 'standard protection' might attract criticism and the countries might be regarded as in breach of their obligations under the WTO law (including the TRIPs Agreement).[117]

Due to the ambiguity of Article 27.3(b), developing countries such as India, Kenya (on behalf of the African Group), Pakistan and Zimbabwe, have suggested during the review process that the provision be made clear by excluding all life forms and biological materials such as cells, cell lines, genes and genomes.[118] These countries argued that the latter are not patentable since they cannot qualify as micro-organisms, being the only category that is mandatorily patentable under Article 27.3(b). In particular, the African Group[119] asserted that there is only an 'artificial distinction' between animals and micro-organisms, since there is no scientific basis for this division and allowing patents for these materials contravenes the basic principle of patent law, in which only invention (and not discovery) can be patentable. Opposing this view, developed countries have averred that the meaning of the terms used in Article 27.3(b) need not be defined and that the distinctions made in Article 27.3(b) are in accordance with the generally accepted scientific classification of organisms and widely accepted in existing international agreements.[120]

There is little doubt that a precise meaning to the terms in Article 27.3(b) would assist a Signatory to implement their obligation where any decision either to allow or refuse animal inventions could be made on a firm basis. In other words, any ambiguity could at least be guided by the Agreement. Yet, subjectivity is still the rule, and therefore any argument for

[117] ibid.
[118] WTO, n 92 above, 8.
[119] ibid.
[120] ibid.

interpreting a particular term remains possible. This point can be illustrated by the fact that in many national legislations even though there is normally a section for 'definition' or 'interpretation' of terms used in the statute, thousands of cases have landed in courts merely due to interpretational problems. Assuming the terms are defined, this would contradict developing countries' stance during the Uruguay Round Meeting, where they were against any prescribed scope and standard of patent protection. Moreover, in a situation where a term is defined differently in a Signatory's patent law, compared to the one underlined by the TRIPs Agreement, this could be argued by another Signatory as non-compliance with the treaty. Consequently, this may cause the dispute settlement mechanism to be invoked against the relevant Signatory, which would cause an adverse effect politically and economically to the same country.[121]

3.2.1.4 Could animal inventions be patentable?

The suggestion of developing countries that all life forms be excluded from the patent regime amounted to arguing that the patentability of life forms which have been well accepted in developed countries since the 1980s be reversed. As aptly observed by critics[122] this would require developed countries to overturn all their jurisprudence on the subject matter. It seems unrealistic for the US and Europe (for instance) to agree to this proposal through the revision of Article 27.3(b),[123] in view of the value of patents of biotechnological inventions to developed countries. As expected, the suggestion by developing countries has been strongly opposed by developed countries during the review process. They maintained that biotechnological inventions (including animal inventions) should be accorded adequate

[121] ibid. 7. Peru made an observation to this possible adverse implication during the review process.
[122] Graham Dutfield, n 83 above, 929.
[123] ibid.

patent protection in the same way as inventions in other fields of technology.[124] Intrinsically, this argument echoed Article 27.1 of the TRIPs Agreement.

Underpinning the contrasting view of developing and developed countries as to whether animal inventions should be patentable at all is the question of whether they can be considered as inventions or are discoveries. This relates the question to the ability of the inventions to fulfil the patent qualification criteria, where the discussion now turns. In the context of this thesis, livestock animals which are produced through animal biotechnology applications such as cattle with increased amount of milk and leaner meat (discussed in chapter 1), can meet the requirement of industrial application without much hurdle. This is because they are created with the aim of being used in the animal husbandry industry. Showing this purpose in a patent claim is therefore sufficient for an applicant for the purpose of satisfying the prerequisite.[125]

Since living matter is involved, novelty and inventive step are two patent conditions which are more crucial. Patent protection is a tool to recognise the intellectual contribution of an inventor. The protection creates a right of exclusivity for the inventor, which he can legally enforce. The concept of novelty for the purpose of patent protection has been specifically defined as something which has not been disclosed in prior art. An inventive step under patent law means the invention must not be obvious to 'the person skilled in the art'. i.e. it must not follow plainly or logically from what is already known. Animal inventions as the term suggests are the result of human manipulation, and can be achieved in three ways:

> (1) direct transgenic alteration of the animal by injecting 'foreign' DNA into freeze-dried sperm, before inserting the recombined sperm into an ovum; (2)

[124] WTO, n 92 above, 2.
[125] Article 57 of the EPC 2000; s4 of the UK Patents Act 1977; L. Bently et al, n 111 above, 393.

> transporting recombined DNA into an animal's embryonic stem cells; and (3) treating the animal at the adult stage by injecting it with transgenically altered DNA.[126]

These procedures involve fundamental human intervention at a micro level to alter an animal's attributes. Animal resources which have not been manipulated in any of these ways (in other words, mere discoveries) are clearly beyond the ambit of patent protection. Therefore, based on the principle of patentability, it is argued that animal inventions which can fulfil these two other conditions are patentable.

Yet another challenging question would arise from the above: are the three above-mentioned ways of alteration sufficient for animal inventions to be treated as having attained novelty and inventive step? The general principle under patent law states that life forms in their natural state would not satisfy the criteria of patentability in the TRIPs Agreement. However, patent jurisprudence and guidelines for patent examiners in developed countries such as the US, Japan and Europe have explicitly provided a certain degree of flexibility to the general rule. For instance, under Article 3.2 of the EU Directive on the Legal Protection of Biotechnological Inventions (EU Biotechnology Directive),[127] 'biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.' Similarly, paragraph 2.3, Part C-IV of the Guidelines of Examination of the European Patent Office[128] provides that 'a substance found in nature is patentable if it is isolated from its surrounding and a process for obtaining it is developed.'

---

[126] A. Warren-Jones, *Patenting rDNA: human and animal biotechnology in the United Kingdom and Europe* (Oxford: Lawtext Publishing, 2001) 23.

[127] The Directive 98/44/EC of the European Parliament and of the Council of July 6, 1988 on the legal protection of biotechnological inventions. Available at: Eur-Lex Europa, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML (Accessed : 3 June 2011).

[128] Available at: EPO, http://documents.epo.org/projects/babylon/eponet.nsf/0/7FFC755AD943703DC12576F00054CACC/$File/guidelines_2010_complete_en.pdf (Accessed: 26 July 2010).

As the TRIPs Agreement does not prescribe the exact threshold of novelty and inventive step that an animal invention needs to achieve, it is too subjective for a precise answer. Therefore, it appears that Signatories are at liberty to impose any threshold on the patentability criteria. Notably, it has been emphasised [129] that due to the lack of consensus on fundamental principles relating to biotechnological inventions such as the degree of novelty, utility, non-obviousness and disclosure, it seems unlikely that a Signatory could use the WTO framework to compel other Signatory to adopt high levels of patent protection for such inventions in the near future. This is why some Signatories in the Andean Community have utilised the flexibility under Article 27.3(b) by including in their patent laws exclusions of biotechnological inventions with specific conditions attached to them. For example, Article 10.IX of the Brazilian Industrial Property Code 1996 excludes:

> all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germplasm of any natural living being, and the natural biological processes. [130]

Similarly, Article 7(b) of the Argentina Invention Patents and Utility Models Act excludes from patentability:

> all biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature. [131]

[129] J.H. Reichman, Universal minimum standards of intellectual property protection in C.M. Correa et al, n 84 above, 38-39.

[130] Law No. 9,279 of 14 May 1996 that Regulates Rights and Obligations Relating to Industrial Property, available at WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=125396 (Accessed: 29 March 2011).

[131] Available at WIPO, http://www.jpo.go.jp/shiryou_e/s_sonota_e/fips_e/pdf/argentine_e/e_tokkyo.pdf (Accessed: 29 March 2011).

Appreciating the current development in the review process, the chances of reaching a definite meaning for the term 'animals' adopted under Article 27.3(b) that would satisfy the perception of all the negotiation parties, are negligible. On the one hand, as far as developing countries are concerned, the provision would be best left as it stands since this is the basis of the flexibility achieved at the end of the Uruguay Round. The non-definitive meaning to the term allows them to interpret the aspect in accordance with their national socio-economic situations and needs. On the other hand, the suggestion of developed countries for the deletion of the exclusion of animal inventions under Article 27.3(b) seems difficult to attain, at least not in the near future. The deletion will invite prevalent criticism since the WTO has itself explicitly recognised the 'demand' of developing countries in its negotiation forum. This can be demonstrated by the agreement of the Organisation for the review process of Article 27.3(b) to also consider issues relating to the CBD within the WTO, which is a result of strong pressure from developing countries before the beginning of the review process.[132]

3.2.2 Issues relating to the CBD

3.2.2.1 Progress of the review

It has been widely accepted that developing countries are the source of the world's biological diversity. However, advanced technology, and the expertise to develop the resources to produce beneficial products, often lies with developed countries. It is this strength and constraint of both developing and developed countries which underpins the three

[132] The proposal to include the CBD issues within the WTO negotiation forum has been forwarded to the WTO General Council by twelve developing countries from Asia (including Malaysia), Africa and Latin America since October 1999. See detailed account of the events which led to the inclusion of the issues on access and benefit-sharing of genetic resources and the traditional knowledge within the WTO framework in G. Dutfield, n 83 above, 916.

requirements concerning the access and benefit-sharing of genetic resources under Article 15 of the CBD:

> (1) the access must be preceded by prior informed consent by the producer countries; [133] (2) there shall be full participation in scientific research by the producer countries;[134] and (3) there shall be benefit-sharing of research results and commercialisation between the Contracting Parties.[135]

So far, issues relating to the CBD within the review of Article 27.3(b) have not been resolved. The most important point where developing and developed countries have different views is with regard to the question of whether Article 27.3(b) is compatible with the CBD requirements. It is important to bear in mind the different primary objectives that the TRIPs Agreement and the CBD have. The former sets a minimum standard of IPRs protection, whereas the concern of the latter is the regulation and utilisation of biodiversity for sustainable development. It has been the concern of the countries which are Signatories to both treaties (in particular developing countries) that, since under Article 27.3(b) biotechnological inventions may be patentable, it undermines the recognition given by the CBD that a state has a sovereign right to its natural resources, including animal genetic resources.[136] According to these countries, Article 27.3(b) is not compatible with the CBD and unless the treaties are reconciled, their commitments under both treaties are problematic. Consequently, it has been argued that Article 27.3(b) should be amended to include all the CBD requirements. This argument has been vehemently opposed by developed countries which are of the view that Article 27.3(b) and the CBD are mutually supportive: there is no incompatibility between them; there is no necessity to amend to Article 27.3(b), as proposed by developing countries; and that the issues relating to the CBD would best be addressed

[133] Article 15(5) of the CBD.
[134] Article 15(6) of the CBD.
[135] Article 15(7) of the CBD.
[136] Article 3 of the CBD.

within the relevant national laws rather than the TRIPs Agreement. These opposing views will be discussed and analysed further in sub-section 3.2.2.3. But before that, sub-section 3.2.2.2 below will assess the issue on access and transfer of technology, an aspect which has also been discussed in connection with the protection of life forms during the review of Article 27.3(b). It is a prerequisite to be considered by a Signatory in assessing the need and extent of allowing patent protection to animal inventions within its national patent law.

3.2.2.2 Access and transfer of technology

The efficiency of strict patent protection in ensuring the flow of technology from developed to developing countries as a result of the implementation of the TRIPs Agreement has been seen in different lights. Foreign direct investment (FDI), technology transfer and strict intellectual property protection have been perceived by developed countries as a recipe for technological growth and industrialisation.[137] Proponents of the principle have contended[138] that strict patent protection, including that for biotechnological inventions, could promote private sector investment in R&D activities in fields such as agriculture, health and environment. Social welfare benefits from these fields are said to be meant not only for the populations in developed countries, but also those in developing countries.[139] It has been further contended [140] that strict patent protection serves as an attractive tool that would lead to transfer of technology to developing countries which means the enhancement of their national technological knowledge, and ultimately the development of their economy. Intrinsically, this is because it is unlikely for developed countries to invest in R&D activities in countries

[137] C. Oh, n 40 above, 403.
[138] K.W. Mc Cabe, n 29 above, 47.
[139] ibid.
[140] ibid.

which lack patent protection for biotechnological inventions.[141] Nevertheless, input from developing countries during the review process of Article 27.3(b) has been very sceptical about these views. Many of those countries have conversely perceived that giving exclusive rights to patent holders could in fact prevent the effective dissemination of technology to their countries.[142] This concern stems from the considerable costs that they have to bear due to the licensing of the technology for having access to the relevant technologies.[143]

Pessimistic views as to the interface between strict IPRs and transfer of technology has been similarly highlighted in research. For instance, a survey by the United Nations University on the FDI and technology transfer concluded that IPRs did not play a significant role in influencing the pattern of FDI and technology transfer.[144] From the perspective of developing countries, it has been argued[145] that patents on biotechnological inventions would act as a barrier to the transfer of technology. Consequently, it leads to a disincentive for local research agencies, since their ability to utilise the necessary technology becomes limited.[146] These concerns are not without basis especially if assessed in the context of the type of technologies at issue, where a distinction has been made between technologies which have reached 'maturity' stage and new technologies.[147] Mature technologies are relatively easy for users to acquire by users, whereas it has been observed that there are considerable difficulties for

[141] ibid. 65; K.E. Maskus, Using the international trading system to foster technology transfer for economic development (2005) *Michigan State Law Review*, 219; A.M. Imam, How does patent protection help developing countries? (2006) 37 *International Review of Intellectual Property and Competition Law*, 3, 245-259.
[142] D. Gervais, n 107 above, 364.
[143] ibid.
[144] C. Oh, n 40 above, 405.
[145] J. Kuanpoth, Intellectual property protection after TRIPs: an Asian perspective in J. Malbon and C. Lawson (eds), *Interpreting and implementing the TRIPs Agreement: is it fair?* (Edward Elgar, 2008) 76.
[146] ibid.
[147] C.M. Correa, n 1 above, 951.

developing countries to obtain technologies that fall under the latter, including modern biotechnology. This is because these technologies are still changing and profitable.[148]

To take sides with any one of the opposing views of the negotiating countries during the review or any views of the critics would not be reasonable without assessing them in the light of the context of the focus of the thesis; namely the importance of animal biotechnology applications to develop the livestock industry of developing countries. While the problem of expensive technology due to the licensing agreement may be circumvented if patent protection is not granted to animal inventions, arguably the socio-economic implications for developing countries are more crucial. In this regard, it has been observed that there are three factors which could influence the effect of IPRs on the flow of FDI into a country.[149] They are: (1) the market size of the host country;[150] (2) the nature of the product itself; and (3) whether or not the industry is export-based.[151] The last of these has been identified[152] as directly relevant to the issue of intellectual property protection, thus requiring further elaboration. As already shown in chapter 1, developing countries are importers of livestock products so as to meet the growing demands and needs of the population. Notably, while animal biotechnology applications have been applied in the countries to assist with the development of their livestock industry, they are mostly at the research stage. According to economists, stronger intellectual property protection could, in theory, either promote or restrict economic growth. [153] Nevertheless, they have also observed two important aspects: (1)

[148] ibid.
[149] C. Oh, n 40 above, 405.
[150] ibid. An example cited was the investment by Boeing in China. Notwithstanding the lack of enforcement of IPRs in the country, the huge market for Boeing aircrafts has influenced the company to continue investing in China.
[151] ibid.
[152] ibid.
[153] See for instance K.E. Maskus, Intellectual property rights and economic development (2000) 32 *Case Western Reserve Journal of International Law*, 471- 506.

the strong and positive impact of patents on investments and R&D spending;[154] and (2) IPRs (including patents) as an important factor influencing the international transfer of technology. [155] Therefore, it is argued that for both users and importers of modern biotechnologies,[156] patent protection is necessary in developing countries so as to attract research collaboration, and hence transfer of technology from their developed counterparts. Eventually, a supply of livestock products to meet the demand can be secured.

Developing countries themselves can be categorised further as those which are more economically developed than others. For instance, for the 'BRIIC' (Brazil, Russia, India, Indonesia and China), which are the world's developing and emerging economies the need for transfer of technology to develop their industries may be less pressing than for other developing countries. It has, however, been identified[157] that in order to ensure effective technology transfer to developing countries, it is pertinent that they develop an indigenous scientific and technological capacity and have the ability to absorb knowledge from other countries for the purpose of adaption to their interests.[158] Intrinsically, transfer of technology to countries where the facilitating factors are absent will serve no purpose. In this respect, a more specific distinction appears necessary between the LDCs which have no technological capabilities to utilise modern biotechnologies in any of their industries and developing countries which have the ability to do so. The former would not be able to reap the benefits of patent protection because the cost of reforming or creating the patent system outweighs the benefits they could achieve from it,[159] and it would be unlikely for them to adapt and absorb

[154] ibid.
[155] K.E. Maskus, n 141 above, 223.
[156] Commission on IPRs, 'Integrating IPRs and development policy: report of the Commission on IPRs' (London: 2002) 21.
[157] ibid. 20; K.E. Maskus, n 141 above, 220.
[158] ibid.
[159] A.M. Imam, n 141 above, 245.

the technology into domestic industry[160] (including, animal biotechnology). Consequently, it is argued that for developing countries, which have started to develop their biotechnological industries or have the technological ability to achieve this end, allowing patent protection to biotechnological inventions is a pertinent matter for consideration. This would assist the countries to enhance their R&D activities by having the necessary technologies to develop the relevant fields further. Overall, it is also possible to argue that the need to provide patent protection to biotechnological inventions will increase as a particular country transforms its developmental policy toward promoting technology-based industries.

3.2.2.3 The disclosure requirements

Developing countries in their communication to the WTO during the review of Article 27.3(b) proposed that the TRIPs Agreement should include all the three aspects underlined by Article 15 of the CBD (as identified in sub-section 3.2.2.1 above). Specifically it was proposed that information as to the source and country of origin of the genetic materials and associated traditional knowledge used in developing an invention claimed in a patent application should be disclosed. The information should include the evidence of prior informed consent and evidence of a benefit-sharing agreement (the disclosure requirements).[161] Two options have been proposed by developing countries: (1) which is by way of an amendment to Article 27 of the TRIPs Agreement, that Signatories should be allowed to exclude from patentability, products or processes which have not included information of prior informed consent,

[160] K.E. Maskus, n 141 above, 240.

[161] WTO, 'The relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge: Technical observations on the United States submission IP/C/W/449 by Bolivia, Brazil, Colombia, Cuba, India and Pakistan', Document IP/C/W/459 (18 November 2005) paragraph 5.

sources and origin of genetic resources and a benefit-sharing agreement;[162] and (2) which is by way of an amendment to Article 29,[163] that, where appropriate, Signatories shall require the disclosure of origin and legal provenance in the patent applications to be submitted.[164]

Developing countries' concern, which led to the proposals, has been mainly on the grant of patents to inventions involving turmeric and hoodia plants, and the neem tree patent which originate from developing countries.[165] These plant genetic resources have been used for centuries as medicines, appetite suppressant and insecticide. In the turmeric patent for instance, the patent has been revoked by the USPTO after it was proved that the use of turmeric powder to heal wounds has for a long time been common in India.[166] It has been argued by developing countries[167] that the cost of revocation of an erroneously granted patent is more expensive and burdensome than including the disclosure requirements in a patent application. It is for the avoidance of the granting of an inappropriate patent that developing countries have been pressing for the disclosure requirements to be considered within the TRIPs Agreement.[168] Opposing the proposals and the views, the US[169] has been advocating the argument that implementing the disclosure requirements within the TRIPs Agreement

[162] WTO, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from Peru', Document IP/C/W/447 (8 June 2005) paragraph VII.

[163] Article 29 provides for 'conditions on patent applicants' which include the requirements that 'an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application'.

[164] WTO, n 162 above, ibid; WTO, 'Taking forward the review of Article 27.3(b) of the TRIPs Agreement: Joint communication from the African Group', Document IP/C/W/404 (26 June 2003) paragraph III.3. For detailed discussion of the opposing views between developed and developing countries, see also J. Carr, Agreements that divide: TRIPs vs CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications (2008) 18 *Journal of Transnational Law and Policy*, 1, 131-154.

[165] WTO, n 161 above, paragraph 6.

[166] ibid.

[167] ibid.

[168] ibid.

[169] WTO, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from the United States', Document IP/C/W/469 (13 March 2006) paragraph 5.

would lead to 'legal uncertainty and other negative consequences' since the access and benefit-sharing system are new to many Signatories. It has also been contended[170] that the disclosure of sources and origin of genetic resources in patent applications is rarely relevant to avoid the granting of inappropriate patent. This is due to the fact that the patentability of an invention would only be subject to the fulfilment of the relevant qualifications; where novelty and the inventiveness of an invention would depend on the state of prior art. According to the US, [171] the more suitable options to deal with the issue include the use of organized and searchable databases and the use of effective post-grant opposition or re-examination systems. Other than this, it has also been pointed out that since many of the plant genetic resources are grown in many countries, it would be difficult to determine the exact origin or source of genetic material. [172] This would burden the applicants, hence discouraging innovations. Developing countries do not share these views. They highlighted the limitations in organised databases in protecting traditional knowledge and genetic resources.[173] It was asserted[174] that the disclosure requirements would function as a check and balance tool to ensure that patent protection is granted only to proper applications without denying the rights of the provider of the genetic resources. Moreover, the disclosure requirements are not overly burdensome because a simple statement by the patent applicant to comply with the requirement is sufficient.[175]

Another proposal from developed countries is that a national contract-based system is the best way to deal with issues relating to prior informed consent, access and benefit-sharing of

[170] WTO, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication by the United States', Document IP/C/W/449 (10 June 2005) paragraph 30.
[171] ibid. paragraph 31.
[172] WTO, n 169 above, paragraph 13.
[173] WTO, n 170 above, paragraph 132.
[174] WTO, n 161 above, paragraph 6.
[175] ibid.

genetic resources. In this respect, apart from the proposals from the US, Switzerland[176] has proposed that the disclosure requirements be regulated through a WIPO-administered mechanism: the Patent Co-operation Treaty 1970 (PCT). Specifically it was suggested that an amendment to the Treaty should be made so that domestic laws may require inventors to disclose the source of genetic resources and traditional knowledge when they apply for patents. Failure to meet the requirement could delay a patent being granted, or, when done with fraudulent intent could entail a granted patent being invalidated.[177] The EU[178] in its latest communication has indicated its willingness to support the inclusion of the disclosure obligation within the TRIPs Agreement. Nevertheless, two limitations were mentioned: (1) the disclosure is restricted to the origin of genetic materials which is known to the patent applicants, or have reason to know; and (2) penalties for non-compliance are to be left outside the patent system.[179]

It is important that the opposing views of developing and developed countries be assessed so as to appreciate their advantages, disadvantages, and implications. While the implications for failure to comply with the disclosure as proposed by Switzerland seem promising to developing countries, the fact that the penalties are to be contained in the PCT or outside the patent system would still be seen as an attempt to circumvent the built-in dispute settlement mechanisms under the TRIPs Agreement. The PCT is a treaty which concerns procedures of

[176] WTO, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from Switzerland', Document IP/C/W/400/Rev.1, (18 June 2003) paragraph II. The PCT is available at: WIPO, http://www.wipo.int/export/sites/www/pct/en/texts/pdf/pct.pdf (Accessed: 4 March 2012).

[177] ibid. According to Dutfield, disclosure requirements as contained in various patent law legislations can be classified to three forms: weak, medium and strong. Weak form of disclosure means such disclosure that would be encouraged or even expected but not required, and its omission would not disqualify the patent from being granted. The medium form of disclosure is that disclosure of origin would be mandatory and strong form of disclosure goes beyond disclosure in the patent specification to require that patent applicants comply with the CBD's access and benefit-sharing provisions. See G. Dutfield, n 83 above, 918-920.

[178] WTO, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from the European Communities and their Member States', Document IP/C/W/383 (17 October 2002).

[179] ibid. paragraph 54.

application and granting of patents. It does not yet possess compliance enforcement procedures. Hence, how the non-compliance should be enforced is very uncertain. Moving on to the EU's proposal, the proposed methods of enforcing the non-compliance for disclosure are through civil law or administrative law.[180] These national measures have less powerful implications compared to the dispute settlement mechanisms under the TRIPs Agreement which could carry international trade sanctions. Notably, this strategy is used by negotiators who oppose a particular regulatory arrangement which could compromise the interests they are pursuing.[181] Consequently, while a national contract-based system is undeniably an option for implementing the proposed disclosure requirements, the inclusion of the requirements within the TRIPs Agreement would have greater prospects for being enforced and generating international compliance, compared to other methods or forums for application.

In this respect, there is little doubt that disclosing the information about the sources and origins of genetic resources will not guarantee the non-granting of patent protection to inappropriate applications. The mere presence of the information in patent applications would not necessarily trigger patent examiners' suspicion of the illegal possession of the genetic materials used in biotechnological inventions. Nevertheless, the requirement for the information may emphasise the transparency of the patent system which underpins the demand of developing countries. It would allow the relevant patent office to request further information should any need arise to verify the legality of the sources. In the context of the limited number of traditional knowledge databases worldwide (currently available only in India and China)[182] the disclosure requirements as proposed by developing countries are not unreasonable.

---

[180] ibid. paragraph 55.
[181] D.D. Bièvre et al, n 5 above, 9.
[182] EPO, India's traditional knowledge digital library (TKDL): a powerful tool for patent examiners, http://www.epo.org/news-issues/issues/traditional.html (Accessed: 31 March 2011).

After many years of negotiations, the future of including the disclosure requirements within the TRIPs Agreement seems politically challenging, since there are so far, no indications that technologically-developed parties will accept the mandatory disclosure requirements as proposed by developing countries. While the disclosure requirements debated during the review closely relate to plant genetic resources, they would also be applicable to livestock animals derived from modern biotechnology (for similarly being biotechnological inventions). Therefore, if capable of being fulfilled, the requirements would ideally benefit the community in developing countries in at least two ways. Firstly, they give recognition to farmers' associated knowledge in developing particular breeds of livestock animals which are involved in scientific research. Secondly, in case patents are granted to related inventions, it could ensure an economic return to the farmers.

The various conflicting views arising within the review process are in the light of many patent disputes involving plant genetic resources, which are located mainly within developing countries. For this reason, the proposed mandatory disclosure requirements may be seen as leading to an unequal distribution of benefit in terms of the potential beneficiary. The disclosure requirements would seem to impose one-sided obligations or additional burdens on developed countries where most life-sciences companies are located, albeit 'unfortunately' for the benefit of developing countries. Consequently, the response of the US to the proposal is not surprising.

A question could be raised at this juncture: would developed countries have responded the same way if the subject matter of the inventions involved animal genetic resources pertaining to the livestock industry? Arguably for animal inventions, the proposal of developing

countries would be considered more favourably by developed countries. As already discussed in chapter 1, the shortage of productive breeding stock and fish seed, the risk of livestock and aquatic diseases and the constraints of animal and fish feed are problems for the global livestock industry. In the production of transgenic livestock animals, the genetic resources could come from any country, not limited to developing countries. Therefore, for example, in research to produce a transgenic cow which can stand extreme weather condition, scientists from South Africa may need the genetic material of a cow from the US. In terms of the developed transgenic animal, the transgenic Atlantic Salmon is perhaps the best example of a clear trans-boundary movement of genetic material from the donor salmon (originating from the Pacific Ocean) to the host salmon (which originates from the Atlantic Ocean). While in the latter instance it may be quite difficult to exactly identify the provider of the genetic resources, in both examples, the disclosure requirements should become important to both developed and developing countries since each is a potential provider of animal genetic materials.[183]

Nevertheless, the implementation of the requirements is not without problems. On the disclosure of origin or source of genetic materials, the ability to fulfil the requirement would depend on the ability to trace these two things. The 'source of origin' has been said to mean the country from where the applicant received the genetic material, whereas the 'country of origin' is the country to which the genetic resource is indigenous.[184] While to disclose the information as to the former seems manageable, since an applicant would know where the genetic resources are obtained from, the latter may be more problematic. Before a genetic

[183] Trans-boundary movement of livestock animals (sheep, goats, cattle and pigs) between developed and developing countries has been observed in A.V. Zarate, Current and projected future flows of AnGR between countries and regions in S. Biber-Klemm and M. Temmerman, Rights to animal genetic resources for food and agriculture: notes from an interdisciplinary workshop, Working Paper No 2010/05, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652166 (Accessed: 31 March 2011) 29-32.

[184] WTO, n 161 above, ibid.

resource is involved in a modern biotechnological application such as genetic engineering to produce transgenic livestock animals, the product of the original source may be the result of years of breeding processes. According to the FAO,[185] farm animal resources (and the genetic diversity they represent) have developed over 12,000 years of domestication as a result of selection by human communities and adaption to new environments and environmental challenges. Largely involved in the process is a practice which is prevalent in livestock breeding, namely the trans-boundary movement of the resources. As a result, an animal genetic resource which is found in country 'A' may not be indigenous to that country. Yet in another instance, the resource may originate from many countries. Therefore, to be accurate on the 'country of origin' of a genetic resource involved in an animal invention may be challenging to a patent applicant.[186] Apart from this, the difficulty in identifying the true providers of animal genetic resources would also make it problematic to facilitate the prior informed consent requirement and to ensure that the deserving parties would benefit from the potential commercial gains. The challenge in detecting commercial gains from the use of the genetic resources itself is another hurdle in ensuring that the provider countries could claim their benefit.[187] Related to this, specifically on the disclosure of a benefit-sharing agreement in a patent application, the implementation is not always easy since the agreement, if any, would be in terms of contractual agreements between private parties. The unveiling of information, such as disclosure of ownership information and consent from the provider countries, pertaining to the agreement may be subject to various contractual conditions making it costly and burdensome for an applicant.

[185] FAO, World watch list for domestic animal diversity, 2008, ftp://ftp.fao.org/docrep/fao/009/x8750e/x8750e.pdf (Accessed: 25 February 2011) 3.

[186] See observation in G.K. Rosendal, n 41 above, 439.

[187] N.P. 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) *Washington University Journal Law and Policy*, 372.

While the implementation of the requirements may seem theoretically achievable, problems as to the practical side of it may be the reason why the requirements are still subject to on-going debates. Therefore, due to the challenges illustrated above, arguably the disclosure requirements should be introduced within the TRIPs Agreement possibly by amending Article 29. This would encourage patent applications to include additional information as to the source and country of origin. This approach is more realistic for developing countries in pursuing their interest (which arise from the CBD) within the WTO framework where the concept of forum shopping is a major hurdle. Albeit with lesser weight in terms of international enforcement, it offers a greater prospect for the requirements being introduced within national patent laws, hence global acceptance in the long run. Otherwise, a stronger option which ties the disclosure requirements to the enforcement aspect has been suggested by critics,[188] which is by utilising Article 62. The provision allows the imposition of reasonable procedures and formalities which need to be complied with by patent applicants, in the light of national laws of relevant Signatories, in order to acquire patent rights in those countries.[189] The only condition is that the procedures shall not run contrary to the principle of the TRIPs Agreement which prohibits the provisions which amount to denial of patents to inventions which fulfil the patentability criteria.[190] As such, it has been suggested that the disclosure requirements be made as conditions for enforcement of the granted patent.[191] Following these approaches, it is argued that the interest under the CBD should not have deterred developing countries from considering the grant of patent protection to animal inventions. In this way, the transfer of technology, investment, and economic development all remain possible to be achieved.

[188] ibid. 381.
[189] ibid.
[190] ibid.
[191] ibid.

This section has shown two things. Firstly, notwithstanding the diverse arguments of developed countries (that the exclusion of animal inventions is unnecessary) and developing countries (that all life forms are unpatentable) during the review of Article 27.3(b), the flexibility to construe the meaning of the term 'animals' and the subject matter of the exclusion remains. This is pertinent and necessary given the difference in the socio-economic levels of the Signatories to the TRIPs Agreement, and national economic interests of the negotiating countries. In particular, the flexibility relating to the exclusion will allow developing countries to shape the application of the provision in accordance with their national requirements and technological development. Secondly, while the issues involved in the review of Article 27.3(b) have not yet been resolved, they are pertinent to be considered by a Signatory which intends to implement the flexibility. This is because, implications arising from issues such as access and transfer of technology and disclosure requirements will influence the decision of whether or not to allow patent to animal inventions within national patent law. The following section identifies the options which a Signatory may have when interpreting the exclusion of animal inventions.

4. The Future: a way forward for interpreting the exclusion of animal inventions within national patent law

In the absence of any specific resolution to the issues relating to the patentability of animal inventions in the review of Article 27.3(b), Signatories to the TRIPS Agreement (including a developing country such as Malaysia) have the right to determine how the exclusion of animal inventions within their national law is to be construed. Due to the flexibility, any approach that a country may choose should not be criticised by other countries merely because it interprets the aspect differently. A Signatory may develop its own interpretation

based on any approach it thinks fit. Nevertheless, an assessment of existing interpretations by other Signatories within the international patent law framework is arguably the most appropriate approach that a Signatory could opt for. This will ensure that any interpretation that is made corresponds with international practice. For the purpose of this thesis, two approaches will be examined and assessed: (1) the permissive approach as modelled by the interpretation of Article 53(b) of the EPC; and (2) the restrictive approach as modelled by the interpretation of s2 of the Canadian Patent Act 1985.

5. Conclusion

The TRIPs Agreement was negotiated where there was no international agreement as to the patentability of animal inventions. As this chapter has shown the basis and purpose of the exclusion within the TRIPs Agreement is not explicitly explained. Nevertheless, it is clear that the introduction of the exclusion into the TRIPs Agreement was based on proposals from the negotiating countries, which derived from existing patent provisions within their national patent laws. On the one hand, developed countries, which principally allow patent protection to animal inventions, proposed broad protection of living matter to secure their intellectual property interests worldwide. On the other hand, developing countries suggested the exclusion of such material due to various national needs and constraints, in particular, their economic and technological development. Faced with this difference of views, the most practical way to ensure that an agreement between the countries on the protection of animal inventions could be achieved in the TRIPs Agreement was to allow these countries to continue practising the policy which underpinned their national patent laws. This has led to the flexibility to exclude the inventions under Article 27.3(b) at the end of the Uruguay Round Meeting.

The review of Article 27.3(b) which started just four years after the TRIPs Agreement came into effect, demonstrates that the flexibility which was adopted as a 'compromised solution' is still a subject of much disagreement between developed and developing countries. The second round of the negotiations has seen how, on the one hand, developed countries, in their concerted effort to pursue their economic interests globally, have argued that the exclusion should be deleted. Underpinning this view was that its retention would undermine R&D activities, hence affecting the progress of technology and economy. On the other hand, developing countries argued that all life forms should be unpatentable for being discoveries rather than inventions. Unless and until a decision as to the deletion of the exclusion of animal inventions under the review of Article 27.3(b) is achieved, the *status quo*[192] remains. Signatories retain an option either to exclude animal inventions or include them within their national patent system. Notably, the TRIPs Agreement is not prescriptive in terms of what the meaning of 'animals' is and how the exclusion under Article 27.3(b) should be interpreted: either narrowly or broadly. Therefore, for Signatories which have the exclusionary provision under their national patent laws, the flexibility would allow them to interpret the exclusion in tandem with various national policies and economic interests which they intend to pursue.

The scope of the review of Article 27.3(b) was broadened when developing countries argued that the need for the retention of the exclusion is to be linked to the implications of patenting biotechnological inventions to technology transfer and the conservation of biodiversity. It has been emphasised that allowing patents for biotechnological inventions which are mainly developed by the experts in developed countries would amount to the recognition of misappropriation of genetic resources, without appropriate economic return to them as

[192] Latin expression which means: 'the existing condition or state of affairs'. See http://www.thefreedictionary.com/status+quo (Accessed: 3 March 2012).

providers of the genetic resources. This contention is underpinned by the provisions of the CBD which aim to regulate the utilisation of genetic material for global sustainable development. So far, issues relating to Article 27.3(b) under the review process remain unresolved. Nevertheless, their assessment would inform the relevant Signatories of the various advantages, disadvantages and implications for their economic development should they decide to implement any policy measures proposed therein. In the context of the thesis, this chapter highlights that in order to assist with the interpretation of the exclusion of animal inventions under a national patent law it is pertinent for the relevant Signatories to the TRIPs Agreement to firstly identify their interest and ability in utilising animal biotechnology applications to enhance the development of livestock industry and economic development. This enables them to decide whether or not allowing patent to animal inventions will assist them in pursuing their national requirements.

A key issue in the review process is the patentability of life forms. This chapter contends that animal inventions can be patentable for being able to fulfil the patentability criteria. Nevertheless, strengthened patent protection for biotechnological inventions (including animal inventions) in developing countries has been criticised for hindering the transfer of technology as the technology would become expensive due to their licensing. This would eventually limit access to the technology. This chapter argues that while the problem of licensing may be circumvented by not allowing patent to animal inventions, the socio-economic implications for developing countries are more crucial. In this respect, it is important to note the widely accepted economic rule that technology-developed countries (mostly developed countries) are unlikely to invest in R&D in countries which lack patent protection. The transfer of technology is subject to the same rule. Intrinsically, this arises from the importance to recoup the investment put into developing a biotechnological

invention, including animal invention. While animal biotechnology applications have been applied in developing countries to increase the production of livestock products, widely they are still at the research stage. Being users and importers of the technology, it is important for developing countries which have the technological ability to absorb knowledge from technologically-developed countries to consider allowing patent protection to animal inventions. The protection would attract the transfer of technology and investment into developing countries' R&D activities pertaining to animal livestock. Eventually, this will assist the countries to secure the supply of livestock products to meet the growing demands from the population.

Another central aspect of the review process pertains to the proposal that mandatory disclosure of the source and country of origin of genetic resources involved in animal inventions be introduced under Article 27.3(b). This aims to ensure transparency of commercial gains arising from the use of genetic resources from provider countries (mostly developing countries). While the conditions will economically benefit livestock breeders which may have contributed toward improving particular breeds involved in scientific research, its implementation is not without problems. Mainly, the challenges will come from the condition to precisely identify the 'country of origin' of the relevant animals and disclosure of ownership information. Due to the practice of the trans-boundary movement of livestock animals, the requirements may pose an unnecessary burden on a patent applicant, hence discouraging innovation. Consequently, it is suggested that the disclosure aspect is to be encouraged by amending Article 29 of the TRIPs Agreement, rather than be made mandatory under Article 27.3(b). While of lesser weight in terms of international enforcement, it provides a better opportunity for the requirements be introduced in national patent laws, in the light of the political ramifications of the review process. Attaching the

disclosure requirements to the enforcement of a granted patent is another option for developing countries to consider. Besides meeting the requirement under Article 27.3(b) that inventions which fulfil patent criteria should be granted patents, the option realises the interests of developing countries under the CBD and contributes to their economic growth.

While there is no fixed rule on how the exclusion of animal invention in national patent law is to be interpreted, arguably the examination and assessment of current international interpretation is the most practical way of dealing with this issue. In this way, any decision on how the exclusion should be construed can be justified in a more robust way. Consequently, this thesis will work on two international models of interpretation namely; the permissive approach which has been adopted by the European patent system and the restrictive approach which has been adopted by the Canadian patent system. Detailed analysis of these approaches will be made in chapters 4 and 5, respectively. However, before that, the next chapter will examine the Malaysian exclusionary provision which is s13(1)(b) of the Patents Act 1983. The discussion will include its legislative history and the application of the exclusion so as to understand the intention of the legislature, the country's expectations from the provision and current legal development of the same. In the context of the research questions, the chapter identifies the lack of legal development and clarity within the Malaysian patent law, which ultimately justify this research.

CHAPTER THREE

THE EXCLUSION OF ANIMAL VARIETIES UNDER SECTION 13(1)(b) OF THE MALAYSIAN PATENTS ACT 1983: LEGAL DEVELOPMENT AND APPLICATION

1. Introduction

Malaysia is one of developing countries which exclude animal varieties under national patent law. In the light of the flexibility to interpret the exclusion under Article 27.3(b) of the TRIPs Agreement, it becomes relevant and important to ask the question: how should the exclusion be applied? This is in the context of the country's international obligations under Article 27.1 of the same Agreement, which requires inventions that fulfil the patent qualification criteria be patentable. Nevertheless, there is a scarcity of materials which have discussed how Malaysia should interpret the exclusion. This is not surprising as a similar situation can be observed at the international level where, apart from Europe and Canada, the question of how a Signatory, which has adopted the exclusion, should deal with the implementation of the exclusion is very rarely discussed. The most probable reason leading to this may be that a situation has not yet arisen which requires the exclusionary provision to be interpreted either by national patent offices or judicial authorities of the relevant Signatories to the TRIPs Agreement. Yet as already shown in chapter 2, there have been significant discussions within the WTO on issues relating to the exclusion of animal inventions. It has been further concluded in that chapter that any international development on the exclusion is relevant to be considered by a Signatory in applying its exclusionary provision. But, before that, the relevant Signatory should be clear of what is intended from the exclusionary provision within its national patent law.

This chapter offers an understanding of s13(1)(b) of the Malaysian Patents Act 1983 which contains the exclusion of animal varieties and explains how the country has been dealing with the exclusion. It identifies the gap within the Malaysian patent law (which this thesis seeks to fill), and in the context of international patent law, it highlights the legal provision of a Signatory to the TRIPS Agreement, and its development. For these purposes, this chapter contains five sections. Section 2 gives a background to the country's patent law. It discusses the basis and purpose of the introduction of the Malaysian Patents Act 1983 by highlighting the problems encountered by the country which, prior to the Act, had diverse legislations regulating national patent laws in different regions. It explains how the Malaysian Patents Act 1983 tried to solve the problems. Section 3 focuses on the exclusion of animal varieties under s13(1)(b). It explores the legislative history of the provision in order to appreciate the basis and purpose for having the exclusion under the legislation. The section also assesses if the intended meaning of the term have been made clear by the legislature. Section 4 looks at the current application of the exclusion in Malaysia. In particular, the discussion focuses on the handling of applications involving animal inventions by the MyIPO, and the extent to which the term 'animal varieties' have been considered by the office. Section 5 ends the chapter.

This chapter will show that there is very minimal development of the exclusion within the Malaysian patent law, and so its legal position is vague. In the context of the thesis, the uncertainty will hamper the various efforts of the government to exploit animal biotechnology applications to develop its livestock industry (identified in chapter 1). The ambiguity would also deter foreign investments and technology transfer which are essential for the same purpose (identified in chapter 2). Conversely, a clear position of the law assists Malaysia to pursue its economic interests more effectively. Owing to this, it will be argued that this thesis is pertinent and timely.

2. The Malaysian Patents Act 1983: basis and purpose of introduction

Malaysia is made up of two regions: Peninsular Malaysia (which consists of eleven states)[1] and East Malaysia (which consists of two states).[2] The present Malaysian patent law originated from the English system where during the colonial era, a patent system, based on the English patent system, was introduced in Malaysia. The aim of such a system was mainly to protect the commercial interests of foreign manufacturers (particularly the British) who were involved in primary local industries such as tin and gold mining, rubber, palm oil and mineral oil extraction and refining.[3] As a result, prior to 1983, the country's patent law was governed by three pieces of patent law legislation.[4] The Registration of United Kingdom Patents Act 1951 (Revised 1978) governed the law in Peninsular Malaysia, the Registration of United Kingdom Patents Ordinance (Chapter 125) covered Sabah and the Registration of United Kingdom Patents Ordinance (Chapter 61) was in force in Sarawak.[5] This was based on a re-registration system where any inventor who would like to have their inventions protected would have to apply for a patent in the UK and then apply to register it in Malaysia within three years of the date of the grant in the UK.[6] This system had two major problems: (1) as the examination and search process would be conducted in the UK Patent Office, the whole process toward granting a patent, took a considerable time and incurred high costs.

---

1 Perlis, Kedah, Pulau Pinang, Perak, Selangor, Melaka, Negeri Sembilan, Johor, Pahang, Kelantan and Terengganu.

2 Sabah and Sarawak.

3 L.H. Gee, A study of the historical development of the Malaysian patents system in A. Firth (ed), *The prehistory and development of intellectual property systems* (London: Sweet and Maxwell, 1997) 84.

4 Prior to 1983, patent protection via various sources had existed for many years in different component states of Malaysia. Depending on the status of the component states then (either the Straits Settlement or the Federated Malay States or the Unfederated Malay States), protection granted to inventors originated from sources such as English Statute, Indian legislation and indigenous legislations. See further details in L.H. Gee, ibid. 116-120.

5 These three statutes, together with the Patents (Rights of Government) Act 1967 which provided for the rights of the Government in the legislation relating to patents and for matters incidental thereto, were repealed by s89 of the Patents Act 1983 (Act 291).

6 I.M. Abdul Ghani Azmi, *Patent law in Malaysia: cases and commentary* (Sweet and Maxwell, 2003) 15.

This was an obstacle to inventors in getting their inventions patented; and (2) the separate laws governing each of the regions caused administrative difficulties, as inventors had to register their inventions in each region in order to obtain protection in the whole of Malaysia.[7]

Between the 1980s and the mid-1990s, the Malaysian economy experienced a shift from an agricultural to an industrial basis. Among the most important, for the latter, are the local automotive[8] and manufacturing industries. The introduction of the Malaysian Patents Bill 1983 was intended mainly to support this shift in economic focus. One of the issues that quickly became apparent to the legislature is the importance of protecting technical inventions created by local inventors in order to encourage innovations. The unsatisfactory re-registration system, which was prevalent within the country's patent system,[9] was seen to be a hindrance to the country's aspirations.

The Malaysian Patents Bill 1983 was drafted after consideration of the patent laws of a number of countries, which included the UK, Australia, Sri Lanka, Thailand and Japan. In addition, the views of the WIPO, whose function includes the promotion of the protection of IPRs throughout the world, were also considered.[10] For instance, in November 1982, several expert missions from the WIPO, including consultants from Sweden and the US visited Malaysia to advise the government on the establishment of the new patent system.[11] The Malaysian Patents Act 1983 consolidates the diverse legislations that governed the patent law

---

7 Malaysian Hansard, HR vol 1 cols 7767-7768 (25 July 1983).

8 For instance, DRB-HICOM, is one of Malaysia's leading corporations which play an integral role in the country's effort toward industrialisation. It was established in 1979 to support the production of national vehicles. See USF-HICOM, http://www.usf-hicom.com.my/about_usf.html (Accessed: 29 July 2010).

9 Malaysian Hansard, n 7 above, col 7768.

10 ibid. Speech by Mr Oo Gin Sun, Deputy Minister of Trade and Industry.

11 WIPO, Review of regional project activities in 1981/1982 (1983) *Industrial Property in Asia and the Pacific*, 3.

of Malaysia into a statute. In addition to the introduction of a centralised registration mechanism, the new legislation introduced many new provisions with the aim of clarifying various aspects of patent law [12] and giving better protection to inventors. For instance, the old legislations only provided basic provisions such as procedures for filing an application at the then UK Patent Office, commencement and duration of rights, and powers of the High Court in case of disputes. In contrast, the new patent law provides detailed provisions with respect to (among other aspects) the meaning of an invention, the patentability criteria of an invention, a list of non-patentable inventions, licences, infringement, offences, and enforcement.

In furtherance of the country's newly developed industrial sectors, participation in the international patent law arena was seen by the government to be a necessary step. It was the intention of the government to become a member of international conventions and organisations relating to patent rights, which include the Paris Convention, the PCT and the WIPO. Membership of these (all of which have since been achieved),[13] was considered to be of benefit to Malaysian inventors, where their interests could be secured globally, due to the internationalisation and harmonisation role played by such Conventions and Organisations. [14]

This section has explained the general purpose of the Malaysian Patents Act 1983. Similar to other patent laws worldwide, its introduction within the Malaysian legal system aims at encouraging innovation by providing protection to local and foreign inventors. The next section investigates the basis and purpose of the exclusion of animal varieties by examining the legislative history of s13(1)(b) in order to see if the intention of the legislature was clearly

[12] Malaysian Hansard, n 7 above, cols 7769-7770.
[13] Malaysia became the Member State of the Paris Convention 1883 on 1 January 1989, the WIPO on January 1989 and the Patent Co-operation Treaty 1970 on 16 August 2006.
[14] Malaysian Hansard, col 7941 (26 July 1983).

made. As the following section will demonstrate, there was very little attention given to the exclusion by the legislature during the parliamentary debates, hence rendering the purpose and subject matter of the exclusion unclear.

3. The exclusion of animal varieties under the Malaysian Patents Act 1983

Section 13 provides for 'Non-patentable inventions'. Sub-section (1)(b) states:

> (1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following *shall not be patentable*:
>
> . . .
>
> (b) plant or *animal varieties* or essentially biological processes for the production of plants or animals, other than manmade living micro-organisms, micro-biological processes and the products of such micro-organism processes;
>
> . . .
>
> Provided that this paragraph shall not apply to products used in any such methods.[15] (emphasis added)

This provision has been included in the Malaysian Patents Bill 1983 since it was tabled in the Malaysian Parliament (in 1983), and adopted when the Act came into effect in 1986. It should be noted that even though there was a shift in the country's economy focus from the agricultural to the industrial sector, the former remains one of the country's key sources of income. In terms of Malaysia's biotechnology industry, even though it was not yet developed when the Malaysian Patents Act 1983 was drafted, the government's commitment to develop the industry was evidenced by the creation of the National Biotechnology Committee in 1984. The function of the Committee, among others, was to advise the government on policy issues in research, funding and incentives to industries, to monitor new developments in

[15] Section 13(1)(b) has been amended only once since its promulgation via the Patents (Amendment) Act 1986 (Act A648) where the word 'may be' replaced the previous word 'are'. See Appendix 3 for s12.

biotechnology and to facilitate R&D between research institutions and industry.[16] The emphasis on the development of the industry, particularly agricultural biotechnology, was explicitly made by the government in the Sixth Malaysia Plan (1991-1995).[17] In the context of the aspiration of the government, it is important that two questions relating to the exclusion under s13(1)(b) be understood: (1) the origin of the exclusion; and (2) its basis and purpose.

Materials from secondary sources that would enable a precise conclusion to be made as to the origin of such an exclusion in the Malaysian patent law are very scarce. Nevertheless, an inference for this purpose can be made from two sources mentioned in the parliamentary debates of the Malaysian Patents Bill 1983. The first relates to the five countries' patent law legislations which were considered by the legislature. An inspection of the legislations, disclosed the fact that only the UK Patents Act 1977, the Sri Lanka Code of Intellectual Property Act of 1979[18] and the Thailand Patent Act 1979 exclude 'variety of animal' or 'animals' from patent protection.[19] The position in Australia and Japan at all material times was very different in that no provision that excludes living matter from patent protection can be found in the respective Patents Act 1952[20] and Patents Act 1959.[21] However, in view of the fact that Malaysia was once a colony of the British, and that the Malaysian patent system

---

16 J. Komen and G. Persley, 'Agricultural biotechnology in developing countries: a cross-country review', ISNAR Research Report, 1993, 6. The National Biotechnology Committee was succeeded by the National Biotechnology Working Group in 1991.

17 ibid.

18 WIPO, 'Exclusions from Patent Protection: Memorandum of the International Bureau of WIPO', Document HL/CE/IV/INF/1 (30 May 1988).

19 Patent Act B.E 2522 of 1979 was amended by Patent Act (no.2) B.E 2535 (1992) and Patent Act (no.3) B.E 2542 (1999). See Patent Act B.E 2522 of 1979 which is available at: http://www.asianlii.org/th/legis/consol_act/pa199991/ (Accessed: 20 July 2009).

20 Attorney General's Department, Australian law online, http://152.91.38.99/html/histact/0/261/top.htm (Accessed: 20 July 2009). The Australian Patent Office's practice was to allow patents for processes producing non-human animal varieties and the products of such processes. Even though no patents have been granted for non-human animal varieties, it was understood that patent protection should be available for such inventions on the same general principles as it is available for micro-organisms and plant varieties. See WIPO, n 18 above.

21 Article 32 of the Japan Patent Act 1959 provides for general exclusion: 'Any invention that is liable to injure public order, morality, public health shall not be patented'. See WIPO, n 18 above. See also discussion in section 2.2.1 of chapter 2.

originated from the English patent system, it is possible to conclude that the reason for such an exclusion being included in the Malaysian Patents Act 1983 was the presence of a similar provision in the UK Patents Act 1977. The second source which might have influenced the introduction of the exclusion in the Malaysian Patents Act 1983 was the WIPO's Revised Model Law for Developing Countries on Inventions (WIPO Model Law),[22] where s112 also excluded animal varieties from patent protection.[23]

Yet another insight comes from the parliamentary proceeding of the Malaysian Patents Bill 1983 itself where a question was raised by one of the Ministers as to the rationale for excluding plants and animals from patent protection.[24] In response to this question, three reasons were mentioned by the Minister who tabled the Bill: (1) that they were considered as natural developments; (2) that the exclusion was available in other countries' patent law legislations, and (3) that the provision was one which was normally available in patent laws of other countries.[25] The last two of the reasons suggested the fact that to have a similar exclusion in the Malaysian Patents Act 1983 was deemed necessary by the legislature to ensure that the Malaysian patent law is in line with those of other countries. In addition, it is the government's intention to become a member of the Paris Convention. It is important in this convention that every contracting state should give national treatment in terms of patent protection to foreign citizens.[26] Therefore, the approach taken by Malaysia, to bring its patent law as close as possible to the provisions of international patent law, is expected.

---

[22] WIPO, *WIPO Model Law for Developing Countries on Inventions, Volume 1: Patents* (Geneva, 1979) 19. Section 12 of the Malaysian Patents Act 1983 on the meaning of the term 'invention' is similar to the Model Law for Developing Countries on Inventions.

[23] ibid.

[24] Malaysian Hansard, HR vol 1col 7916 (26 July 1983).

[25] ibid. col 7943. These three reasons were generally stated without any authority being given to support the contention.

[26] Article 2 of the Paris Convention requires each Member State of the Convention to provide national treatment to foreign citizens with regard to patents, industrial designs, trademarks and trade names.

The brief answer during the parliamentary debate of the Malaysian Patents Bill 1983 which reasoned the statutory exclusion of animals from national patent protection would inevitably lead to a question: what was the extent of the legislature's awareness and the information available, as to the ability of scientific technologies to create animal inventions? In this respect, it is important to consider the international patent law scene with regard to scientific developments in biotechnology. Modern biotechnology had begun in the 1970s where technology such as genetic engineering has been used to modify living organisms to obtain certain intended characteristics.[27] Nevertheless, as far as the issue of the patentability of living organisms was concerned, it came to prominence only in 1980 due to the ground-breaking decision of the US Supreme Court in the case of *Diamond v Chakrabarty*.[28] Since such international developments in patenting animal inventions were at a very early stage, it is doubtful if there was much information on the scientific technologies available to the Malaysian legislature when the Malaysian Patents Act 1983 was drafted and debated. Otherwise, the parliamentary debates would have disclosed some of the scientific developments considered by the legislature, and their views on the issue. In the light of this situation, the first reason given by the Minister seems to suggest that it was the legislature's understanding that as animals are products of nature or naturally occurring, they are unpatentable under s13(1)(b). It is worthy of note that during the debate of the Malaysian Patents Bill 1983 there was a proposal that patent protection be allowed for animals and plants in view of the then existing innovative ideas of local scientists to produce some types of plants which were able to produce better quality yields. [29] Nevertheless, the proposal does not appear to have been discussed or explained further. As a result, it is more probable to conclude that the issue of patentability of animal inventions was then not appropriately considered by the legislature, hence the rationale for having the exclusion in the Malaysian

[27] See footnote 12 in chapter 1.
[28] See discussion in section 2.2.1 of chapter 2.
[29] Malaysian Hansard, n 24 above, ibid.

Patents Act 1983 and the actual intended subject matter of the exclusion remains ambiguous.[30]

A key point which determines the subject matter excluded under s13(1)(b) is the intended meaning to the term 'animal varieties'. Notwithstanding the assumption that the exclusion of animal varieties was adopted in accordance with similar provisions of the UK Patents Act 1977 and the WIPO Model Law, to conclude what could be the intention of the Malaysian legislature as to the meaning of the term is not an easy task. A question that may be asked is: can an inspection of the language of the Malaysian Patents Act 1983 shed some light? In Malaysia, the texts of all Acts will normally be prepared in two versions, which are in English and the national language, Malay. In this context, it is relevant to note that s13(1)(b) of the Malay version of the Malaysian Patents Act 1983 states the exclusion as *'berbagai jenis binatang',* which in direct English translation is stated as 'variety of animal'. According to s6 of the National Language Act 1963/1967,[31] the text (of a legislation) in the national language is to be considered as the authoritative text. The provision states:

> The texts of all Bills and Acts of Parliament shall be in the national language and in the English language, the former being authoritative unless the Yang di-Pertuan Agong[32] otherwise prescribed generally or in respect of any particular law or class of laws.

---

[30] There is a difference in this respect with Singapore's patent law (the country is a neighbour of Malaysia). The Singaporean's Patents Act 1994 does not exclude animal inventions from patent protection, albeit the provisions on patentability closely followed the scheme of the English Act. Most importantly, this decision was made due to the recognition by the Select Committee of the promise of developments in biotechnology. In this regard, while noting the exclusion of variety of animals under the s1(3)(b) of the UK Patents Act 1977, the Select Committee clearly reasoned out that non-human animal varieties should not be excluded from patent protection as the right 'provides an incentive for people to invest and innovate.' On the possible application of biotechnology on human beings, the Committee firmly stated that the issue was preferably to be handled through the list of matters not considered as inventions 'as such' under s13(2) of the Act. See detailed discussion on the position of genetically engineered life forms in Singapore in G.W.S. Shun, *Mus Musculus* and *Homo Sapiens*: murine metaphysics and the Canadian Supreme Court (2003) *Singapore Journal of Legal Studies*, 38-79.

[31] Act 32. Available at: http://www.agc.gov.my/Akta/Vol.%201/Act%2032.pdf (Accessed: 8 April 2011).

[32] Yang di-Pertuan Agong is the Head of State of Malaysia.

As a result, based on s6, the Malay term *'berbagai jenis binatang'* is the authoritative text for the exclusion. Nevertheless, whichever may be the authoritative text (English or Malay), the choice of the term 'animal varieties' and therefore, the subject matter of the exclusion were not raised or discussed during the parliamentary debates of the Malaysian Patents Bill 1983. In fact, the brief proceedings demonstrated that no importance was given to these aspects. Therefore, the language of the exclusionary provision is similarly not able to resolve the issue. Yet it can at least be concluded at this juncture that the terms, in both the English and Malay version of the Malaysian Patents Act 1983, should carry the same meaning and refer to the same subject matter, whatever the terms could mean.

Irrespective of the lack of clarity in the purpose and intended subject matter of the exclusion at the time of the tabling of the Malaysian Patents Act 1983 (in 1980s) as demonstrated in this section, it should be noted that the exclusion has been retained, even though various amendments have been made to the Act since it came into effect.[33] While one might argue that such a situation may be created by the 'dormant' nature of the exclusion as there is not yet any issue that has been raised by any parties so far, a counter-argument that the retention indicates its importance is equally reasonable. For this reason, the following section will look at the application of the exclusion in the Malaysian patent law so far. This allows an assessment of whether there has been a conclusive approach adopted by Malaysia in exercising the flexibility under Article 27.3(b) of the TRIPs Agreement, or if there is an area to which this thesis can, theoretically and practically, contribute.

[33] The Patents Act 1983 has been amended five times since it came into effect; in 1986(A648), 1995(A863), 2001(A1088), 2003(A1137) and 2006 (A1196).

4. The current application of the exclusion in Malaysia

Similar to other patent offices throughout the world, one of the aims of the MyIPO is to provide an efficient administrative system to encourage greater creativity and exploitation of intellectual property.[34] It is indicated[35] that, from 1986 to January 2010, the MyIPO received thirty-two applications (relating to the production of antibodies) for patent protection involving what the Organisation termed 'transgenic animals'.[36] These include transgenic mice and transgenic cattle. Thirteen of these applications involved claims to patent the transgenic animals as products. Such applications were received from international countries such as the US, the UK, Sweden, Cuba, Thailand and Finland.[37] So far, nine claims have been refused. Two of the claims were refused based on s31(1) of the Patents Act 1983[38] for being contrary to public order or morality.[39] Seven others were refused due to other administrative grounds such as the absence of a response from applicants and non-payment of required fees.[40] There were however, three claims relating to antibodies involving animal inventions, which have been allowed.[41] According to the office's practice, patents will be granted for

---

[34] Intellectual Property Corporation of Malaysia, Corporate information, http://www.myipo.gov.my/en/about-myipo.html (Accessed: 8 April 2011).

[35] Personal communication with an official of the MyIPO dated 29 January 2010.

[36] According to the MyIPO, 'transgenic animal' is: 'an animal that has been genetically engineered using recombinant DNA techniques to make animals with new characteristics. Transgenic animals are produced by adding one or more genes to an animal genome, using a process called transformation'.

[37] Personal communication with an official of the MyIPO dated 3 May 2010.

[38] Personal communication with an official of the MyIPO dated 21 January 2010.

[39] Personal communication with an official of the MyIPO dated 5 May 2010. For s31(1) see Appendix 3. The provision has been included in the Act via Patents (Amendment) Act 2000 (Act A1088) so as to comply with the minimum requirement under Article 27.3(b) of the TRIPs Agreement. The question of whether an invention is contrary to 'public order or morality' is currently determined by a patent examiner in the MyIPO. Personal communication with an official of the MyIPO dated 5 May 2010. Since many applications of modern biotechnology are in the field of agricultural food and pharmaceuticals which involve public interest, it has been argued by Abdul Ghani Adzmi that the determination of what constitutes 'morality' should be shouldered by a special Ethics Committee (which should comprise of parties involved in the process standards, halal certification and religious bodies) rather than solely entrusted to the patent office. This could gain public confidence in the products of biotechnology. See I.M. Abdul Ghani Azmi, Patenting whilst being ethical (2009) *International Islamic University Malaysia (IIUM) Law Review*, 499. There is not yet any decision made by the Malaysian courts to determine the test for 'public order' or 'morality' within the Malaysian patent law.

[40] Personal communication with an official of the MyIPO dated 5 May 2010.

[41] Personal communication with an official of the MyIPO dated 19 January 2010.

inventions involving animal materials such as genes and plasmids provided they fulfil the patentability criteria.[42]

According to the MyIPO, the term 'animal varieties' in s13(1)(b) is defined based on the practice of European countries'.[43] Therefore, the term is understood to carry the meaning of:

> [a]ny of various groups of animals ranking below a species (subspecies). Therefore, in the taxonomic hierarchy, 'variety' clearly appears below the category of 'species'. That category is in turn defined as a category of biological classification ranking immediately below the genus or subgenus, comprising related organisms or populations potentially capable of interbreeding, and being designated by a binomial that consists of the name of a genus followed by a Latin or latinized uncapitalized noun or adjective agreeing grammatically with the genus name. Thus, examples of species include *Mus musculus (M. musculus), M. abbottii,* and *M. caroli;* and *M. musculus*, for instance, is further subdivided into subspecies such as *M. musculus domesticus* and *M. musculus bractianus*. 'Genus' itself is defined as a category of biological classification ranking between the family and the species, comprising structurally or phylogenetically related species or an isolated species exhibiting unusual differentiation, and being designated by a Latin or latinized capitalized singular noun. An example of a genus would thus be *Mus* (Mice).[44]

This is clearly an adoption of the meaning given by the Technical Board of Appeal (TBA) of the EPO in the *Harvard/Onco-mouse* case.[45] Although the MyIPO has continued to handle applications involving animal inventions, and the above meaning, an in-depth examination of the exclusion is arguably crucial for at least four reasons. Firstly, the discussion in section 2 has disclosed the fact that the derivation, intended meaning and subject matter, of the exclusion, within the Malaysian patent law, are not at all clear.[46] Secondly, the meaning of

---

[42] Personal communications with an official of the MyIPO dated 4 December 2009 and 4 March 2010. Under Chapter IV, paragraph 3.1 of the MyIPO Guidelines for Patent Examination, genes which are discovered to exist in nature may be patentable if a technical effect is revealed. Plasmids which fall under the term 'micro-organism' under paragraph 3.3 of the same Chapter are also patentable. See MyIPO Guidelines for Patent Examination, http://www.myipo.gov.my/files/PT_Guidelines.pdf (Accessed: 24 December 2009).

[43] Personal communication with an official of the MyIPO dated 29 January 2010.

[44] ibid.

[45] The decision is discussed in detailed in sub-section 3.2 of chapter 4.

[46] The Malaysian Biotechnology Corporation has similarly identified that while the Malaysian Patents Act 1983 recognised some exclusions, the current position as to the patenting of biotechnological inventions in Malaysia is still vague. Therefore, a request has been made that in the light of the increasing demands for the protection of inventions, the Act is reviewed and amended to include clearer provisions and provide

the term 'animal varieties' and therefore the subject matter excluded under s13(1)(b) has not yet been tested by the Malaysian courts. Thirdly, so far, there is no formal interpretation to the term 'animal varieties' has been made by the patent office.[47] Finally, it is important that the meaning of the term be clarified, should a grant or rejection of patents to animal inventions under s13(1)(b) be deemed relevant to be applied by the MyIPO in the future. In addition, it is pertinent to note that under s88 of the Malaysian Patents Act 1983, an aggrieved party to the decision or order by the Registrar (of the MyIPO) or the Corporation is given recourse for an appeal to the High Court. Due to these reasons, this thesis is timely and its findings will fill the vacuum mentioned. The thesis may also provide some input to the on-going efforts by the MyIPO to review and amend the Malaysian Patents Act 1983, Malaysian Patent Regulations 1986,[48] and the Organisation's Guidelines for Patent Examination, where issues relating to transgenic animals are also being considered.[49]

5. Conclusion

It has been shown in this chapter that the exclusion of animal varieties was included under s13(1)(b) of the Malaysian Patents Act 1983, mainly due to the country's intention to participate in the international patent scene. Among the earliest steps adopted by the country to place itself within the international intellectual property (including patent) rights framework, was the application to become a member of the international IPRs-related conventions, treaties and organisations such as the Paris Convention, PCT and the WIPO.

---

direction to the issue. See Malaysian Biotechnology Corporation, Patent protection in Malaysia – a basic information guide, http://www.biotechcorp.com.my/wp-content/uploads/2011/11/downloads_aboutmalaysia/IP_Booklet_Patents_V1.pdf (Accessed: 5 March 2012) 9.

47 Personal communication with an official of the MyIPO dated 19 January 2010. So far, no application to patent the Harvard Mouse has been filed in the MyIPO.

48 PU(A) 327/86. Available at MyIPO, http://www.myipo.gov.my/acts/Patent%20Regulations%201986-.pdf (Accessed: 6 April 2012).

49 Personal communication with an official of the MyIPO dated 4 March 2010.

Another important reason for having the exclusion in the Malaysian Patents Act 1983 was to ensure that the national patent law is in line with other countries' patent legislations. However, the meaning of the term 'animal varieties' under s13(1)(b) is unclear. This is due to the lack of consideration given by the legislature to the needs and implications of the exclusion. The parliamentary debates and the language of the exclusionary provision offer little assistance with these uncertainties.

The presence of the exclusion of animal varieties under the Malaysian Patents Act 1983 should not be concluded as depicting the country's pessimistic position toward innovations. This is because, currently, there is a gap in terms of its application within the Malaysian patent law. The MyIPO has not thoroughly considered the exclusion because s13(1)(b) has not been applied in any patent applications involving transgenic animals filed with the patent office. More importantly, the Malaysian courts have not construed the exclusion.

The basis and purpose of introducing the Patents Act 1983 in Malaysia, was to give protection to inventors (local and international) for the enhancement of the country's economy and ultimately the socio-economic interests of the population. While originally introduced with the aim of supporting the country's shift of economy from agriculture to industrial (mainly automotive and manufacturing) the purpose of the Malaysian Patents Act 1983 can be concluded to be similarly applicable to other types of industry, which become equally important as the country's economy develops. Malaysia's biotechnology industry (including agricultural or livestock) is one of these, as it is one of the industries which the government has been aiming to develop since the time the Malaysian Patents Act was introduced in 1983.

In the absence of the clear intention and direction from the legislature as to how the exclusion of the term ‘animal varieties’ is to be construed, the door is wide open for Malaysia to determine its application, either broadly or narrowly, as seemingly allowed under Article 27.3(b) of the TRIPs Agreement. This thesis proposes to fill the gap by proposing which one is the most practical for Malaysia to adopt. Nevertheless, since the exclusion relates to animal inventions, it is only logical that any interpretation of the exclusionary provision should consider the area in which the inventions are applied in a relevant Signatory’s economic activities, as any decision would heavily affect the interest of the public. As far as Malaysia is concerned, the problems of its livestock industry in securing a food supply for the population (as identified in chapter 1) should be the main consideration. With this guiding principle in mind, the next chapter will examine the European-wide permissive approach. The discussion will include a legislative examination of Article 53(b) of the EPC, the analysis of relevant legal cases and an assessment of the implications of the approach on the livestock industry. With regard to the whole thesis, the chapter will show that the permissive approach promotes animal biotechnology applications relating to livestock animals. As a result, the production and quality of the livestock products will be enhanced.

CHAPTER FOUR

THE PERMISSIVE APPROACH FOR PATENTING ANIMAL INVENTIONS AND ITS IMPLICATIONS ON THE LIVESTOCK INDUSTRY: THE EUROPE PERSPECTIVE

1. Introduction

Together with developed countries such as the US and Japan, the EU has made rapid advances in the field of biotechnology. According to the 2010 World Intellectual Property Indicators,[1] the largest number of patent applications in the field of biotechnology originated from the US (10,769) followed by the European Member States (4,299) and Japan (2,827). While the three are considered the key players in the international patent law scene, [2] the EU has adopted a different approach to its economic competitors by having the exclusion of animal varieties under Article 53(b) of the EPC.[3] Notwithstanding the exclusion, which might suggest that the continent is a less-attractive place for investment in biotechnology compared to its main competitors,[4] the EU has put considerable effort into diminishing the 'negative'

---

1 WIPO, World Intellectual Property Indicators 2010: Foreign-oriented patent families by field of technology, http://www.wipo.int/ipstats/en/ (Accessed: 9 April 2011) 60. The top fifteen countries of origin which were involved are Austria, Australia, Canada, China, Switzerland, Germany, Finland, France, Italy, Japan, Republic of Korea, the Netherlands, Sweden, the UK and the US.

2 China is among the top three intellectual property offices (apart from the US and Japan) which account for 60% of the total patent applications filed worldwide. See WIPO, WIPO IP facts and figures 2011, http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo_pub_943_2011.pdf (Accessed: 26 October 2011). However, in terms of patent applications in the field of biotechnology, according to the World Intellectual Property Indicators 2010, only 238 applications originated from China.

3 Similar to the EU, under Article 25(4) of the Patent Law of the People's Republic of China 1984, animal varieties are excluded from patent protection. See WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=178664 (Accessed: 31 October 2011). However, within the international patent law framework, it is not yet clear how China would interpret the exclusion. See for instance, C. Smith, A practical guide to Chinese patent law (2005) 29 *Seton Hall Legislative Journal*, 2, 643-664; K. Geng, Should China provide intellectual property protection for genetically modified animals? (2003) 23 *Northwestern Journal of International Law and Business*, 467-486.

4 There are no similar exclusionary provisions under the 35th Title US Code and Japan Patent Act 1959. See detailed discussion in sub-section 2.2.1 of chapter 2. See also J. Straus, *The present state of patent systems in the European Union: as compared with the situation in the United States and Japan* (Luxembourg: Office for Official Publications of the European Communities Stationery Office, 1997) 45.

perceptions. In particular this has been implemented through its biotechnology policies, legislative framework and decisions of the EPO as demonstrated here.

The EPC was drafted with the Strasbourg Convention as its predecessor, albeit with a different purpose (discussed in section 2 below). Despite the existence of these treaties, the EU was concerned with differences in the implementation aspects.[5] Mainly they were about the interpretation of the term 'invention', the patentability criteria, and the nature of excluded subject matter, which were left with the patent offices and national courts of the Member States.[6] As stated by the Commission White Paper on completing the Internal Market[7] in 1985 such differences 'have a direct and negative impact on intra-Community trade and the ability of enterprises to treat the Common Market as a single environment for their economic activities.'[8] As a result, the EU proposed to have a supplementary document which was meant to provide the Member States with a better understanding and application of the EPC's provisions. This led to the adoption of the EU Biotechnology Directive[9] which aims at clarifying provisions of the EPC. For instance, as regards the exclusion of animal varieties, Recital 29 and Article 4(2) of the EU Biotechnology Directive explain that inventions concerning animals are patentable 'if the technical manipulation of the invention is not restricted to a particular animal variety'.[10] Whether or not these provisions have actually

5 G. Kamstra, M. Döring, N. Scott-Ram, A. Sheard and H. Wixon, *Special report: patents on biotechnological inventions: The E.C Directive* (Sweet and Maxwell, 2002) 2.

6 ibid.

7 Previously known as 'Common Market'.

8 G. Kamstra et al, n 5 above, ibid.

9 The EU has no direct influence on the operation of the EPC or the EPO. Thus, the Directive at the outset will not bind Member States of the EPC. Having the EPC and the Directive in place (which are issued by different administrative bodies), problems might arise for a state which is both a contracting state to the EPC and a member state of the EU. If there is a conflict between the provisions of the two texts, the EPO is under no obligation to comply with the provisions of the Directive. This anticipated problem has however been resolved by the Administrative Council of the EPO with the incorporation of the Directive's provisions into the Implementing Regulations to the EPC (Rule 26 to 29; previously Rule 23b to 23e under the EPC 1973). The incorporation ensured harmonisation between the two texts. The Implementing Regulations to the Convention on the Grant of European Patents is available at: EPO, http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma2.html (Accessed: 22 August 2011).

10 For the provisions, see Appendix 6.

clarified the meaning of the term 'animal varieties' and therefore, the subject matter excluded under Article 53(b), will be seen in section 3 of this chapter.

As already explained in the Introduction chapter, the term 'permissive approach' refers to the ease with which an inventor may obtain patent protection for animal inventions (as products) in the EPC Member States, notwithstanding the explicit exclusion of animal varieties under Article 53(b). This chapter assesses the approach and identifies how permissive it is. It also examines the impact of the approach to the livestock industry and other applications of animal biotechnology. Consequently, the chapter is divided into five sections. Section 2 begins with a legislative overview of Article 53(b) so as to understand the intended meaning of the term 'animal varieties', and the basis, purpose and subject matter of the exclusion. This identifies the permissive approach adopted by the EPO in interpreting the exclusion. The importance and influence of Article 2(b) of the Strasbourg Convention to Article 53(b), on which the current law rests, will also be examined. Reliance will be mainly placed upon the preparatory working papers *(travaux preparatoires)*[11] of the two conventions. Despite both being Conventions for the European patent laws, it is observed that the exclusion is framed in a different manner in each Convention: Article 53(b) of the EPC requires Member States to exclude the subject matter, whereas Article 2(b) of the Strasbourg Convention permits Member States to do the same. In the light of the different nature of the exclusions, and also the flexibility for Signatories to the TRIPs Agreement to exclude animal inventions under Article 27.3(b) (identified in chapter 2), an account of the reasons behind the distinction in the relevant provisions will be made. Section 3 examines the narrow interpretation of the term 'animal varieties' in the light of judicial interpretation and legal commentary. Mainly,

[11] French expression. *Travaux preparatoires* are the official record of negotiations, often useful in clarifying the intentions of a treaty or other instrument. As from 4 April 2011, the record relating to Article 53(b) is available online at the EPO website, http://www.epo.org/law-practice/legal-texts/archive/epc-1973/traveaux.html?update=law (Accessed: 6 April 2011).

this focuses the analysis on the cases of *Harvard/Onco-mouse* and *Leland Stanford/Modified Animals*,[12] which have underlined various important principles pertaining to the exclusion of animal inventions under the European patent law. The discussion includes the facts of the case and decisions of the various Boards of the EPO. Central to this section is an analysis of leading critics' views so as to assess the feasibility of their previous arguments on the interpretation by the EPO. The section also examines the reasons underpinning the permissive approach to appreciate its broader stance to the importance of patent protection of animal inventions. Section 4 assesses the impact of the permissive approach on the livestock industry. The chapter is concluded by section 5.

As regards the whole thesis, this chapter deals with the first model of interpretation and its practical implications from which Malaysia could learn in deciding how it should apply its exclusionary provision which is *in pari materia*[13] with Article 53(b). Malaysia is not a Member State of the EPC. Nevertheless, as the country's patent law originated from the UK's patent system, the permissive approach would be relevant for the Malaysian patent office and courts[14] to consider because it is the same approach which would be adopted by the UK's courts when interpreting the exception in the UK Patents Act 1977.[15] Although decisions of foreign judicial authorities are not legally binding on the Malaysian courts, they are of highly persuasive value if they were decided by courts with a similar common law background. Decisions of this nature have often been followed by national courts when Malaysia's law is

[12] *Leland Stanford/Modified Animals* [2002] EPOR 2.

[13] Latin expression which means: 'of the same matter or on the same subject'. See http://legal-dictionary.thefreedictionary.com/pari+materia (Accessed: 7 April 2011).

[14] I.M. Abdul Ghani Azmi, Research on human embryos and stem cells: weaving ethical and religious concerns into the framework of patent law in Malaysia in P.L.C. Torremans (ed), *Intellectual property and human rights: enhanced edition of copyright and human rights* (Wolters Kluwer, 2008) 510-512.

[15] Paragraph 3(f) of Schedule A2 of the Patents Act 1977. See Appendix 9 for the provision.

unclear.[16] Findings of this chapter will form a basis for various conclusions that will be laid down in the Discussion and Conclusion chapter.

2. The exclusion of animal inventions under the European patent laws

The main concepts of European substantive patent law were established by the Strasbourg Convention[17] under the aegis of the Council of Europe (COE). The Convention[18] laid down general rules for the adoption of national laws. It dealt principally with conditions relating to the patentability of inventions and attempted to define the prerequisites for patent protection, namely novelty, inventive step and industrial application.[19] The initiative to create a patent convention for the EU[20] was inspired by the broader aim to create a Common Market where trade barriers among the Member States of the then European Economic Community (EEC)[21]

---

16 See for instance S.S. Syed Ahmad, *Malaysian legal system* (Lexis Nexis: 2007) 155; A. Ibrahim and A. Joned, *The Malaysian legal system* (Kuala Lumpur: Dewan Bahasa dan Pustaka, 1995) 133. The Federal Court in the case of *DG of Inland v Kulim Rubber Plantations Ltd [*1981] 1 MLJ 214 commented on the effect of decisions of other countries' courts on the interpretation of legislation which are *in pari materia* with Malaysian legislation. The court held that those decisions, although not binding, should be paid due and proper attention by the Malaysian courts. In fact, judgements of courts of foreign jurisdictions have never been lightly treated or refused unless the Malaysian courts could successfully distinguish or hold them as *per incuriam*. *Per incuriam* is a Latin expression which means: 'through lack of care'. See http://legal-dictionary.thefreedictionary.com/ (Accessed: 30 May 2011).

17 Work on patents under the era of the COE started in 1949. See D. Thompson, The draft Convention for a European Patent (1973) 22 *International and Comparative Law Quarterly*, 52. The Convention was signed on 27 November 1963 and came into effect on 1 August 1980.

18 The Convention was largely based on the preparatory work undertaken by Scandinavian countries (Denmark, Norway, Sweden and Finland) in preparation for a Nordic patent law. See M. Singer and D. Stauder, *European Patent Convention: a commentary: Vol. I* (Sweet and Maxwell, 2003) 64. The Nordic patent law came into force on 1 January 1968. It was the result of close collaboration between the joint government-appointed committees of Denmark, Norway and Sweden which had been working since 1950 on an assignment to present a system of Scandinavian patents and to propose the legislation necessitated thereby. See The Joint Scandinavian Patent Committees, 'The Preliminary Report by the Joint Scandinavian Patent Committees: Draft Patent Law and Extracts from the Explanatory Notes' (25 March 1971) 1.

19 See D. Thompson, n 17 above, 53.

20 The initiative was taken in November 1959 by the Secretaries of State of the six member states of the Rome Treaty, which had established what was then called the EEC. The EEC was established on 1 January 1958. See G. Oudemans, *The draft European Patent Convention: a commentary with english and french texts* (London: Stevens & Sons Limited, 1963) 1.

21 Belgium, France, Germany, Holland, Italy and Luxembourg.

were to be removed in order to promote a single market for community trade.[22] Through the unified patent system, the EU aspires to compete economically with the US and Japan.

The EPC specifically aims to establish a system of law, common to the Member States, for the granting of European patents for invention.[23] Thus, when compared to the Strasbourg Convention, the EPC has a broader aim, which is to harmonise[24] the patent systems of the Member States for the granting of patents for innovation. The two important provisions under the European patent law which provide for matters which are to be excluded from patent protection are Article 2(b) of the Strasbourg Convention and Article 53(b) of the EPC. As regards the exclusion of animal inventions, Article 2(b) of the Strasbourg Convention provides:

> The Member States *shall not be bound to provide for the grant of patents* in respect of:
>
> Plant or *animal varieties* or essentially biological processes for the production of plants or animals; this provision does not apply to micro-biological processes and the products thereof. (emphasis added)

In turn, Article 53(b) of the EPC states:

> *European patents shall not be granted* in respect of:
> plant or *animal varieties* or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof. (emphasis added)

---

22 K. Haertal, *European Patent Convention: english translation by Volker Vossius* (C.Heymanns, 1981) 2.

23 Article 1 of the EPC.

24 The terms 'harmonisation' and 'unification' have been frequently used by commentators when discussing the development of the European patent laws. According to Cataldo, by underlining the rules governing patent application and examination procedures the EPC played both the roles of harmonising and unifying the European patent law. On the one hand, the unification is achieved by having a set of granting rules under the Convention, whereas the harmonisation is achieved when the rules are later adopted by the national patent laws of the Member States, creating a uniform granting system for European patents. See V.D. Cataldo, From the European patent to a community patent (2002) 8 *Columbia Journal of the European Law*, 19-35.

Before the legislative examination of the exclusion under Article 53(b), the following sub-section will examine the main reasons underpinning the manner in which the above exclusions are formed, and its comparison with Article 27.3(b) of the TRIPs Agreement. This provides an understanding of why the exclusion is framed in a different manner by framers of each patent law treaty.

2.1 The exclusion of animal inventions under the European patent laws and the TRIPs Agreement: a comparison

While Article 2(b) and Article 53(b) are similar in terms of materials which are to be excluded by Member States of each Convention, the former prescribes the exclusion of animal varieties in an optional manner in contrast to the mandatory nature of the latter. In turn, in comparison to the TRIPs Agreement, it is important to note the similarity between Article 2(b) and Article 27.3(b)[25] where each allows their Member States and Signatories either to grant, or not to grant, patent protection to animal inventions. Conversely, Article 53(b) and Article 27.3(b) are different where the former imposes a mandatory obligation on its Member States, whereas the latter is worded in a permissive manner. It is pertinent to consider why these differences arose.

The permissive nature of Article 2(b) and Article 27.3(b) arises from the common feature of the Strasbourg Convention and the TRIPs Agreement, respectively. Each treaty regulates national patents, only to the extent of establishing basic principles for substantive patent law such as the patent qualification criteria and the period for patent protection. The individual Contracting State maintains its discretion either to grant patent protection, or not, to animal

[25] For Article 27.3(b), see Appendix 4.

inventions. Nevertheless, where a State decides to grant a patent under its national patent law, it is obliged to adhere to the requirements underlined by these parent treaties.[26]

In contrast, the mandatory nature of the exclusion under Article 53(b) is due to the function of the EPC in regulating the grant of European patents.[27] The Convention governs the patents which an inventor could apply for via a single application,[28] and if granted, will create a bundle of national patents as if it had been granted by the local granting offices[29] and enforceable through the national courts.[30] Thus, as it is the EPC which underwrites the granting procedures for the European patent, it is only reasonable that it imposes a uniform system. The mandatory obligation to exclude animal inventions under Article 53(b) is an example of the EPC attempting to achieve parity among the Member States in terms of the implementation of the EPC provisions. Given that the granting of European patents is regulated by the EPC, the function of the national courts is then only to determine the validity or infringement of rights of the granted patent.

The importance of the mandatory obligation also arises from the fact that, while the EPC does not oblige the Member States to bring their national laws into conformity with it, most have amended their national laws to achieve such uniformity.[31] This is due to the various legal

---

[26] For detailed discussion see J. Pila, Article 53(b) EPC: a challenge to the Novartis theory of European patent history (2009) 72 *The Modern Law Review*, 3, 442.

[27] Article 1 of the EPC.

[28] However, in practice, an applicant has an option to file a series of applications in each of the EPC Member State countries in which the relevant invention is intended to be protected, and claim priority of an application through priority provisions. See Articles 87 to 89 of the EPC; L. Bently and B. Sherman, *Intellectual property law* (Oxford University Press, 2009) 372; H. MacQueen, C. Waelde and G. Laurie, *Contemporary intellectual property: law and policy* (Oxford University Press, 2007) 415-417.

[29] Articles 2(2) and 64(1) of the EPC.

[30] Article 64(3) of the EPC; L. Bently et al, n 28 above, 330; H. MacQueen et al, n 28 above, 368.

[31] See G. Tritton, *Intellectual property in Europe* (London: Sweet and Maxwell, 1996) 53-54; G. Paterson, *The European patent system: the law and practice of the European Patent Convention* (Sweet and Maxwell, 1992) 3. For instance the UK Patents Bill 1977 was drafted to bring the UK patent law into compliance with the provisions of the EPC. The UK Patents Act 1977 replaces the Patents Act 1949. See M. Victoria (ed), *The Patents Act 1977: Queen Mary College Patent Conference Papers* (London: Sweet and Maxwell, 1978) 3; Committee to Examine the Patent System and Patent Law, *The British patent system: Report of the*

requirements imposed on the Member States by the Convention.[32] Allowing a permissive exclusion of animal inventions under Article 53(b), which in turn, would be adopted by the national patent laws, would invite Member States to dispute the granting or refusal of the European patent by the EPO. This arises from the power of national courts to interpret the permissive obligation differently. Eventually, this would lead to greater challenges in achieving the uniformity of the European patent laws.

This sub-section has explained that the way in which the exclusion of animal inventions is framed in the European patent laws and the TRIPs Agreement, depends on the function of each treaty. In essence, treaties such as the Strasbourg Convention and the TRIPs Agreement which underline the European or international substantive aspects of patent law (such as the patentability criteria) grant the flexibility for Member States and Signatories to either allow patents on animal inventions or otherwise. This is due to the right of the individual Member State and Signatory to decide on the patentability of the inventions according to national intellectual property policies. Conversely, the treaty which regulates the granting of patents for its Member States, such as the EPC, imposes compulsory exclusion to ensure consistency in the taking up of the exclusion. Nevertheless, in those countries and regions where the exclusion is adopted it is how the exclusion is interpreted which allows permissiveness to arise.

The next sub-section focuses on the exclusion of animal varieties under Article 53(b). The discussion investigates four aspects: (1) the basis of the exclusion; (2) the intended meaning of the term 'animal varieties'; (3) the intended purpose for the exclusion; and (4) the intended

---

Committee to Examine the Patent System and Patent Law (London: Her Majesty's Stationery Office, 1970) xvii.

[32] For instance, Articles 2 and 64 of the EPC, respectively, require that a Member State must ensure that the European patent has the same effect and is subject to the same conditions, and that the same rights are conferred, as would be conferred by a national patent granted by the relevant State.

subject matter of the exclusion. For these purposes, the preparatory working documents of Article 53(b) of the EPC and Article 2(b) of the Strasbourg Convention will be examined. It will be shown that, except for the first aspect, the last three of these are unclear. Nevertheless, as to the subject matter of the exclusion, it is apparent that the framers intended to exclude from the patent system only inventions which do not involve technical intervention. In terms of the thesis, the discussion is important to facilitate an understanding of the legislative background of the exclusion under Article 53(b) which is *in pari materia* with s13(1)(b) of the Malaysian Patents Act 1983.

2.2 The legislative examination of the exclusion of animal varieties under Article 53(b)

The exclusion of animal varieties, in the work of the EEC Patents Working Party (PWP), was influenced by the Strasbourg Convention, which in turn aspired to the harmonisation of European patent law. Administratively this situation was due to at least two reasons: (1) the majority of Member States of both Conventions are the same, making it understandable that both Conventions should contain similar provisions in order to maintain consistency in the implementation of the European patent law; and (2) a number of the members of the Committee of Experts on Patents of the Council of Europe of the Strasbourg Convention (Committee of Experts) were also leading figures in the PWP. They include G. Finniss (who was the Rapporteur-General of the Committee of Experts and Chairman of the PWP), M. Haertel (who was the German expert in the Committee of Experts and President of the PWP), B. van Bentham (the expert for Holland in both Committees) and M. Rosciani (the expert for Italy in both Committees).[33] For these reasons, the tendency to have the exclusion in the EPC

[33] The Working Group for Patents was nominated in the beginning of 1960 and is composed of: K. Haertel (President), F. Froschmaier (Secretary), J. de Reuse, J. Degavre, P. Verlinden (Belgium), P. Fressonnet, R. Gajac, J. Roller (France), K. Pfanner, R. Singer, O. Bossung (Germany), B. van Bentham, G. van Exter (Holland), M. Roscioni, F. Nunziata, R. Briganti (Italy), A. de Muyser (Luxembourg), H. Sünner, J. Lannoy,

(as in the Strasbourg Convention) and the use of similar wording are to be expected, rather than for the framers to 'reinvent the wheel', drafting a new provision.

2.2.1 Basis of the exclusion and meaning of the term 'animal varieties'

Article 12 of the first preliminary draft Convention relating to a European patent law (which came into being in 1961) provides that: 'European patents shall not be granted in respect of inventions relating to the production of or a process for producing a new plant variety or a new animal species.'[34] Nevertheless, 'processes of a technical nature are not excluded'.[35] The draft provision discloses that there was a distinction between the terms used by the framers of the EPC to represent the exclusion in contrast to the corresponding provision in the preliminary draft of the Strasbourg Convention (which was also drafted in March 1961). The former used the term 'new plant variety or a new animal species', while the latter used the term 'new plant or animal species'. The early use of different terms for plant (variety) and animal (species) in the draft of the EPC suggested that there was an understanding among the framers of the EPC of the terms that were appropriate for each category of exclusion. Nevertheless, as the negotiations developed, and during the process of finalising the terms to be used, the Chairman of the PWP reminded the Committee that the wording of Article 12 was not to be altered too much.[36] Otherwise, they would have to inform the COE, since the text of the Strasbourg Convention which similarly excluded plant or animal varieties[37] had

---

J.P. Petitbon, E. Ciasca (European Atomic Energy Committee - Euratom), R. Knöpfle (European Coal and Steel Cummunity – S.A.C.C), J. Dieu, P. Pujade, J.P. Lauwers, Miss M. Kapten (European Economic Community – E.E.C). See G. Oudemans, n 19 above, 1.

34 PWP, 'Comments on the First Preliminary Draft Convention Relating to a European Patent Law of 14 March 1961', Document IV/2071/61-E, section 13, 3.

35 ibid.

36 PWP, 'Proceedings of the 5th Meeting of the Patents Working Party held at Brussels from 2-18 April 1962', Document 3076/IV/62-E (22 May 1962) section 4, 137.

37 In the then paragraph 2(2) of the draft Council of Europe Convention. See COE, 'Memorandum by the Secretariat on the Meeting held at Strasbourg from 7th to 10th November 1961', Document EXP/Brev (61) 8 (13 December 1961) 16.

been submitted to the governments of the negotiating countries.[38] Consequently, the PWP decided to adopt the expression used in Article 2(b) of the Strasbourg Convention.[39]

The discussion concerning Article 53(b) revealed that the reason for having the exclusion in the EPC arose from the need for consistency with Article 2(b). In particular, this is due to the recognised need for the framers of the EPC and the Strasbourg Convention to work in 'co-operation', so as to ensure that the aim for the creation of an Internal Market would not prejudice the work of the COE which aims at establishing the basic principles of European substantive patent law.[40] This motivation was also observed by critics[41] who stated that the identical wording of (the then) Articles 9 to 14[42] of the draft of the EPC and the draft of the Strasbourg Convention was chosen in order to ensure that, once both Conventions were adopted, there should be no discrepancy between these basic provisions.[43] Others[44] made similar observations about the adoption of Article 53 of the EPC based on Article 2 of the Strasbourg Convention where it was said that 'Article 53 was adopted without further discussion as to its purport'.

Notwithstanding the clear need for consistency between Article 53(b) and 2(b), the preparatory working documents for the Strasbourg Convention do not provide any reason for the adoption of the term 'plant or animal varieties' (a change from the term 'new plant or

---

38 PWP, n 36 above, ibid.

39 ibid. 138.

40 COE, 'Report by the Committee of Experts to the Committee of Ministers on the meeting held at The Hague from 28 November to 2 December 1960', Document CM (60) 150 (2 December 1960); J. Pila, n 26 above, 442.

41 See G. Oudemans, n 20 above, 21.

42 Article 9: patentable inventions; Article 10: Exceptions to patentability; Article 11: Novelty; Article 12: Non-prejudicial disclosures; Article 13: Inventive step; Article 14: Industrial application. ibid.

43 ibid.

44 E. Armitage CB and I. Davis CB, *Patents and morality in perspectives* (London: Common Law Institute of Intellectual Property, 1994) 24. The former was closely involved in the preparatory work on the Strasbourg Convention and the EPC.

animal species', previously used in the preliminary draft of the Convention).[45] Arguably, the discussion on the protection of new plant varieties which took place alongside the work on the unification of the substantive aspects of the European patent law, could have contributed to the change of terms adopted. This is evidenced by the similarity of phrase used to define the protectable subject matter.[46] The discussion, which finally led to the adoption of the UPOV Convention, gave specific protection to plant varieties which were considered not appropriate to be protected by the patent regime.[47] In the negotiations over Article 53(b), the PWP made an explicit reference to the Convention where the debate on the terms 'new plant variety' and 'new animal species' arose in its first meeting. A delegate[48] questioned the use of the term *'nouvelles espêces animales'* (which could be translated as: new animal species). He was of the opinion that the exclusion of new animal species would not cover any new animal breeds.[49] In response to this, the PWP decided 'to wait and see what terminology would shortly be adopted in the UPOV Convention before changing those terms'.[50]

It can be observed that the term 'plant or animal varieties' under the EPC was adopted by the PWP only four months after the adoption of the UPOV Convention which provides a *sui generis* protection to plant varieties. Intrinsically, the term 'plant varieties' was chosen as the most appropriate for the exclusion of plants in the EPC. As regards the term 'animal varieties', in the absence of an equivalent legal instrument relating to animals, the term used to represent the exclusion is most likely to have been influenced by the term 'variety' when applied to plants. Given that the term 'variety' was already being used in the discussion

---

45 COE, 'Report of the meeting on 16 and 17th March 1961', Document EXP/Brev B (61) 3 (24 March 1961) 6. The change was due to proposals that were received from the Working Group and the Drafting Committee. See COE, 'Proposal by the Working Group', Document EXP/Brev/Misc (61) 13 (8 November 1961); COE, 'Proposal of the Drafting Committee', Document EXP/Brev/Misc (61) 14 (9 November 1961).

46 See comment in J. Pila, n 26 above, 453.

47 Plants which are novel, distinct, uniform and stable.

48 Mr. De Reuse, an expert from Belgium. See PWP, 'Proceedings of the 1st Meeting of the Patents Working Party held at Brussels from 17-28 April 1961', Document IV/2767/61-E (3 May 1961) section 6, 45.

49 PWP, ibid.

50 ibid.

surrounding plant variety protection, its use, and the extension to animals, which appears in the same draft provision, might have seemed both obvious and logical.

2.2.2 Purpose of the exclusion

The purpose of the exclusion of animal varieties from the patent regime was neither explicitly discussed nor raised in the negotiating process of Article 53(b) and 2(b). It has been highlighted in the negotiation of Article 2(b) that novel plant inventions[51] should be excluded from the patent system as the potential monopoly would raise issues of public interest. Further, there was disagreement among negotiating countries as to the concept of 'industrial character'[52] that should be attached to agricultural inventions.[53] In the same context, it can only be assumed that animal varieties are excluded for the same reason. Nevertheless, despite the specific prerequisites and concept for plant varieties under the UPOV Convention, critics have asserted that the conceptual exclusion for plant varieties under the EPC should be extended to animal varieties. For instance, it has been stated that:

---

[51] Terms such as 'vegetable novelties', 'vegetable species', 'plant varieties' and 'plant species' were used interchangeably to represent novel plant inventions in communications among delegates of participating countries. While there was no specific meaning attached to the term 'novel plant inventions', the early discussion of the Committee of Experts on Patents of the Council of Europe which started with a comparative study made by the Secretariat General of the Committee with regard to new horticultural products might shed some light as to the nature of products which were under discussion. Therefore, the terms used by the delegates may cover fruits, vegetables, flowers and ornamental plants. In the context of patent protection, the term 'novel plant inventions' may be intended for any plant products which may be patentable as they were new in the patent law sense of novelty, rather than those which are naturally occurring.

[52] Industrial applicability is one of three granting criteria for patent protection beside novelty and inventiveness. Industrial applicability means an invention must be able to be used in an industry. For an inventor to be able to claim protection for his invention he needs to show that the invention has a technical character which exhibits useful purpose in solving a technical problem. While processes in agricultural activities may be easily understood to be able to fulfil this criterion, participating countries of the Strasbourg Convention varied in opinion whether the end products *per se* could have an 'industrial' method of operation to solve a technical problem.

[53] COE, 'Report of the French Delegation on the Unification of European Laws in respect of Patents', Document EXP/Brev (57) 3 (13 May 1957) 5.

> [t]he extension of the exclusion to animal varieties was *a logical consequence* because to accord protection to *a corresponding category of animals* whilst refusing protection to a certain category of plants (variety) would be deemed anomalous.[54] (emphasis added)

Similarly, it has also been contended[55] that the extension was logical for the possible creation of a similar *sui generis* system to plant varieties for animal breeds that may take place in the future. Notwithstanding these arguments, it seems possible to argue that the critics' conclusions are difficult to appreciate, as there is no equal or alternative Convention which provides for the protection of animal varieties (including its concepts). While it is appropriate for plant varieties to be excluded from patent protection due to the availability of an alternative protection, there were no calls for protection of any kind to be provided for animal inventions. Therefore, it can only be surmised that the reason animal varieties were excluded under Article 53(b) was because of some sense of the need for completeness.

The lack of consideration for the purpose of excluding animal inventions from the European patent laws may be further explained by two reasons based on the negotiation of Article 2(b) of the Strasbourg Convention: (1) in comparison to novel plant inventions, which were handled differently in most of the negotiating countries, thus requiring a decision on suitable protection,[56] the need for legal protection for novel animal inventions had not yet developed. Nevertheless, the negotiating countries had no objection to the patenting of processes

---

54 E. Armitage CB et al, n 44 above, 14. See also observation by M.W. Tvedt, Patent protection in the field of animal breeding (2007) 57 *Acta Agriculturae Scand Section A*, 108.

55 O. Mills, *Biotechnological inventions: moral restraints and patent law* (Ashgate, 2005) 27.

56 COE, 'Draft Minutes of the Fourth Meeting held at Strasbourg on 10th July 1952', Document EXP/Brev (52) PV 10 prov (11 July 1952). The comparative study by the Secretariat General of the Committee of Experts disclosed that there was no national legislation of the participating countries which made express provision for the patenting of novel plant inventions. For instance, France at that time provided an inventor of novel plant inventions with a limited protection outside the patents legislation through the decree of 16 November 1932 for certain kinds and species of plants. See COE, 'Draft Official Report of the Meeting of 6th July 1951', Document CM/WP/IV (51) PV 8 (7 July 1951); COE, 'Criteria of Novelty and Patentability', Document CM/WP/IV (51) 9.

involving animals for agricultural reasons.[57] However, there seems to have been no reason for the framers to seriously consider the idea that patents might be granted for novel animal inventions as products;[58] (2) apart from this, plant varieties and animal species may be seen as sharing a similar characteristic; they are living organisms which are of agricultural relevance, hence, important to the public. In view of the absence of a specific concept for animal varieties, a separate discussion for this issue might be seen as premature or unnecessary by the Meeting. Yet their exclusion under Article 2(b) may be considered as justified by the framers should issues relating to their legal protection arise in the future.

2.2.3 Subject matter of the exclusion

A pertinent issue arising from the non-definitive meaning of the term 'animal varieties', concerns the subject matter of the exclusion. The intended meaning and, therefore, the subject matter which the framers intended to exclude for the term 'animal varieties' remained indefinite. However, looking at the whole provisions of Article 53(b) and 2(b), a relevant conclusion can be reached. The framers of both provisions had made it clear from the negotiations that processes of a technical nature, although being applicable to animals, are patentable.[59] In evidence, the drafts of Article 53(b) and 2(b) clearly stated that 'essentially

[57] Such as methods of rearing animals. See COE, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe, from the point of view of the German legislation', Document EXP/Brev (53) 1 (12 January 1953) 3; COE, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe from the point of view of legislation in Norway', Document EXP/Brev (53) 9 (7 April 1953) 2.

[58] COE, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the French legislation', Document EXP/Brev (53) 4 (10 February 1953) 3-4; J. Pila, n 26 above, 453-454.

[59] COE, 'Observations and proposals of the German experts on the unification of general conditions of patentability', Document EXP/Brev (56) 8 (26 October 1956) 2. See also PWP, n 34 above, section 13, 6. It was stated in the document that: 'Even if protection of new plant varieties and processes for producing new plants is excluded under European patent law, European patents will still have to be granted for processes which, while being applicable to plants, are of a technical nature, e.g, processes for producing new plants by irradiation of the plants themselves or of the seed with isotopes'. As regards new animal species, it was stated that the comments for new plant varieties 'also apply *mutatis mutandis* to the patentability of new animal species'. *Mutatis mutandis* is a Latin expression which means: 'the necessary changes'. See http://legal-dictionary.thefreedictionary.com/Mutatis+mutandis (Accessed: 10 April 2012).

biological processes for the production of plants and animals', can (or should) be excluded from patent protection whereas 'micro-biological processes and the products thereof' are not bound by the exceptions.[60] In other words, the framers of the provisions only intended to exclude from the patents system inventions involving no technical intervention which would render it eligible for patent protection. However, the question which remained concerns the lack of legal protection for 'animal varieties' (as products) as compared to plant varieties. In this, whether or not animal inventions are unpatentable under the European patent law, will be seen in the next section.

Based on the examination of the preparatory working papers of the Strasbourg Convention and the EPC, this sub-section has shown three things: (1) the work of the draft of the EPC which ran parallel with the final stage of the Strasbourg Convention shows that the latter influenced the former in terms of the basis of, and the terminology used to represent, the exclusion. Essentially, this was to ensure consistency between the two European patent law treaties so that the objective for the creation of an Internal Market was not prejudiced; (2) the purpose of the exclusion under both Conventions was not explicit. Apart from the assumption that it is based on the importance of agricultural products to the public, the exclusion of animal varieties is arguably a complement to the exclusion of plant varieties; and (3) although what exactly was intended to be excluded by the term 'animal varieties' under Article 53(b) is unclear, it can be concluded that inventions with technical intervention, albeit relating to animals, are to be protected under the European patent law.

[60] COE, 'Report of the Committee of Experts to the Committee of Ministers on the meeting held from Strasbourg from 14th to 17th May 1963', Document CM (63) 101 (27 May 1963) 10; Intergovernmental Conference for the Setting Up of a European System for the Grant of Patents, 'First Preliminary Draft of a Convention Establishing a European System for the Grants of Patents', Document BR/88/71 (15 February 1971) 12.

Notwithstanding these conclusions, it is important to note Articles 31 and 32 of the Vienna Convention on the Law of Treaties 1969 (Vienna Convention)[61] which laid down the convention in international law. According to the provisions, if the relevant treaty or Convention fails to provide a definition, 'then the ordinary meaning of that term should be used, in the context and in the light of the object and purpose of the Convention'.[62] In the absence of a definitive meaning for the term 'animal varieties' as shown in this sub-section, it is significant to see how the EPO, being the granting office of European patents, has defined the term and shaped the application of the exclusion.

Under the European patent law, biotechnological inventions, as with other types of invention, should be patentable provided the patent qualification criteria under Article 52(1) of the EPC are met. Article 3 of the EU Biotechnology Directive reiterates this principle where it clearly states that the fact that an invention involves living organisms is not a bar to its patentability. With these general principles as a pillar, the exclusion of animal varieties under Article 53(b) has been narrowly applied by the EPO.[63] The *Harvard/Onco-mouse* and *Leland Stanford/Modified Animals* are two important decisions of the EPO which directly address the issues of the patentability of animal inventions, and so the next sub-section will focus on them.[64] Brief facts of the cases will first be discussed, followed by an analysis of the decisions of the EPO in the context of critics' views about the decisions.

---

61 Available at: http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (Accessed: 27 May 2011).

62 M. Adcock and M. Llewelyn, Micro-organisms, definitions and options under TRIPS, Paper prepared for a discussion meeting hosted by the Quaker UN Office (Geneva) and the International Centre for Trade and Sustainable Development, 23 November 2000, 4. See also the EPO's statement in the case of EISAI G5/83 (Second medical indication). Available at EPO, http://www.epo.org/law-practice/case-law-appeals/recent/g830005ep1.html (Accessed: 31 May 2011).

63 G. Kamstra et al, n 5 above; M.W. Tvedt, n 54 above.

64 A line of decisions of the *Harvard/Onco-mouse* case has been widely discussed within the European patent law jurisprudence on the exclusion of biotechnological inventions. They explain extensively several legal considerations on the patentability of animals. Nevertheless, the *Leland Stanford/Modified Animals* case is no less important in underlining the European patent law policy on the subject matter. This is because, unlike the *onco-mouse* which was held patentable by being an animal genetically modified at the molecular level,

The discussion will show that the use of taxonomic definitions confirmed by the TBA in the *Onco-mouse II* to justify the patentability of animal inventions under the European patent law is not free from challenge. However, the isolated category approach which underpins the narrow interpretation aiming at the grant of patent protection to animal inventions, would eventually promote inventive efforts and technological advancement. In terms of the research questions, the analysis contained in the next section (which is based on the final decision of the *Harvard/Onco-mouse* case)[65] informs Malaysia (and other countries with the same exclusion) of two things: (1) how permissive is the European-wide approach; and (2) which of the leading critics' views (all of which were based on the earlier decisions of the *Harvard/Onco-mouse* case) could still stand or have been otherwise refuted. The analysis of the latter would serve as a pertinent guide to Malaysia as the implications of the critics' arguments for the progression of scientific R&D involving animal inventions, will be concluded.

3. The narrow interpretation for the exclusion of animal varieties under Article 53(b) of the EPC

3.1 The Harvard/Onco-mouse and Leland Stanford/Modified Animals: facts and issues for determination

Both cases have straight forward facts and issues for determination. The *Harvard/Onco-mouse* case involved a European patent application filed by Harvard University for two types

hence altering the whole genome of the animal, and, therefore, should have easily fulfilled the patentability qualifications, the *Leland Stanford/Modified Animals* decision held that chimeric (simply means: hybrid) animals which are altered at the neonatal stage (hence should have been more difficult to prove novelty) are also patentable under the European patent law.

[65] The decision of *Transgenic Animals/Harvard*, T 315/03, Decision of Technical Board of Appeal, 6 July 2004.

of patents: (1) process patents; and (2) product patents. The claims for the main process patent were for a method for producing a transgenic mouse, for which the process involved the alteration of the genetic sequence of the mouse by the injection of onco-genes (cancer-inducing genes) to develop cancer tumours. The mouse would then be used for testing new anti-cancer drugs. The product claim was for the transgenic mouse itself.[66] Patents relating to the process to create the mouse, cell cultures and plasmids associated with the transgenic mouse were allowed.[67] Therefore, the issue for the EPO to decide was whether the genetically engineered mouse fell within the term 'animal varieties' in Article 53(b) and therefore, was unpatentable.

As regards the *Leland Stanford/Modified Animals* case, the patentee produced an immuno-compromised[68] human-animal chimera (hybrid) mouse. The mouse was produced using tissues from aborted human foetuses and children below three years old, for the purpose of modelling HIV-1 infections. The issue before the Opposition Division (OD) was whether the patent granted to the proprietor for 'a chimeric non-human mammalian' was valid. One of the oppositions to the patent was that the subject matter involved contravened Article 53(b) for being animal varieties.

The *Harvard/Onco-mouse* case was the first case where the EPO was required to determine the excluded subject matter under Article 53(b). While the case was also decided by the Examining Division (ED) (in 1989 and 1992) and by the OD (in 2001), the *ratio decidendi*[69]

---

66 *Harvard* V 0004/89, Examining and Opposition Division, Official Journal of the EPO 1989, 451, paragraph 3.

67 ibid.

68 Means: a health condition where an organism suffers from 'an incapability to develop a normal immune response, usually as a result of disease, malnutrition, or immunosuppressive therapy'. See http://www.thefreedictionary.com/immunocompromised (Accessed: 19 August 2011).

69 A Latin expression which means: 'the ground or reason of decision; the legal principle upon which the decision in a specific case is founded'. See http://legal-dictionary.thefreedictionary.com/ratio+decidendi (Accessed: 19 April 2011).

of the case was laid down by two decisions of the TBA (in 1990, sometimes referred to as the *Onco-mouse I*; and in 2004, sometimes referred to as the *Onco-mouse II*).[70] Intrinsically, this is due to the hierarchy of the decision-making within the EPO, which afford primacy to the decisions of the Technical Board in this context. The analysis in the next sub-section will use the *Onco-mouse II* decision as a focal point with the support of the decision of the *Leland Stanford/Modified Animals* case (where relevant).

3.2 The decision of the Onco-mouse II: an analysis

The EPC has three versions, namely English, French and German, which, according to Article 177(1) of the EPC, are equally authentic. Consequently, the exclusionary terms under Article 53(b) are represented differently: 'animal varieties' in English, *'races animales'* in French and *'Tierarten'* in German (the three terms). Each of the versions of Article 53(b) contains a reference to the terms 'animal varieties' and 'animals'; *'races animales'* and *'animaux'*; and, *'Tierarten'* and '*Tiere'*; in the same provision.[71] Therefore, the TBA in the *Onco-mouse I* was of the view that the framers intended the former (of each term) to have a narrower meaning than the latter. Ultimately, the Board decided that under Article 53(b) the framers intended that only certain categories of animals should be excluded and not animals *per se*.[72] Underpinning the decision is the principle that as Article 53(b) is an exception to the general rule of patentability under Article 52(1) it should be narrowly construed.[73] Notably,

---

[70] The *Onco-mouse II* decision was the result of the opposition to the patents granted by the Examining Division in 1992, where the issue of whether the *onco-mouse* should be patentable as it constitutes 'animal varieties' under Article 53(b) was again raised. Seventeen Notices of Opposition were filed against the granted patent. See *Onco-mouse/Harvard*, Decision of the Opposition Division 7 November 2001, Official Journal of the EPO, October 2003, 473, at 474.

[71] *Harvard* T 0019/90, Technical Board of Appeal, Official Journal of the EPO 1990, 476, paragraph 4.2.

[72] ibid. paragraph 4.6.

[73] See further discussion about the legal principle in H. Holzapfel and G. Werner, Interpreting exceptions in intellectual property law in Wolrad Prinz zu Waldeck und Pyrmont, M.J. Adelman, R. Brauneis, J. Drexl and R. Nack (eds), *Patents and technological progress in a globalized world* (Berlin: Springer, 2009).

the rule was adopted by the long-held decisions of the Boards of the EPO in some earlier cases involving plant varieties such as *Lubrizol/Hybrid Plants.*[74]

In both the *Harvard/Onco-mouse* and *Leland Stanford/Modified Animals* the granted patents were held to be valid as the claims are not caught by the exclusion of animal varieties under Article 53(b). How did the EPO define the term 'animal varieties' (in the light of the three different terms), hence, reaching the conclusion? Before analysing the decisions, it is pertinent to appreciate the salient principles underlined by the *Onco-mouse II*, to which the discussion now turns.

3.2.1 Salient principles of the *Onco-mouse II*

In reference to the Merriam-Webster OnLine Dictionary,[75] the *Onco-mouse II*[76] has discussed the taxonomic classifications for the terms 'variety', 'race' and 'species' as below.

> 'Animal variety' is defined as:
> any of various groups of animals ranking below a species (sub-species).
>
> 'Animal race':
> an actually or potentially interbreeding group within a species; also a taxonomic category (as a sub-species) representing such a group.
>
> 'Animal species':
> a category of biological classification ranking immediately below the genus or sub-genus, comprising related organisms or populations potentially capable of

[74] [1990] EPOR 173, at paragraph 6. This principle should be distinguished from the broad construction adopted in the cases involving human embryonic and human embryonic stem cells which have been specifically excluded from patentability under Rule 28(c) and Rule 29(1) of the Implementing Regulations to the EPC. The issue has been discussed in the lead case of *WARF/Stem Cells* [2009] EPOR 1; Decision of the Board of Appeal 3 November 2008 T 1374/04, and the earlier case of *Edinburgh Patent case* European patent (EP) no 0695351; Opposition Division's Interlocutory Decision of 21 July 2003. Underpinning the broad construction, as stated by the EBA in paragraph 28 of the *WARF* decision, was 'the concern of the framers to prevent misuse in the sense of a modification of human embryos and one of the essential objectives of the whole Biotechnology Directive to protect human dignity.'

[75] Understandably the Board was specific about the source of classification that they adopted as there is more than one standard adopted in the science of animal taxonomy.

[76] *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 11.6.

> interbreeding, and being designated by a binomial that consists of the name of a genus followed by a Latin or Latinized uncapitalized noun or adjective agreeing grammatically with the genus name.

In turn, the decision has discussed the definition below for 'genus':

> a category of biological classification ranking between the family and the species, comprising structurally or phylogenetically related species or an isolated species exhibiting unusual differentiation, and being designated by a Latin or latinized capitalized singular noun.[77]

These definitions are based on the taxonomic classification of the animal kingdom where each category (taxon) denotes the categorisation of an individual animal (and its relatives), into groupings based on their inheritable characteristics or traits (such as animals with or without backbones, hot or cold blooded, and two-legged or four-legged). Known as a reproductive community or an ecological unit or a genetic unit, species is the lowest category in the classification rank.[78] It refers to a population of animals which can breed and produce viable offspring.[79] The *Onco-mouse II* exemplified species 'to include *Mus musculus (M. musculus)*, *M. abbotti* and *M. caroli*; and *M. musculus* can be further sub-divided into sub-species such as *M. musculus domesticus* and *M. musculus bractianus*.'[80] Animals are treated as sub-species and given sub-specific names if different populations within a species can be shown to differ consistently from other populations.[81] It is also important to note that genus is preceded by five other higher theoretical categories: family, order, class, phylum and Kingdom.[82] Therefore, a full animal taxonomic classification (based on the definitions discussed in the *Onco-mouse II*) can be illustrated as Diagram 1 below (with a demonstration

---

77 ibid.

78 E. Mayr, *Principles of systematic zoology* (New York: McGraw-Hill Book Company, 1969) 23; W.H. Johnson, L.E. Delanney, E.C. Williams and T.A. Cole, *Principles of zoology* (Holt, Rinehart and Winston, 1969) 274.

79 ibid.

80 *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 11.6.

81 R. Freeman, *Classification of the animal kingdom* (London: English Universities Press Ltd, 1972) 3.

82 G.G. Simpson, *Principles of animal taxonomy* (London: Oxford University Press, 1961) 3; E. Mayr, n 78 above.

for the taxonomic classification of the species of house mouse i.e *Mus musculus or M. musculus*).

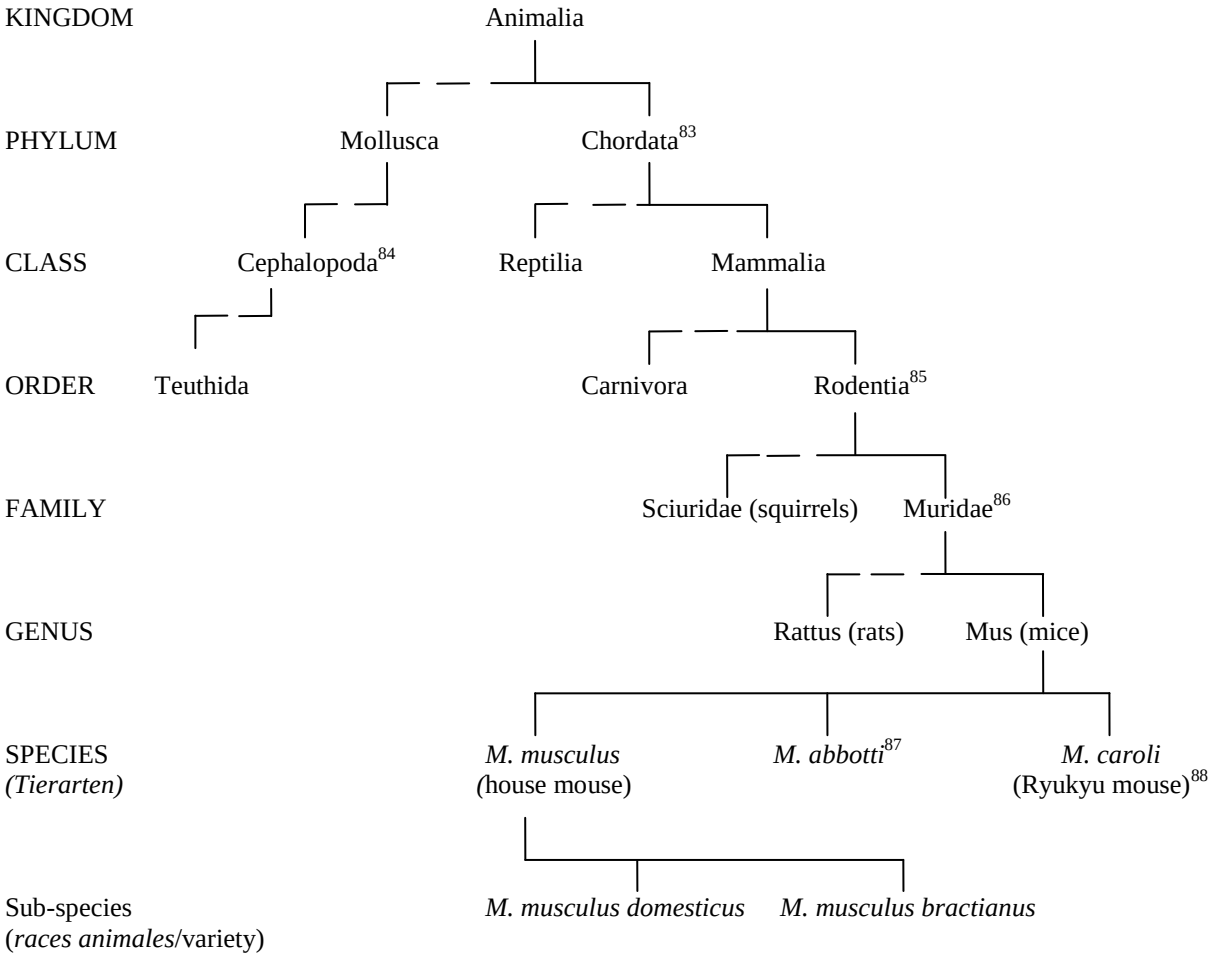

Diagram 1: The full taxonomic classification of *Mus musculus* (house mouse)[89]

---

[83] Vertebrates animal. See http://www.thefreedictionary.com/Chordata (Accessed: 9 May 2011).

[84] Includes squid, cuttlefish, octopus and squid. See Taxonomy of the Cephalopods, http://www.molluscs.at/cephalopoda/taxonomy.html (Accessed: 5 October 2011).

[85] Animal characterised by large incisors, adapted for gnawing or nibbling. See http://www.thefreedictionary.com/rodent (Accessed: 9 May 2011).

[86] The family includes mice and rats, gerbils, whistling rats and relatives. See http://www.globalspecies.org/ntaxa/115756 (Accessed: 9 May 2011).

[87] According to the International Union for Conservation of Nature and Natural Resources (IUCN), *Mus abbotti* is a synonym of *Mus musculus*. See IUCN, Red list of threatened species, http://www.iucnredlist.org/apps/redlist/details/13972/0 (Accessed: 2 November 2011).

[88] Also known as Ricefield Mouse. ibid.

[89] The diagram is adopted from Figure 6 of Warren Jones's 'Taxonomic Classification' with modification based on the *Onco-mouse II* decision as regards the placement for the taxon of Rodentia, *Mus* (mice) and downwards. See A. Warren-Jones, *Patenting rDNA: human and animal biotechnology in the United Kingdom and Europe* (Oxford: Lawtext Publishing, 2001) 114. Albeit the difference (where, in Figure 6 she reduces some taxa to lower ranks; such as by placing *Mus* under species; Rodentia under genus and downwards) her analysis on the subject matter remains relevant for consideration as taxonomic classification is an inexact science where classification of animals to a particular category is quite subjective depending on the knowledge of the taxonomist. The most important point to bear in mind is that the taxonomic classification is a system which relies on inheritable characterisation of an animal.

The Diagram demonstrates two important points: (1) A species is a group of animals which are grouped together in a genus due to shared general inheritable characteristics, but which are divided further into sub-species (or further sub-specific categories) due to more specific characteristics (arising, for example, from a common geographical location); and (2) the terms 'animal varieties' (variety), *'races animales'* (race) and *'Tierarten'* (species) adopted under Article 53(b) are taxonomically not equal to each other. The categories of 'race' and 'variety' come below the category of 'species' for being sub-species. Notwithstanding the latter point, the *Onco-mouse II*[90] has confirmed that a definition by reference to taxonomical rank 'was the most appropriate so that it would be consistent with the position to plant varieties and in the interests of legal certainty'. According to the TBA, the definition would enable an assessment under Rule 27(b) of the Implementing Regulations to the Convention on the Grant of European Patents (Implementing Regulations to the EPC) which states *inter alia* that 'if the technical manipulation of the claimed subject matter is not limited to a particular animal variety, the claims do not fall within the exclusion'.[91] Therefore, adopting the principle underlined by the Enlarged Board of Appeal (EBA)[92] in the case of *Novartis/Transgenic Plant,*[93] the *Onco-mouse II*[94] decided that: '[a] patent should not be granted for a single animal variety (or species or race, depending on which language text of the EPC is used) but can be granted even if varieties may fall within the scope of its claim.'[95]

---

90 *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 11.5.

91 The principle simply means, while animal varieties are not patentable in Europe, if an invention is not restricted to a particular variety of animal, the exclusion does not apply. For example, if an invention involves genetically engineering a gene construct for expressing an enzyme into a mammary gland of a pig, but the technical manipulation of the invention can be applied to different varieties of pigs or different mammals (not to a particular variety of pig), then the invention would not be deemed an animal variety, thus not barred from patentability.

92 The EBA is a higher rank of decision-making panel than the TBA within the EPO.

93 G 01/98 [2000] EPOR 303; T 1054/96 [1999] EPOR 123. The EBA in its decision held that a claim will not be excluded from patentability where specific plant varieties are not individually claimed.

94 *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 11.8.

95 ibid. In the context of animal, the principle simply means, a single animal variety (in terms of the taxonomic classification) is not patentable. However, where (for example) patent is granted to a gene which is contained

This principle has been similarly adopted by the OD in the case of *Leland Stanford/Modified Animals*,[96] and will be further discussed in sub-sections 3.2.2 and 3.3 below.

One of the aspects which the TBA (in *Onco-mouse I*) had directed the ED to consider was to determine the common meaning of the three terms.[97] Nevertheless, an examination of the decision of the ED identifies that the Division did not reach this point. Rather, the patentability of the claimed transgenic mouse was generically decided by looking at the terms used in the specification of the claims filed by the applicant to describe the invention.[98] As a result, the Division simply held that, 'as the claims referred to the invention as 'mammals' and 'rodents', which were taxonomically higher than 'species', 'race' and 'variety', the transgenic mouse was not caught by Article 53(b)'.[99] The decision suggested that a common meaning for the three terms is not attainable. Yet, the ED reversed its earlier decision which refused the applicant's claim. While the subject matter excluded under Article 53(b) appears to have been decided by the *Onco-mouse I* through the generic approach adopted by the ED, hence suggesting an explicit distinction between patentable and unpatentable animal inventions, what remains vague from the decision is: what precisely is excluded?

In response to the generic approach of the *Onco-mouse I,* Vossius,[100] Beyleveld and Brownsword,[101] and Warren-Jones[102] have offered their views on the excluded subject matter

---

in an animal variety, the patent covers the animal with that gene contained within it. For example, according to Diagram 1, an applicant cannot claim patent to *M. musculus domesticus*, but if a patent is granted to a gene contained in the mouse, it is covered by the patent.

96 *Leland Stanford/Modified Animals*, n 12 above, paragraph 42.

97 *Harvard* T 0019/90, n 71 above, paragraph 4.3.

98 *Harvard* V 0006/92, Examining and Opposition Divisions, Official Journal of the EPO 1992, 589, paragraph 2; A. Warren-Jones, n 89 above, 117.

99 *Harvard* V 0004/89, n 66 above, paragraph 2.

100 V. Vossius, Patent protection for animals; Onco-Mouse/Harvard (1990) 12 *European Intellectual Property Review*, 7.

101 D. Beyleveld and R. Brownsword, *Mice, morality and patents* (London: Common Law Institute of Intellectual Property, 1993).

102 A. Warren-Jones, n 89 above.

actually intended under Article 53(b). Sub-section 3.2.2 below will analyse their arguments which are pertinent to this thesis for two reasons: (1) the *Onco-mouse II* has confirmed most principles underlined in the previous *Harvard/Onco-mouse* decisions (which were the basis of the critics' arguments); and (2) therefore, any points and arguments that the critics have considered and advocated are relevant in the current analysis of the *Onco-mouse II*.

3.2.2 An analysis of the *Onco-mouse II* in the light of the leading critics' arguments and the EU Biotechnology Directive

The *Onco-mouse II* affirmed that taxonomic definition is the most appropriate approach to define the term 'animal varieties' (where Vossius and Warren-Jones are proponents of this principle). It is important to firstly appreciate the meaning of the term in the science of animal taxonomy in order to see if the TBA decision to adopt the taxonomic definition is firmly supported by scientific definition. While intrinsically, the meaning of the term should have come from the EU Biotechnology Directive, unfortunately, it fails to define the term. Article 4(1) of the Directive simply repeats the wording of Article 53(b), whereas Recital 29 and Article 4(2),[103] and Rule 27(b) of the Implementing Regulation to the EPC[104] do not help much in clarifying the meaning of the term. Due to this deficiency, the definition provided by the decisions of the EPO, and the views of experts in the field of animal taxonomy and critics of the exclusion under Article 53(b) become particularly important.

The ED and OD in the cases of *Harvard/Onco-mouse*[105] and *Leland Stanford/Modified Animal*,[106] respectively, admitted that the meaning of the term is not clear. Similarly, critics

[103] See Appendix 6.
[104] See Appendix 7.
[105] *Harvard* V 0004/89, n 66 above, paragraph 2.
[106] *Leland Stanford/Modified Animals*, n 12 above, paragraph 42.

from the field of animal taxonomy observed that the term 'variety' is either not commonly used by taxonomists or used in a subjective manner. The subjectivity of the definition for the term arises from the differences in views of taxonomists in classifying variants of species.[107] In this respect, discussion on lower categories of animals focuses on species which is the most defined category in animal classification. While being recognised as the only subdivision of species by Linnaeus[108] and the early taxonomists,[109] it has been strongly urged[110] that the term 'variety' be abandoned due to the absence of a clear and defined meaning for it. The term was said[111] to simply denote 'anything that deviated from the ideal type of the species'. The unclear scientific definition for the term 'variety' has also been observed by some other critics. Their arguments range from: (1) the term is 'more vague for animals than for plants and that the use of the term in natural science is less defined'; [112] and (2) the term is challenging both from the areas of active breeding and legal definition.[113]

Focusing on the appropriateness of the usage of terminology for the three terms, rather than assessing the excluded subject matter intended by the ED, Vossius[114] argued some important points. According to him, the choice of the word 'variety' indicates the framers' intention not to exclude animals *per se* from the patent system, but rather only certain category of animals. Otherwise the framers would have used the term 'animals' to represent the exclusion. He argued, this interpretation corresponds with the ethos of the EPC which aims at promoting the

[107] R. Freeman, n 81 above, 3.
[108] Linnaeus was a botanist who produced the system of classification of living organisms in the 18th century and his system still forms a basis of animal taxonomy today. See for instance, R.T. Schuh, *Biological systematic: principles and applications* (Ithaca: Cornell University Press, 2000) 3; E. Mayr, n 77 above; G.G. Simpson, n 82 above, 16.
[109] E. Mayr, n 78 above, 346.
[110] G.G. Simpson, n 82 above, 178.
[111] E. Mayr, n 78 above, 346.
[112] R. Teschemacher, Patentable subject matter under the European Patent Convention (EPC) in the field of biotechnology and disclosure and manner of claiming of biotechnological inventions before the European Patent Office, Paper presented in the Symposium on the Protection of Biotechnological Inventions, 1987, 89-115.
[113] M.W. Tvedt, n 54 above, 107.
[114] V. Vossius, n 100 above, 252.

development of science by giving incentives to inventors for a limited period of time to encourage them to innovate.[115] Therefore, he further argued that the decision of the ED which held animals *per se* as unpatentable (in the first instance of its decision) was wrong.[116] Notwithstanding this view, he admitted that the three terms do not have the same meaning as regards 'the scientifically recognised definition in biological usage',[117] making them unequal to each other. The term 'variety' carries a different meaning from the term 'species' and 'race'. The last two of these refer to populations of animals produced through interbreeding.[118] Therefore, being a group of animals which is subject to natural conditions, he asserted that they are not suitable subject matter for patents.[119]

In agreement with the views of the taxonomists, Vossius further asserted that the term 'variety' simply denotes structural and physical variations (such as in colour, size or shape due to ecological, environmental or geographical factors) from a species or sub-species.[120] While acknowledging the fact that the term could be a precise one to describe 'new kinds of animals' and individuals, he was of the view that the term 'strain' or 'breeding stock' are the most appropriate terms to describe a uniform group of animals which are genetically altered through modern biotechnology methods (arguably this refers to transgenic animals as well).[121] As a result, he concluded that the three terms should not be synonymously used under Article 53(b), and proposed that the terms be changed to: 'animal species', *'espèces animales'* and *'Tierarten'*, for consistency purposes.[122] In essence, Vossius's main argument is that Article 53(b) only excludes animals which are produced through traditional breeding,

[115] ibid.
[116] ibid.
[117] ibid. 251.
[118] ibid.
[119] ibid.
[120] ibid.
[121] ibid.
[122] ibid. 254.

but not animals which could fulfil patent qualification criteria. Due to the inconsistent taxonomic definition of the term 'variety' as demonstrated here, the *Onco-mouse II* decision to adopt the taxonomic definition is arguable. Nevertheless, since this definition has been adopted by the TBA, the more important question is therefore: is the decision, which only excludes from patent protection claims that relate to species, justifiable? Pertinent issues relating to this question will be analysed here.

Two conclusions can be made from the earlier-mentioned statement in the *Onco-mouse II* that: 'A patent should not be granted for a single animal variety (or species or race, depending on which language text of the EPC is used)'. Firstly, the TBA has tried to equate the three terms irrespective of their different taxonomic classification. Secondly, the Board left open the question about the precise meaning of the terms used in each of the official languages. Therefore, it is possible to conclude that based on the TBA decision, theoretically (due to the linguistic usage), species, variety and race are at the same level of taxonomic classification, hence, are unpatentable. This approach corresponds to the three versions of the EPC which provides that species or race or variety is to be excluded under each of the three official languages of the Article 53(b). However, due to the TBA's non-definitive meaning for the three terms, on a practical level, it is unclear if the term 'race' and 'variety' would have similar taxonomic meaning as 'species'.

In this respect, the *Onco-mouse II* coincides with Warren-Jones's[123] isolated category construction which she advocated in response to the *Onco-mouse I*. The construction states that if the exclusion is intended to cover a particular category within the animal taxonomic classification, only that category is unpatentable. Therefore, if species is the standard,

[123] A. Warren-Jones, n 89 above, 115. The meaning, application and implication of the construction are detailed in her work.

theoretically, only claims which relate to the category of species are caught by Article 53(b), whereas claims which relate to other categories (sub-genus upwards and sub-species downwards) are patentable. However, on a practical level, the construction leads to the unpatentability of species downwards, whereas patent protection can still be obtained for sub-genus upwards.[124] This is because, taxonomically, by excluding species, sub-species and below (which are the genetic variants) are also excluded.

Notwithstanding the practical implications which may arise from the isolated category construction mentioned here, the *Onco-mouse II* appears to have decided that only the theoretical application of the isolated category construction can be adopted whereas its practical application is no longer possible. In evidence, the TBA has taken a stance in the decision that transgenic animals (such as the Onco-mouse) are to be classified as sub-species. In this, the TBA has explicitly stated that it is not sufficient for mice which inherited a certain characteristic due to the insertion of a cancer-gene to its genome to be called a new species.[125] This point has been earlier discussed by Warren-Jones[126] who argued that transgenic animals are taxonomically classified as sub-species, in contrast to the creation of chimera which produce animals that are sufficiently distinct from the original animals for them to be categorised as a new species. In the hierarchy of taxonomic classification, she describes the former as 'moving downwards', in contrast to the latter which was said to 'move sideways'.[127] The TBA did not explain the reason which underpins its classification. Nevertheless, the classification by the Board and Warren-Jones, and the argument by the latter about the categorisation of transgenic animals are logical. The relevant novel trait within transgenic animals as a result of genetic manipulation amounts to genetic variation

[124] ibid.
[125] *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 13.3.1.
[126] A. Warren-Jones, n 89 above, 116.
[127] ibid.

from their parent animal (species). Therefore, it is justified for the transgenic animals to be classified as sub-species due to the distinct inheritable characteristic. However, they are not as sufficiently distinct as chimera because the latter is an animal which contains at least two genetically different groups of cells originating from different animals. This enables the creation of a new species.

Two other possible options of construction explored by Warren-Jones[128] are the 'top down' and 'bottom up' approaches. According to the 'top down' construction, if a category is selected to represent the intended exclusion, animal inventions from the top of the taxonomic classification downwards to the selected category are unpatentable. The categories below the selected level are patentable. If the category of species is selected as a standard, animal inventions which fall in the category of Kingdom down to the selected category are unpatentable. Those which fall in the category of sub-species and below are patentable. Conversely, the 'bottom-up' construction means if a category is selected, animal inventions from the bottom of the taxonomic classification up to the selected category are unpatentable. Those which fall above the selected category are patentable. Again, if species is the selected category, animal inventions which fall in the category of sub-category of sub-species (sub-sub-species) up to species are unpatentable. Those which fall under sub-genus upwards are patentable.[129] The three-constructions proposed by Warren-Jones can be illustrated in Table 2 below.

[128] ibid. 115-116.
[129] ibid.

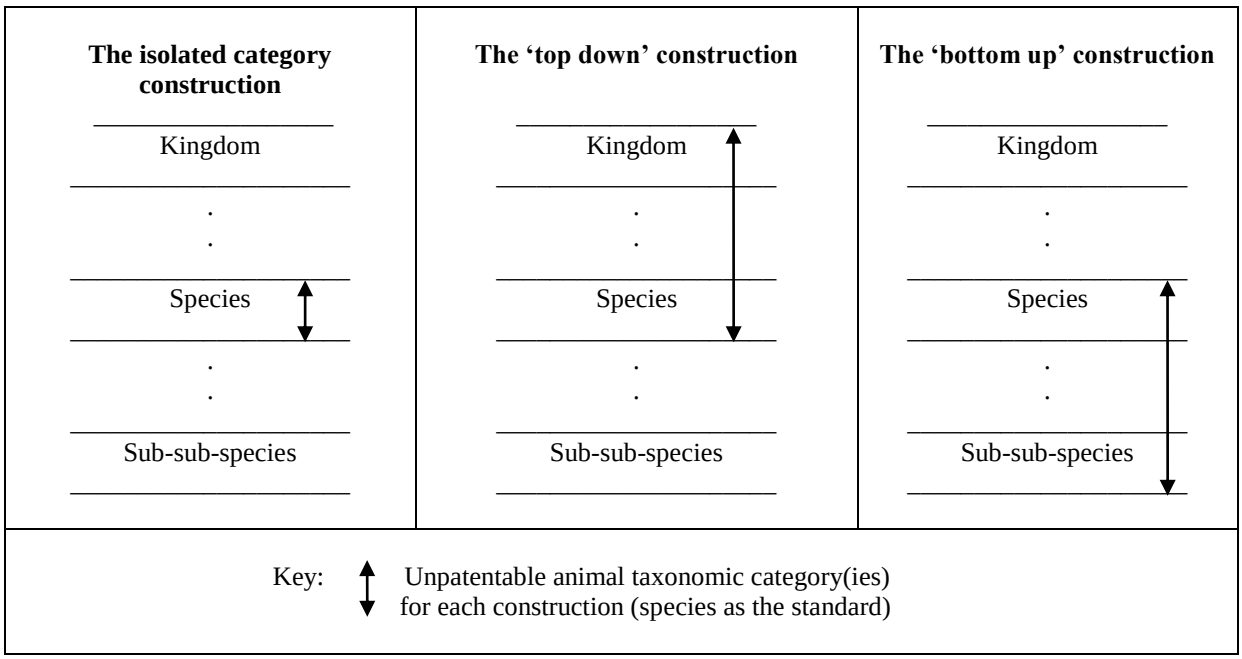

Table 2: The Warren-Jones three-proposed-constructions for interpreting the exclusion of animal inventions under Article 53(b) of the EPC

Arguably, the *Onco-mouse II* has limited the feasibility of adopting both the 'top down' and 'bottom up' constructions. As regards the 'top down' construction, theoretically and practically, it would amount to the exclusion of broad categories of animals since higher categories which consist of large numbers of animals are involved. In addition, having the category of Kingdom to fall within the construction would amount to the unpatentability of animals *per se* from the European patent law. This contravenes the policy of narrow interpretation as underlined by the *Onco-mouse I*. Further, as identified by Warren-Jones,[130] the construction would negate all the three versions of the EPC which require lower categories of animals to be unpatentable rather than the higher categories. Moving on from this, the 'bottom up' construction would appear to be more in line with the *Onco-mouse II* decision where lower categories of animal taxonomic classification are excluded.[131] Therefore, the three official languages of the EPC are satisfied. However, in the context of

[130] ibid. 116.
[131] ibid.

the decision, arguably the adoption of the construction is no longer possible because the *Onco-mouse II* only allows the exclusion of species.

The TBA's approach to equate the three terms, hence adopting the isolated category approach resolves some problems left by the *Onco-mouse I*. Nevertheless, more generally, the approach is not without implications. On the one hand, by leaving the languages to split across two taxons, the *Onco-mouse I* demonstrates an indefinite classification of animal inventions. The *Onco-mouse II* resolves this problem by deciding that the inventions are to fall under the category of sub-species (rather than species, that are naturally occurring animals). On the other hand, the isolated category approach may raise some issues due to a number of potential arguments by an applicant. Firstly, the approach appears to put paramount importance on linguistic evaluation. This would lead to easy circumvention of the exclusion through skilful drafting as the only condition is that a claim for patent protection should not mention the categories of 'species', 'race' and 'variety'. Secondly, as only species are excluded, an applicant may try to argue that an animal invention falls under higher categories of animals in the taxonomic classification, and claim those higher categories. Arguments in favour of the attempt would include that: (1) it serves as a time-saving approach.[132] By allowing an applicant to claim higher categories, an inventor could avoid filing an application with a long (maybe endless) list of various species of animals upon which the method claimed can be applied. While this may be seen as a trivial technical issue, undoubtedly it would help an applicant with the administration aspect of his claim;[133] and (2) it could prevent easy circumvention by competitors where an inventor might unintentionally

[132] ibid. 127.

[133] The only conditions for patent claims under the EPC are that the claims must relate to one invention or group of inventions, and be clear and concise, and be supported by description. See Articles 82 and 84 of the EPC respectively.

leave out any species of animals (which are similarly applicable to the claimed method) from the list in the specification.[134]

These two advantages are difficult to refute, but some disadvantages may equally surface from the same arguments. For instance, an inventor who genetically manipulates a house mouse (a species) may try to claim the order of rodentia which includes various families such as canidae (dogs), felidae (cats), ursidae (bears) and many others, by alleging that the teaching[135] is similarly applicable. Apart from this, a few orders may also be claimed, including primates (mammals which include humans, apes and monkeys), insectivores (insect-eating mammals) and carnivores (flesh-eating mammals). At most, the inventor may want to claim mammals as a class or even chordata as a phylum, being the higher categories where the relevant house mouse is taxonomically grouped. In the case that the claimed method is not actually applicable to such a broad category of animals, the implication of this would be the monopolisation of animal genetic resources and materials by a small number of applicants who are financially able to venture into new inventions. Eventually, the rights of other researchers who may require other types of genetic materials as starting materials for their research (apart from the one actually developed by the applicant, but which has been broadly claimed) would be prejudiced. This contention corresponds with the ethos of patent law which disallows inventors' claims for protection over and above the legal rights that they

[134] A. Warren-Jones, A mouse in sheep's clothing: the challenge to the patent morality criterion posed by "Dolly" [1998] *European Intellectual Property Review*, 447.

[135] The term 'teaching' under the patent law refers to the enablement disclosure that an applicant should make in the specification filed with an application. The description should allow a person skilled in the art to repeat the invention based on the information disclosed. See L. Bently et al, n 28 above, 362-363; W. Cornish and D. Llewelyn, *Intellectual property: patents, copyright, trade marks and allied rights* (London: Sweet and Maxwell, 2007) 238-241.

are entitled to. Nevertheless, in practice, this concern has been safeguarded by requiring an applicant to include an enabling disclosure in the application.[136]

Beyleveld and Brownsword hold opposite views from Vossius and Warren-Jones. According to them, as there is no precise definition for the term 'variety', the generic meaning for the term should be adopted.[137] They argued that this approach would assist in achieving the common meaning of the three terms and avoid the allegation that the EPC is not able to be treated as a single Convention (due to diverse scientific meaning of the three terms).[138] The generic meaning of the term 'variety' is taken by Beyleveld and Brownsword to mean 'types of animals in general' or 'classifications within the Animal Kingdom'.[139] Based on the latter definition, their assessment of animal classification initially covers the category of Kingdom downwards to sub-species,[140] but was later extended to sub-sub-species (which they termed as 'informal specific category').[141] Therefore, they argued that under Article 53(b) animal varieties in the generic sense (all animals) are unpatentable. Yet, they qualify this argument by a recognition that since 'taxonomic classification is defined strictly in terms of genetically transmissible (germ line) gametes features', what is excluded are only animals with germ-line modification rather than animals with somatic alteration.[142] Due to their distinction between germ-line and somatic alteration, it is possible to conclude that they hold the view that the Onco-mouse is not patentable.

---

[136] This principle underpins the requirement of Article 84 of the EPC. National patent laws such as s14(5) of the UK Patents Act 1977 contain similar provision. See arguments on this point in *Onco-mouse/Harvard*, Decision of the Opposition Division 7 November 2001, n 70 above, 483 and 495-496.

[137] D. Beyleveld et al, n 101 above, 15.

[138] ibid. 16, at footnote 36.

[139] ibid. 18.

[140] This is because 'sub-species' was an infraspecific category recognised under the International Code of Zoological Nomenclature 1961. See D. Beyleveld et al, n 101 above, 4, at footnote 11.

[141] ibid. The critics are of the view that due to the recognition that while post 1961, the term 'variety' was not recognised in scientific usage, the field treated it as an 'infra-subspecific category informally'.

[142] ibid. 18-19.

Beyleveld and Brownsword's argument of generic meaning and, hence, the exclusion of animals *per se* is reasonable given the non-definitive intention of the framers of the EPC of what is to be excluded under Article 53(b). Nevertheless, the *Onco-mouse II* has refuted their arguments both on the meaning of the term 'animal variety' and the subject matter of the exclusion under Article 53(b) because the contention runs contrary to the principle of narrow exclusion (affirmed by the decision). In addition, by also accepting the meaning of 'animal variety' to mean taxonomic classification of animal Kingdom and extending the exclusion to sub-sub-species, Beyleveld and Brownsword have qualified their arguments on the generic meaning of the term and the excluded subject matter. This is because, based on their final estimation of the taxonomic definition of the term 'variety', it would amount to suggesting that the indefinite categories below sub-sub-species are patentable. However, the reason why only these taxonomic categories are distinctively deemed patentable is unclear.

A distinction between animal inventions which involve germ-line modification (unpatentable) and those which are somatically altered (patentable), as argued by Beyleveld and Brownsword, has no parallel with the *Onco-mouse II*. One of the reasons for the absence of this assessment in the decision would have been the understanding that it is obvious that only animals whose germ-line is altered could be protected under patent law. It has been argued by Warren-Jones[143] that Beyleveld and Brownsword's assessment would lead to an unnecessary emphasis and reliance on the stage at which the alteration is made, rather than the ability of the end result to fulfil patent qualification criteria. If Beyleveld and Brownsword's estimation is put into context, for instance, a mouse whose germ-line is altered at no later than the 8-cell stage (such as the *onco-mouse*) is not patentable, whereas if it is altered at the stage after the germ-line cells have fully differentiated, the same subject-matter will be patentable. The

[143] A. Warren-Jones, n 89 above, 118.

distinction is arguable because principally, germ-line alteration (which involves the manipulation of a lineage of cells from which gametes are derived) should be more likely to produce novel animal inventions as required by patent law than mere somatic alteration. This arises from the inheritable characteristics that could be passed on to the offspring from the process of germ-line alteration rather than non-inheritance of the manipulated traits by progeny through somatic alteration.[144] Consequently, Beyleveld and Brownsword's argument on this point contradicts the general understanding of characteristic inheritance and the *Onco-mouse II*. In addition, their conclusion that products of germ-line alteration are unpatentable is not supported by other conditions for exclusion under Article 53(b). In this regard, apart from animal varieties, the only other exception from patentability under the provision is an 'essentially biological process'. In contrast, the provision explicitly provides that 'microbiological processes and products' derived from the process are patentable. These principles and contention will be further elaborated here.

3.2.3 Essentially biological process and microbiological process

The word 'essential' rather than 'pure' in the phrase 'essentially biological process' demonstrates that a pure biological process is clearly beyond patentability. Yet under the European patent law 'essentially biological processes' are not *per se* unpatentable. Specific conditions are provided by Article 2(2) of the EU Biotechnology Directive and Rule 26(5) of the Implementing Regulations to the EPC. The provisions state: 'a process for the production of animals is essentially biological if it consists entirely of natural phenomena such as

[144] Nevertheless, germ-line alteration cannot be regarded as being fundamentally different where somatically-altered animals are subsequently cloned. This means that, while the trait may not be inherited through the natural reproductive process, but through cloning, it has the effect of retaining the trait over even more generations than inheritance would. In this way, the cloned animals should be able to obtain patent protection if the patent prerequisites are met. This distinction was not made in Beyleveld and Brownsword's work.

crossing or selection.' This condition intrinsically brings microbiological processes such as genetic engineering outside the exclusion of an 'essentially biological process'. A similar conclusion could be achieved for breeding methods such as artificial insemination and super-ovulation due to the involvement of technical processes beyond mere human intervention in arranging the mating of animals for nature to take its course.

The meaning of 'essentially biological process' within Article 53(b) has also been dealt with by some cases of the EPO. While all the cases involve plant varieties, the principles have been similarly applicable to cases of animal inventions due to the *Onco-mouse II*[145] ruling on the extension. The test for an 'essentially biological process' was first underlined in the case of *Lubrizol/Hybrid Plants*[146] where in order to escape the exclusion, human intervention must go beyond the trivial level and its impact on the result must be decisive. The *PGS/Glutamine Synthetase Inhibitors*[147] case confirmed and further clarified this principle where the TBA ruled that a process for the production of plants comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result, falls outside the exception. However, in the latest ruling of the EBA for appeals to the cases of *Plant Bioscience/Broccoli* and *State of Israel/Tomatoes*,[148] it was held *inter alia*[149] that the requirements underlined by the cases of *Lubrizol* and *PGS* were no longer the determining factor for the exclusion of an 'essentially biological process' under Article 53(b).[150] In the context of its application to animal inventions, the relevant ruling of the EBA can be summarised in two principles: (1) The exclusion of an 'essentially biological

[145] *Transgenic Animals/Harvard*, T 315/03, n 65 above, paragraph 11.4.
[146] *Lubrizol/Hybrid Plants*, n 74 above.
[147] *PGS/Glutamine Synthetase Inhibitors* [1995] EPOR 357, reason point 28.
[148] *Essentially Biological Processes*, G2/07 and G1/08 [2011] EPOR 27. The former is an appeal from the Technical Board of Appeal, T 83/05, while the latter is an appeal from the Technical Board of Appeal, T 1242/06.
[149] Latin expression which means: 'among other things'. See http://www.thefreedictionary.com/inter+alia (Accessed: 9 April 2012).
[150] *Essentially Biological Processes*, n 148 above, 27.

process' is not saved by a step of a technical nature which enables or assists the performance of the steps of sexually crossing the whole genomes of animals or of subsequently selecting animals, irrespective of the extent of the role played by the technical work in the final result; (2) However, if an 'essentially biological process' contains within it a step which introduces or modifies a trait in an animal causing novel characteristics, so that the introduction or modification of the trait is not the result of sexually crossing the whole genomes of animals or of subsequently selecting animals, then the process escapes the exclusion under Article 53(b). Based on these principles, it appears now that the breeding methods such as artificial insemination and super-ovulation (mentioned earlier), which are otherwise patentable under Article 53(b), could no longer enjoy the right. It is because the methods merely assist the normal reproduction process without directly introducing or modifying any traits in the resulting animals.[151]

The phrase 'microbiological process' is defined under Rule 26(6) of the Implementing Regulations to the EPC as 'any process involving or performed upon or resulting in microbiological material'.[152] Its patentability can be appreciated by the involvement of a technical process which warrants legal protection. It is also pertinent to note that the patentability of products of microbiological processes and their offspring (provided they retain the essential identity of the transgenic animals) has been acknowledged by Article 8 of the EU Biotechnology Directive.[153] Intrinsically, this is because the process of genetic

[151] Warren-Jones has argued before, that these breeding methods are mere alternatives to 'natural' reproduction process, and thus should not sufficiently qualify to be protected as 'essentially biological process' under Article 53(b). See A. Warren-Jones, n 89 above, 122-123.

[152] However, a strict reading of this definition may raise an issue because there are many 'macro' biological materials (such as the Onco-mouse and Leland Stanford modified mouse) which have been similarly produced through the process.

[153] Article 8(1) provides: 'the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristic.' In turn, Article 8(2) states: 'the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend

engineering and resulting animals can qualify under the exception to Article 53(b). The alteration at the microbiological level is capable of altering the hereditary material, and hence of having a decisive impact on the final result. In this, it is pertinent to note Beyleveld and Brownsword's[154] view that while transgenic animals fall within the term 'animal varieties' under Article 53(b), the ED should have considered whether the animals (and the processes and the products of genetic engineering, generally) are 'microbiological process or the products thereof' under the same provision. This demonstrates their view that genetically modified animals are appropriate subject matter to be protected under the exception to the 'animal variety' exclusion.[155] Therefore, if the above principles on essentially biological and microbiological processes are applied to their conclusion on the unpatentability of products of germ-line alteration, their assessment is arguable.[156] Germ-line alteration constitutes a microbiological process and products derived from it (such as the Onco-mouse) constitute products of the process, and therefore, are patentable.

This sub-section has shown that the TBA's approach in the *Onco-mouse II* which equates the three terms: (1) clarifies and responds to the criticism arising from the *Onco-mouse I* which dealt with the patentability of the Onco-mouse by adopting a generic approach based on the wording of the claims; and (2) resolves the linguistic ramifications surrounding the three official languages of Article 53(b) which pose a long-term challenge to the patentability of animal inventions under the European patent law. Nevertheless, as the meaning of the three equated terms is not resolved by the Board, the decision may be challenged as mainly aiming

---

to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.'

154 D. Beyleveld et al, n 101 above, 19-20.

155 A. Warren-Jones, n 89 above, 122.

156 However, given that Beyleveld and Brownsword's assessment was made before the Boards of Appeal had considered the point on essentially biological and microbiological processes, and that subsequently their construction of the law was not taken up by the Boards, their analysis cannot be said to be wrong. It is simply that they did not accurately predict the approach eventually adopted on the issue.

at the granting of patent without appropriately considering the implications for the meaning of the three terms in the context of taxonomic classification. The analysis has also shown how permissive the European-wide approach is by identifying that transgenic animals (including livestock) would be patentable for being classified as sub-species. In this, claims to sub-species would be excluded only where the terms 'variety' or 'race' adopt the German meaning of species. The principles relating to the exclusion of 'essentially biological processes' provide further evidence of the permissiveness of the approach. As the European patent law currently stands, the involvement of a microbiological process in the production of animals, in whatever percentage and irrespective of its decisive impact on the end result, would render the claims to products derived from there as patentable. This reiterates the principle that the European patent law excludes only non-technical processes. Others, which can fulfil the patent qualification criteria, albeit relating to animals, are widely open to patent protection.

Moving on from here, it is crucial to have a broader understanding of why the *Onco-mouse II* has confirmed the patentability of the Onco-mouse, despite an explicit exclusion of animal varieties under Article 53(b). This is the aim of the next sub-section which examines the rationale underpinning the permissive approach. It will be shown that the economic importance of patents requires that animal inventions, which are capable of fulfilling the patent prerequisites, are not to be left legally unprotected.

3.3 The rationale for the Onco-mouse II narrow interpretation

It has already been mentioned in sub-section 3.2.1 that the *Onco-mouse II* adopts the principles underlined by the decision of the *Novartis/Transgenic Plant*. In essence, while

animal varieties are not patentable under Article 53(b), the rules are: (1) where technical manipulation is not confined to a particular animal variety, the invention is patentable; and (2) patent granted to a genetic material contained in an animal variety covers the host animal, even if it is an animal variety.[157] It is argued that underpinning the isolated category approach and the extension of principles relating to the exclusion of plant varieties to animal varieties is a broader recognition of the economic need to protect animal inventions which can fulfil the patent prerequisites. Plant varieties are excluded from the patent regime due to the non-involvement of technical intervention in the patent law sense. However, an alternative *sui generis* protection is available under the UPOV Convention in the event that they meet the required qualifications. Unfortunately, animal varieties (even where they fulfil patent qualification criteria) will be left without any legal protection if the *Onco-mouse II* decides that the subject matter is not patentable, because there is no alternative protection available to date. While the *sui generis* system (equal to plant varieties) for the animal breeding sector has been the subject of much discussion,[158] the establishment of an efficient system has not widely materialised because of problems including: (1) the concept is not easily defined; (2) the difficulty in identifying the key characteristics of the subject matter; and (3) the rationale for the protection of 'animal varieties' (when in animal breeding, the protection is said to be more relevant for 'breeds').[159]

[157] See explanation of the rules in footnotes 91 and 95.

[158] See for instance M.W. Tvedt, S.J. Hiemstra, A.G. Drucker, N. Louwaars and K. Oldenbroek, Legal aspects of exchange, use and conservation of farm animal genetic resources, Fridtjof Nansens Institut (FNI) Report 1/2007, 29-30; S. Biber-Klemm, and M. Temmerman, Rights to animal genetic resources for food and agriculture: notes from an interdisciplinary workshop, Working paper No 2010/05, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652166 (Accessed: 31 March 2011) 81. In relation to the legal protection for animal genetic resources (i.e breeds) it has been raised in the workshop that one of the important issues which require careful consideration is whether the *sui generis* system or other forms of protection includes the scope and duration of protection, and the extension of the protection to the progeny.

[159] ibid.

In some countries such as India[160] and the Czech Republic,[161] the *sui generis* system of protection of animal genetic resources is in place, as an alternative, due to the unpatentability of animals as such. In these countries, the criteria required for new animal breeds resemble plant varieties under their *sui generis* system of protection. Nevertheless, it is observed that so far the system only covers administrative aspects such as the registration and documentation of new and improved breeds and strains (of poultry, fish and animals developed by selective breeding by farmers, researchers or communities). There is not yet any provision in the relevant guidelines or legislation on pertinent aspects such as the infringement of the rights granted under the system and intended benefit-sharing arising from the use of the animals.[162]

The economic importance of patent protection relating to animal inventions in the EU has long been expressly stated. For instance, in 1988, in the Meeting of the Committee of Experts on Biotechnological Inventions and Industrial Property, a delegate from the Netherlands said:

> in view of the cost of biotechnological research and development, improved legal protection was necessary and, in these circumstances, it was understandable that the EPO had tried to limit the scope of the restriction in the EPC concerning plant and animal varieties.[163]

[160] P.J. Singh, *Sui generis* protection of animal genetic resources: An initiative by the Indian Council of Agricultural Research (ICAR) in S. Biber-Klemm et al, n 158 above, 67-68. In India, the guidelines for the registration and documentation of new and improved breeds are contained in Guidelines for Registration of Livestock and Poultry Breeds. See National Bureau of Animal Genetic Resources, India, http://www.nbagr.res.in/guidelines.html (Accessed: 21 May 2011).

[161] M. Temmerman, The patentability of animal genetic inventions. Pt.1, NCCR International Trade: Stocktaking paper no. 2006/4, 66-67. In the Czech Republic, the protection for new animal breeds is provided under the Law on the Legal Protection of New Varieties of Plants and Breeds of Animals. Available at: http://www.wipo.int/wipolex/en/text.jsp?file_id=126145 (Accessed: 21 May 2011).

[162] ibid.; P.J. Singh, n 160 above, 67-68.

[163] WIPO, 'Industrial Property Protection of Biotechnological Inventions: Report adopted by the Committee of Experts', Document BiOT/CE/IV/4 (28 October 1988) 3.

The TBA in the *Onco-mouse I*[164] observed a similar economic need to protect animal inventions, in view of the absence of alternative protection, when it highlighted three important points for the ED to consider:

> (1) the presumed intention of the framers of the Strasbourg Convention and EPC in the context of changes of circumstances (scientific development) since the law was adopted; (2) the need to appropriately balance the interests of inventors in this field which sought reasonable protection for their intellectual labours and the interests of society to exclude animal inventions from the patent regime; and (3) the need to seriously consider the non-availability of alternative protection for animal inventions in the event that the patent is not allowed to relevant inventions.[165]

In recognition of these principles, the absence of appropriate legal protection for animal inventions would have been seen by the EPO as able to prejudice the interest of inventors to create inventions for the benefit of the public and the large amount of investment put in by investors to develop the relevant inventions.

This sub-section has shown that economic motivation for protecting animal inventions under the patent system has influenced the EPO to interpret the exclusion of animal varieties under Article 53(b) narrowly. The next section examines the EU animal biotechnology applications relating to livestock animals so as to identify its importance and development. In addition, the impact of the permissive approach on the livestock industry will be assessed. The discussion will show that the EU puts much emphasis on the importance of animal biotechnology applications which is largely at the research stage. Notwithstanding public pessimism towards animal biotechnology food, the potential of the technology to contribute to the sustainable development of the livestock and fisheries industries has driven the active research in the field. Patent protection which is available to transgenic livestock animals (through the

[164] *Harvard* T 0019/90, n 71 above, paragraph 4.7.
[165] ibid. This statement appears to give a clear 'indication' to the ED to revise its decision which refused to grant patent to the onco-mouse in the first instance of its decision.

decision of the *Harvard/Onco-mouse*) will enhance the progress of the technology. This will realise the demand of the population for animal protein-based products. In terms of the research questions, the discussion informs Malaysia about the advantages and disadvantages of adopting the European-wide permissive approach in interpreting its exclusionary provision, in the light of the problems and needs of the country's livestock industry (identified in chapter 1).

4. The implications of the permissive approach on the livestock and fisheries (and aquaculture) industries: an assessment

Biotechnology is a developing discipline in the EU with an extremely robust market.[166] For instance, there was an increase of 15% in global revenue to $60 billion in 2006, compared to 2005.[167] In reviewing its strategy on 'Life Science and Biotechnology', the EU launched the 'Eight Technology Platforms' in the area of life sciences and biotechnology in order to develop and foster public-private partnerships at European level.[168] One of the areas under consideration is animal breeding and reproduction.[169] Under the Seventh Framework Programme (started in 2007) €2 billion is dedicated to supporting research on food, agriculture and fisheries, and biotechnology.[170] This is a significant increase in the amount of investment compared to the Sixth Framework Programme (2002 to 2006) where €756 million

[166] EPO, Biotechnology in European patents – threat or promise?, http://www.epo.org/news-issues/issues/biotechnology.html (Accessed: 20 April 2011).
[167] ibid.
[168] Europa, Life sciences and biotechnology – a key sector for Europe's competitiveness and sustainability, Press Release, 11 April 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/130&format=HTML&aged=1&language=EN&guiLanguage=en (Accessed: 19 May 2011).
[169] ibid. Other areas are (1) innovative medicines initiatives; (2) nanomedicine – nanotechnologies for medical applications; (3) plant genomics and biotechnology; (4) industrial biotechnology under the sustainable chemistry technology platform; (5) food for life; (6) global animal health; and (7) forestry and biofuels.
[170] ibid.

was allocated to fund projects in various fields including animal biotechnology.[171] As regards the livestock industry, one of the reasons for the investment could have been the explicit recognition that the technology would relieve Europe from being heavily dependent on imports of animal feed due to the shortage of land for growing animal feeds.[172] In this respect, the growth in publication activities in a biotechnological sector is one way to indicate the importance of the sector to a particular country.[173] The higher the growth the more important the sector is. In the EU, publication activities in animal biotechnology grew about 0.08% for the period between 1995 and 2000. Although placed behind environmental (0.59% growth) and industrial (0.2% growth) biotechnologies, animal biotechnology appears to be more important to the EU, if compared to plant biotechnology which has lost considerable importance (-0.15% growth) for the same period.[174]

Similar to the situation worldwide, there has been no commercial application of animal biotechnology to livestock animals and marketing of the products in the EU Member States.[175] Nevertheless, it is pertinent to note that several Member States have been applying various molecular breeding methods to improve livestock production. Methods adopted by Member States include embryo sexing, transgenetics and cloning.[176] It is shown in a study that twenty four country reports indicate the use of molecular technologies: marker assisted

---

[171] ibid.

[172] Europa, Biotechnology and Europe - The speech of Peter Mandelson (Europe Trade Commissioner) on the European biotechnology info day, 14 June 2007, Speech/07/397, http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/397&format=HTML&aged=0&language=EN&guiLanguage=en (Accessed: 19 May 2011).

[173] T. Reiss, S. Hinze and I.D. Lacasa, Performance of European Member States in biotechnology (2004) *Science and Public Policy*, 31, 5, 351-352.

[174] ibid.

[175] United States Department of Agriculture (USDA) Foreign Agricultural Service, Animal Biotech Policy and Research in the EU, Global Agricultural Information Network (GAIN) Report, 14 September 2009, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Animals_Berlin_EU-27_9-1-2009.pdf (Accessed: 23 September 2011).

[176] D. Pilling, R. Cardellino, M. Zjalic, B. Rischkowsky, K.A. Tempelman and I. Hoffmann, The use of reproductive and molecular biotechnology in animal genetic resource management – a global overview (2007) *Animal Genetic Resources Information*, 40, 7-8. See also FAO, The state of capacities in animal genetic resources management: reproductive and molecular biotechnology, 2007, ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (Accessed: 17 December 2010) 269-271.

selection is used in commercial animal production in eight EU countries and eleven Member States specify the implementation of molecular distancing studies.[177]

Many public and private institutions in the EU Member States are currently conducting research on biotechnologies relating to livestock animals.[178] Some of the initiatives will be discussed here to demonstrate the situation in the EU. At the regional level, the European Animal Disease Genomics Network of Excellence for Animal Health and Food Safety (EADGENE) was established with the aim of co-ordinating a genomics approach to host-pathogens interactions in domestic animals.[179] For this purpose, it co-ordinates activities of fifteen partners from ten European countries[180] by bringing together expertise which focuses on research including the investigation of the interaction of Salmonella (pathogen) in pigs and poultry (hosts), *E.coli* (bacteria) in cattle, mastitis in cattle, goats and sheep, and Infectious Salmon Anaemia (ISA) and Infectious Pancreatic Necrosis viruses in Atlantic salmon and rainbow trout.[181]

At national level, in the UK, for example, active research on genetics and genomics with regard to livestock animals is on-going at the Roslin Institute of the University of Edinburgh[182] and ARK-Genomics.[183] Research undertaken in the former institution includes the identification of genes involved in immune response aiming at preventing infection and

[177] ibid. The countries include Croatia and Czech Republic.
[178] I. Cassar-Malek, B. Picard, C. Bernard and J.F. Hocquette, Application of gene expression studies in livestock production systems: a European perspective (2008) 48 *Australian Journal of Experimental Agriculture*, 704.
[179] EADGENE, http://www.eadgene.info/ (Accessed: 3 October 2011).
[180] The fifteen partners which work together under EADGENE are: INRA, France; Wageningen University, the Netherlands; Animal Sciences Group Lelystad, the Netherland; Institute for Animal Health, United Kingdom; Roslin Institute, University of Edinburgh; Faculty of Agricultural Sciences, University of Aarhus, Denmark; Liege University, Belgium; Ljubljana University, Slovenia; Cordoba University, Spain; Norwegian School of Veterinary Science, Norway; Research Institute for the Biology of Farm Animals, Germany; Parco Techologico Padano, Italy; European Forum of Farm Animal Breeders, the Netherland; University of Copenhagen, Denmark; Institute for Pig Genetics, the Netherlands.
[181] ibid.
[182] The Roslin Institute, University of Edinburgh, http://www.roslin.ed.ac.uk/ (Accessed: 3 October 2011).
[183] ARK-Genomics, http://www.ark-genomics.org/ (Accessed: 3 October 2011).

controlling disease in livestock animals such as chicken and cattle, and the investigation of the use of genomics to improve productivity and product quality in sheep. The latter institution is a high-technology laboratory which plays a role as a collaborative centre for functional genomics[184] in farm animals (such as chickens, pigs, cattle and sheep).[185] In France, the French National Institute for Agricultural Research (INRA)[186] is a leading European public agricultural research institute. As regards livestock animals, it has been carrying out research in improving fertility in dairy cows and identifying genetic determinism of tenderness of bovine meat. Studies at the Institute focus on a wide range of animals including cattle, pigs, chickens, sheep, trout, goats, and ducks. Rodents (mice and rats) and the Medaka fish are used as models for genetic studies.[187] This evidence is an indication of other Member States' R&D activities, demonstrating the priority given to the animal biotechnology industry.[188] Genomic research is intrinsically expensive and complicated. Therefore, research carried out by the institutions mentioned here is supported by public funding and involves collaborative projects with, and industrial support from, private companies. For instance, research at the EADGENE is funded by the EU, and the Roslin Institute's is mainly funded by the Biotechnology and Biological Sciences Research Council (BBSRC). Other funders for the Roslin Institute include the Department for Environment, Food and Rural Affairs (DEFRA), the EU, the Medical Research Council, the Food Standards Agency, the Wellcome Trust, the Meat and Livestock Commission, Pfizer Ltd and British United Turkeys Ltd.[189]

---

[184] Means: 'the branch of genomics that determines the biological function of the genes and their products'. See http://www.thefreedictionary.com/functional+genomics (Accessed: 3 October 2011).

[185] The Roslin Institute, University of Edinburgh, n 182 above.

[186] INRA, http://www.international.inra.fr/the_institute/a_brief_overview (Accessed: 2 October 2011).

[187] ibid. For other projects involving genomics research relating to livestock animals in the EU, see Sustainable Animal Breeding (SABRE), an integrated project including thirty-three leading animal research groups which focussed on three aspects of sustainable development of livestock: mammary gland, digestive system and fertility, http://www.sabre-eu.eu/ (Accessed: 3 October 2011).

[188] While very little research of this nature appears to take place in countries such as in Finland, Sweden, Spain and Austria, research involving genetically engineered animals in other sectors such as medical and pharmaceutical research is actively carried out in these countries. See USDA Foreign Agricultural Service, n 175 above.

[189] See The Roslin Institute, University of Edinburgh, n 182 above.

Many analyses[190] have described the attitude of the Europeans as: very positive toward medical and environmental biotechnologies; neutral toward agricultural biotechnology; but negative toward GM food[191] and the cloning of animals (and its products). As evidence for the last of these, the latest EU barometer survey has shown that public support for GM food and the cloning of animals for food is declining due to the perception that the products have no benefit and the concern that the products are unnatural and unsafe for consumption.[192] In a research project, under the Sixth Framework Programme, spanning nine Member States of the EU,[193] participants perceived 'safe beef' as 'beef which is not harmful to consumers' health' and that lean beef is considered to be the healthiest type.[194] Notably, the research found that the focus group participants 'supported the development of technologies that can make beef healthier and guarantee eating quality.' Nevertheless, only procedures which are considered not invasive are acceptable and these include: (1) the application of muscle profiling in beef production; (2) marinating by injection for improved healthiness (nutritional

[190] G. Gaskell and J. Jackson, A comparative analysis of public opinion: Canada, the USA and the European Union, in First impressions: understanding public views on emerging technologies, prepared by Genome Prairie GE3LS team as the University of Calgary, funded by the Canadian Biotechnology Secretariat, http://epe.lac-bac.gc.ca/100/200/301/cbs-scb/first_impressions-e/Iu199-4-2005E.pdf#page=64 (Accessed: 29 September 2011); S. Bonny, How have opinions about GMOs changed over time? The situation in the European Union and the USA (2008) *CAB Reviews: Perspectives in agriculture, veterinary science, nutrition and natural resources*, 93, 1-17; M. Canavari, F. Tisselli, R.M. Nayga Jr and R. Scarpa, Italian consumer acceptance of nutritionally enhanced GM food, Paper prepared for presentation at the International Association of Agricultural Economists 2009 Conference, 1-16.

[191] For the purpose of the EU barometer survey, 'GM food' refers to 'the use of modern biotechnology in the production of foods, for example to make them higher in protein, keep longer or change the taste.' See G. Gaskell, N. Allum, M. Bauer, J. Durant, A. Allansdottir, H. Bonfadelli, D. Boy, S. de Cheveigné, B. Fjaestad, J.M. Gutteling, J. Hampel, E. Jelsøe, J.C. Jesuino, M. Kohring, N. Kronberger, C. Midden, T.H. Nielsen, A. Przestalski, T. Rusanen, G. Sakellaris, H. Torgersen, T. Twardowski and W. Wagner, Biotechnology and the European public (2000) 18 *Nature Biotechnology*, 935, http://www.ask-force.org/web/Discourse/Gaskell-Biotechnology-European-Public-2000.pdf (Accessed: 29 September 2011). Arguably the meaning of GM food covers livestock products which are produced through modern biotechnological methods.

[192] The 2010 Eurobarometer on the life sciences (2011) 29 *Nature Biotechnology*, 2, 113-114; European Commission, Europeans and biotechnology in 2010: winds of change? http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf (Accessed: 29 September 2011) 38-44. This has been the trend as observed by commentators since the third EU barometer survey in 1996. See George Gaskell et al, ibid.

[193] France, Germany, Spain, the United Kingdom, Belgium, Denmark, Germany, Greece and Poland.

[194] W. Verbeke, F.J.A. Pérez-Cueto, M.D. de Barcellos, A. Krystallis and K.G. Grunert, European citizen and consumer attitudes and preferences regarding beef and pork (2010) *Meat Science*, 84, 287.

aspect); (3) marinating by injection for improved eating quality (a combination of tenderness, flavour and juiciness); (4) and marinating by submerging for improved eating quality. [195] Processing technology such as injecting substances (such as enzymes) into muscle meat was considered invasive, thus rejected by participants.[196] While this illustration would inevitably demonstrate a pessimistic view of the EU consumers, it could not lead to a conclusion that the EU consumers totally refuse animal biotechnology food; either because of the high risk of the technology used or that the products are unsafe for consumption. If the conclusion is true, one would expect wide consumption of organic foods including livestock products as organic meat and poultry among the EU consumers. Unfortunately, this has not been the case. Pertinent factors appear to be the high price and the uncertain characteristics of such products.[197]

Arguably, information and knowledge are two more important factors in determining consumers' acceptance. In evidence, there have been important findings, from research on consumers and new technologies, that perception and consumers' confidence could be improved by increased communication about food safety, the risks and benefits of novel food products, and label information.[198] In this respect, empirical research has disclosed that EU consumers notably want to be informed of how new technologies can bring benefits (such as health, taste, tenderness) for livestock products for their consumption.[199]

---

[195] ibid.

[196] M.D. de Barcellos, J.O. Kügler, K.G. Grunert, L. van Wezemael, F.J.A. Pérez-Cueto, ø. Ueland, W. Verbeke, European consumers' acceptance of beef processing technologies: a focus group study (2010) *Innovative Food Science and Emerging Technologies*, 11, 730.

[197] J. van Doorn and P.C. Verhoef, Willingness to pay for organic products: differences between virtue and vice foods (2011) 28 *International Journal of Research in Marketing*, 167-180. One of the reasons for this is the limited availability of the products. See also E.V. Loo, V. Caputo, R.M. Nayga Jr., J. Meullenet, P.G. Crandall and S.C. Ricke, Effect of organic poultry purchase frequency on consumer attitudes toward organic poultry meat (2010) 75 *Journal of Food Science*, 384-397.

[198] F. Rollin, J. Kennedy and J. Wills, Consumers and new food technologies, *Trends in Food Science and Technology* (2011), 106-107; W. Verbeke et al, n 194 above, ibid.

[199] M.D. de Barcellos et al, n 196 above, 731; Europa, n 172 above.

Based on this discussion, it seems less likely that animal biotechnology food would be easily approved by the EU consumers. Nevertheless, with concerted effort by the EU and food industries to provide consumers with information on the benefits of the relevant technologies, it is anticipated that their confidence in, and acceptance of, the products would increase. In fact, various efforts have been implemented by the EU to gain public confidence to accept GM food in order to ensure that the products can be commercially marketed. Of particular importance is having the relevant legislations and regulations involving GMOs in place.[200]

It has been identified[201] that while aquaculture is an important alternative to the decreasing fish stock supply from the open sea, a long time is required for the industry to close the gap left by the decline in supply.[202] Moreover, as already identified in chapter 1, challenges to the livestock and fisheries industries, such as a shortage of productive breeding stock and fish seed, livestock and aquatic diseases, and constraints in the supply of animal and fish feed are global problems. As far as the EU is concerned, the BSE crisis (1996), Foot-and-Mouth

[200] The legislations include: (1) Directive 2001/18/EC on the deliberate release into the environment of GMOs which applies to two types of activities: the experimental release of GMOs into the environment (for example, in field test) and the placing on the market of GMOs for example the cultivation, importation or transformation of GMOs into industrial products; (2) Regulation (EC) No 1829/2003 on the placing on the market of GMO food and feed or food and feed products containing or consisting of GMO; (3) Regulation (EC) 1946/2003 on trans-boundary movements of genetically modified organisms which governs unintentional trans-boundary movements of GMOs as well as exports of GMOs to third countries; (4) Directive 90.219/EEC as amended by Directive 98/81/EC on the contained use of genetically modified microorganisms (GMMs); and (5) Regulation (EC) No 1829/2003 (amending Directive 2001/18/EC) concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from GMOs. See Europa, Questions and answers on the regulation of GMOs in the European Union, MEMO/07/117, 26 March 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/117 (Accessed: 29 September 2011) 2.

[201] Europa, The Common Fisheries Policy (CFP), http://ec.europa.eu/fisheries/documentation/publications/pcp2008_en.pdf (Accessed: 8 November 2011).

[202] In particular, the EU has identified that overfishing contributes to the decrease of total catch from open sea. The problem has led to the current effort by the EU to reform its fishing policies which have been argued as failing to achieve sustainable fish stocks. Factors leading to overfishing include the size and power of fishing fleets compared to fish stock, and the weakness of the Total Allowable Catches (TACs) policy imposed by the EU under the Common Fisheries Policy. The latter quota policy which limit catches of each fishing fleet has lead to dead fish been discarded by fishermen back to the sea in order to avoid the limit. In spite of resolving the problem of fish stock depletion, the practice has been identified as leading to other issues including threat to eco-system. See Europa, A fisheries policy for the future, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/873&format=HTML&aged=0&language=EN&guiLanguage=en (Accessed: 8 November 2011).

disease (2000) and avian influenza (2005) have similarly disturbed its animal production and economy.[203] For instance, the BSE outbreak caused the EU an estimated cost of €92 billion.[204] Notably, the livestock disease crisis has resulted in decreased beef production, and consumption and demand from consumers in the EU for the period between 1985 and 2000.[205] In this respect, climate change has been identified by critics[206] as another factor which has a high potential to affect the industry as parasites and pathogens survive the changes in temperature and humidity.[207]

Irrespective of the public's pessimism toward animal biotechnology food, the active research on the application of biotechnology to livestock animals in the EU can be concluded as being motivated by the various challenges to the livestock and fisheries industries shown here. This can be further understood in the context of the OECD-FAO latest projection that the growth in the consumption of meat in the EU will be 7% by 2020,[208] which would lead to a decrease to the exports from the Union.[209] Apart from that, the on-going research appears to be underpinned on the pertinent scientific opinions on the safety of biotechnological products for human consumption. Notably, the European Food Safety Authority (EFSA)[210] has adopted

---

[203] European Commission, Agricultural statistics: main results 2008-2009, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-ED-10-001/EN/KS-ED-10-001-EN.PDF (Accessed: 27 September 2011) 100; T. Garnett, Meat and dairy production and consumption, 2007, http://www.miljopunkt-valby.dk/det-gor-vi-old/ressource-forbrug/klimatildes-kokken/tg-fcrn-livestock-final-6-nov.pdf (Accessed: 29 September 2011) 28.

[204] FAO, The state of food and agriculture: livestock in the balance, 2009, http://www.fao.org/docrep/012/i0680e/i0680e.pdf (26 November 2010) 78.

[205] M. Zjalić, A. Dimitriadou and A. Rosati, Beef production in the European Union and the CAP reform: an overview of situation and trends (2006) *Stočarstvo (Professional paper)* 3, 183-184.

[206] B. McKelvey and G. Marshall, Food supply – can we meet the demand? (2007) *Journal of the Royal Agricultural Society of England*, 168, 3.

[207] ibid.

[208] OECD-FAO, Agricultural Outlook 2011-2020, http://www.agri-outlook.org/dataoecd/2/36/48184304.pdf (Accessed: 27 September 2011) 137.

[209] ibid. 141.

[210] EFSA, Scientific opinion of the scientific committee: Food safety, animal health and welfare and environmental impact of animals derived from cloning by somatic cell nucleus transfer (SCNT) and their offspring and products obtained from those animals, 15 July 2008, http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf (Accessed: 12 March 2012); European Food Safety Authority, Update on the state of play of animal cloning, 14 September 2010, http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf (Accessed: 12 March 2012) 2.

the view that animal cloning poses no increased risk to food consumption. This is based on scientific evidence that there is no indication of difference between meat and milk of clones and their progeny compared to those from conventionally bred animals.[211] At the national level, a similar view has been recently published by the UK Food Standard Agency (UKFSA).[212]

An argument may be raised about the potential of the permissive approach to enhance the livestock industry due to the absence of a commercial market for transgenic livestock animals so far. Nevertheless, it is equally possible to contend that there will be a potential market for the products in the near future if current developments (worldwide) relating to efforts to commercialise animal biotechnology food is analysed. An important example is the persistent effort by Aqua Bounty Technologies, the US biotechnology firm to obtain the USFDA approval for their transgenic salmon, and the University of Guelph, Canada to obtain approval from Health Canada (HC) for their Enviropig.[213] Logically, these efforts should have been underpinned by the potential to market these products and the optimism that consumers will accept the products. Based on this evidence, it is argued that the market for animal biotechnology food is imminent.[214]

The narrow interpretation given to the exclusion of animal inventions under Article 53(b) of the EPC would render transgenic animals for food patentable in the EU. Therefore, in the light of the potential demand for animal biotechnology food demonstrated here, the narrow

---

[211] ibid.

[212] UKFSA, Meat and milk from cloned animals, 7 December 2010, http://www.food.gov.uk/news/newsarchive/2010/dec/boardcloning (Accessed: 8 April 2012).

[213] Although the Enviropig is developed mainly for its environmental-friendly feature. The Canadian regulatory framework for animal biotechnology food is further discussed in section 2 of chapter 5.

[214] H.P.S. Kochhar, G.A. Gifford and S. Kahn, Regulatory and biosafety issues in relation to transgenic animals in food and agriculture, feeds containing genetically modified organisms (GMO) and veterinary biologics in H.P.S. Makkar and G.J. Viljoen (eds), *Applications of gene-based technologies for improving animal production and health in developing countries* (Springer, 2005) 496.

interpretation will enhance the progress of animal biotechnology applications and the livestock industry. The necessary legal protection for the resulting animal inventions encourages the scientists to be more innovative by creating livestock and fisheries products which meet the demands of the population. This is made possible through the motivation from investors to contribute to the growth of the technology due to the sense of security that their investment in the R&D activities would be recouped.[215] The *Onco-mouse II* decision which upheld the patentability of transgenic animals allows an inventor to claim what he actually invented (through genetic alteration, in a laboratory). As a result, this enhances the technology involved, and the livestock industry further.

5. Conclusion

The work of the Strasbourg Convention was to establish the substantive aspects of European patent law. In turn, the work of the EPC was coordinated with it in order to ensure that the creation of a Common Market was not prejudiced by having differing provisions governing patentable inventions. The result of this was the parity of the exclusion of animal varieties from patent protection in both, Article 2(b) of the Strasbourg Convention, and Article 53(b) of the EPC. This chapter has shown that the adoption of the term 'animal varieties' under Article 2(b) and Article 53(b) is due to the sense of completion with the exclusion of plant varieties in the same provisions. The absence of a specific concept for novel animal inventions at the time of the drafting of the Conventions influenced the adoption of the term 'animal varieties' in parallel to the term 'plant varieties' without a specific meaning and concept intended by the framers to the former. The exclusion of plant varieties from the patent regime is backed by the establishment of a specific concept for the materials which

[215] The transgenic salmon has been patented by Aqua Bounty Technologies. See Europe scorns "supersalmon" as GM battle widens, http://uk.reuters.com/article/2011/04/22/food-salmon-idUKLDE73K1EU20110422 (Accessed: 10 November 2011).

warrant its protection under the *sui generis* system of protection. While some critics have argued that the exclusion of animal inventions should have shared similar ground, its acceptance seems difficult due to the absence of an equal concept for them so far. In this, the indefinite meaning to the term 'animal varieties' eventually led to unclear subject matter of the exclusion under Article 53(b). Nevertheless, it is at least clear from the preparatory working papers of the provision that under the European patent system, only inventions which involve no technical intervention are unpatentable.

The absence of a clear intention of the framers as to the meaning of the term 'animal varieties' and the subject matter excluded under Article 53(b), have not deterred the EPO from applying the exclusion, hence determining the two aspects. Underpinning the EPO interpretation is the convention under international law as underlined by Article 31 and 32 of the Vienna Convention. The provisions require that in the absence of meaning to a term in a treaty or convention, their determination should be based on the object and purpose of the convention. The European patent laws were drafted with a clear objective in mind, namely the creation of a Common Market where a uniform patent system among the Member States was seen as an important strategy for the EU to compete with its major economic competitors (the US and Japan). This aim has broadly influenced the EPO to construe the exclusion of animal varieties under Article 53(b) of the EPC narrowly. Specifically, the interpretation is underpinned by the economic importance of patents that any inventions (including animal inventions) which could fulfil the patent qualification criteria should be given the necessary legal protection. The *Onco-mouse II* which decides on the patentability of animal inventions under the European patent law adopts these principles.

The *Onco-mouse II* confirmed the *Onco-mouse I* where the exclusion to patentability under Article 53(b) is to be narrowly construed and the taxonomic approach is the most appropriate approach to determine the patentability of animal inventions. The *Onco-mouse I* held that while species (*Tierarten*) and sub-species (*races animales* and variety) are within two different taxonomic categories, both are not patentable. The *Onco-mouse II* clarifies this position by deciding that the categories are of the same taxonomic level. The decision arises from the approach of the TBA which equates the three terms under the three official languages of the EPC to the term 'species'. As a result, it was decided that genetically engineered animals are classified as sub-species for being genetic variants of species, hence patentable.

While the equation clearly shows the intention of the TBA to grant patent to animal inventions and resolve the long-problematic issue of excluded subject matter under Article 53(b), it has opened another gap as to whether or not the term 'race' or 'variety' now has the same taxonomic meaning with the term 'species'. This issue arises from the Board's action in leaving open the precise meaning of the terms used in each of the official languages. Eventually, animal inventions are widely entitled to patent protection under the European patent law because the exclusion would not take effect unless a particular claim mentions the excluded categories or if sub-species adopt the meaning of the German term 'species'. This demonstrates how permissive the European-wide approach is. The permissiveness is further evidenced by the narrow interpretation to the exclusion of 'essentially biological processes' under Article 53(b). As the European patent law now stands, the process is patentable irrespective of any degree of involvement of a microbiological process and the impact of the process to the final result.

This chapter has shown that animal biotechnology applications are important to the EU as a tool to support the sustainable development of its livestock and fisheries industries, hence, meeting the growing demand from the population. This explains the significant amount of effort and investment in the on-going R&D activities relating to livestock animals, notwithstanding the pessimistic opinions from consumers toward animal biotechnology food and the absence of their current commercial market in the EU. In particular the motivation comes from the potential market for animal biotechnology food where public acceptance could be nurtured by appropriate information and knowledge of the benefit of the food. Patent protection for animal biotechnology food is pertinent to promote the technology involved. The permissive approach serves this objective by attracting investments from public and private institutions due to the patentability of the products. In the long run, this stimulates and advances the relevant R&D activities in the EU.

As regards the previous critics' views analysed in this chapter, Warren-Jones precisely predicted the *Onco-mouse II* decision through her isolated category construction, amid the non-definitive decision of the *Onco-mouse I* as to the subject matter of the exclusion of animal varieties under Article 53(b). In the context of the function of a legal provision, her construction would allow an effective development of the technology as it elevates the unnecessary difficulties with linguistic issues of Article 53(b), but rather focuses on the aspiration for a patent system which aims at encouraging research and innovation. Therefore, in the context of the implications of the isolated category approach on the livestock industry, it can be concluded that the approach is pertinent for the progress of scientific research involving livestock animals. On the other hand, Beyleveld and Brownsword's arguments on the generic meaning of the term 'animal varieties', and, their argument for the exclusion of all animals in general under Article 53(b) has been refuted by the *Onco-mouse II.* The

construction would leave animal inventions legally unprotected. Bearing in mind that there is not yet an efficient *sui generis* system of legal protection for animal inventions, the construction would result in the refusal of investors to support relevant R&D activities which are known-to-be expensive, complicated and time consuming. Equal assessment for Vossius's arguments is quite difficult as he did not advocate any approach on how the matter excluded under Article 53(b) should be determined. This is owing to his focus which was limited to analysing the appropriateness of the usage of the three terms in each of the official language of the EPC in the context of the biological meaning of the terms. Nevertheless, his conclusion that Article 53(b) should be narrowly construed as the three terms do not amount to the exclusion of animals *per se* from patent protection appears to have been confirmed by the *Onco-mouse II*.

The legislative background of Article 53(b) of the EPC is similar to s13(1)(b) of the Malaysian Patents Act 1983 (as identified in chapter 3) where the intended meaning of the term 'animal varieties', the purpose, and the subject matter of the exclusion are unclear. Irrespective of the deficiencies, the EU has demonstrated that the exclusion should have been construed in the light of the intention of the patent system which is to enhance innovation and the economic development of a given country. As a non-Member State to the EPC, Malaysia is not legally bound by the European-wide permissive approach. Nevertheless, the approach remains an option for the MyIPO and Malaysian courts to consider (through its potential adoption by the UK courts) in their attempt to interpret the similar exclusion. Whether or not the permissive approach should be adopted by Malaysia (in the light of the problems and need of its livestock industry) will be determined in the Discussion and Conclusion chapter after the restrictive approach is examined in the next chapter. The chapter covers the examination of the Canadian political perspective and government's policy toward animal

patenting, and an assessment of the restrictive approach adopted by the judicial authorities. Also included is an analysis of the implication of the restrictive approach on the livestock industry. As regards the research questions the chapter identifies a Signatory's (to the TRIPs Agreement) different way of interpreting the exclusion of animal inventions, while not having an exclusionary provision in its national patent law, and the implications arising from it.

CHAPTER FIVE

THE RESTRICTIVE APPROACH FOR PATENTING ANIMAL INVENTIONS, AND ITS IMPLICATIONS ON THE LIVESTOCK INDUSTRY: THE CANADIAN PERSPECTIVE

1. Introduction

The previous chapter demonstrated how the permissive approach in Europe assists the development of the livestock industry by stimulating investment. This chapter examines the approach adopted under the Canadian patent system which is vastly different to the approach of the EPO. The difference will allow suggestions be made to Malaysia on the range of possibilities available to it when construing s13(1)(b) of its Patents Act 1983. Canada has been a Member State of the WTO since 1 January 1995.[1] Therefore, similar to other Member States, the country is expected to provide for a minimum standard of patent protection for biotechnological inventions under Article 27.1 of the TRIPs Agreement. Section 2 of the Canadian Patent Act 1985[2] broadly defines the term 'invention' as:

> any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

The five categories of invention in the provision: 'art, process, machine, manufacture or composition of matter', suggest a broad range of subject matter which could be protected under the Act. Ironically, during the last three decades the Canadian Intellectual Property Office (CIPO) and judicial authorities have made a distinction between biotechnological inventions which are patentable (as products) and those which are not. Under the patent law

[1] WTO, Members and observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (Accessed: 13 October 2011).

[2] Patent Act, R.S.C, 1985, c.P-4.

of the country, only lower life forms such as micro-organisms, yeasts, moulds, fungi, bacteria, viruses or protozoa are patentable. This has been ruled by the Commissioner of Patents in the case of *Re Application of Abitibi Co.* (*Abitibi).*[3] However, the same rule is not applicable for higher life forms (including animals and plants) since they are considered as neither 'manufacture' nor 'composition of matter' within the meaning of the term 'invention' under s2.[4] This principle has been explicitly underlined by the Supreme Court in the precedent case of *Harvard Mouse.*[5] Thus, as a reminder of the Introduction chapter, the term 'restrictive approach' used in this thesis refers to the unpatentability of animal inventions under the Canadian patent law, notwithstanding the absence of express statutory exclusion.

In order to facilitate comparison with the discussion in chapter 4 on the European-wide permissive approach, this chapter follows the same format: it explores how Canada has interpreted the term 'invention' leading to the unpatentability of animal inventions and identifies how restrictive it is. The chapter also assesses the implications of the adopted approach on the livestock industry. To achieve these aims, this chapter is divided into five sections. Section 2 identifies Canada's attitude toward animal inventions. This permits identification of any change of policy adopted by the country, between the time when biotechnology was newly developed and the current position where the technology has proved its potential to produce useful products for the enhancement of life and the economy. Section 3 analyses the relevant principles of law which underpin the decisions of the Commissioner of Patents and the Supreme Court[6] for not allowing patent protection to animal

[3] Decision of the Chairman, Patent Appeal Board, Canada dated 18 March 1982, to the application from the Abitibi Company of Toronto. Available at: CIPO, http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/933/summary.html?query=933+%3cin%3e+comdecnumber&start=1&num=10 (Accessed: 4 May 2010); (1982) 62 C.P.R (2d) 81 (Pat. App. Bd).

[4] The meaning of 'lower life form' and 'higher life form' is elaborated further in sub-section 3.1.2 below.

[5] *Harvard College v Canada (Commissioner of Patents)* [2003] 5 LRC 330.

[6] These are the lead-decision-making bodies in patent cases in Canada.

inventions. This is followed by section 4 which assesses the implications of the restrictive approach on the livestock industry. Section 5 concludes the chapter.

Canada's approach is relevant for Malaysia for two reasons: (1) while the Canadian Patent Act 1985 has no statutory exclusion of animal varieties (as is the case under the Malaysian Patents Act 1983), the decision to exclude animal inventions implies a different approach to interpreting the exclusions to 'animal varieties'; and (2) as Canada is a commonwealth country (similar to Malaysia), the approach becomes relevant for historical reasons. As the EPO interpretation, the Canadian Supreme Court decisions are not binding on Malaysian judicial decisions. Nevertheless, based on the principle of judicial precedence, they represent a persuasive authority for potential cases before the Malaysian courts where the patentability of animal inventions would be in issue.

2. Canada's attitude toward animal inventions

It has been a long-argued debate whether patent law is able to promote innovation.[7] However, progress in the field of science and technology depends largely on the economic value of patents where vast amounts of investment could be secured from their licensing to research and academic institutions. Notably, patents have been used as a principal criterion by venture

[7] It has been observed patents have a positive impact on the increase of investments and R&D spending, hence, advancing economic growth. See K.E. Maskus, Intellectual property rights and economic development (2000) 32 *Case Western Reserve Journal of International Law*, 471- 506. In the recent report to the UK Government, it has been identified that while IPRs are paramount as 'risks and costs are a disincentive to innovate', proliferation of the use of IPRs can increase IP transaction costs and block new (small and young innovative) firms from competing in markets. See an independent report by Professor Ian Hargreaves in I. Hargreaves, Digital opportunity: a review of intellectual property and growth, May 2011, http://www.ipo.gov.uk/ipreview-finalreport.pdf (Accessed: 13 February 2012) 1-130. The review's recommendations include that the UK government works to ensure that patents are not extended into sectors such as non-technical computer programs and business methods without clear evidence of benefit.

capital firms when evaluating funding requests from biotechnology firms.[8] Firms which consider investing in local R&D activities have also put emphasis on the strength of local patent protection.[9] Canadian patent law originates from this basic purpose of patents as clearly underlined in the preamble of the Canadian Patent Act 1826:[10]

> [w]hereas it is expedient for the encouragement of Genius and of Arts in this Province to secure exclusive right to the Inventor of any New and Useful Art, Machine, Manufacture, or Composition of Matter …[11]

Notwithstanding the seemingly broad objective of the Canadian patent law, the country has adopted a pessimistic stance since the time when the patentability of living organisms became an international issue. This contention finds support from some pertinent evidence, including: (1) the country's political perspective; (2) the regulatory framework pertaining to animal biotechnology food; and (3) the opinion of Canadian consumers. These three aspects are elaborated here.

During the negotiations of the Uruguay Round Meeting of the TRIPs Agreement, Canada argued that it was not reasonable to oblige all governments to extend patents to an area such as multi-cellular life forms.[12] More strongly, the country raised the view that 'multi-cellular life forms or processes for producing new multi-cellular life forms should not be patentable'.[13] This initial view is consistent with the attitude of the country to date in regulating animal biotechnology food. Article 15 of the Cartagena Protocol advocates, that

---

8 J. Niosi, Biotechnology in J. Niosi, *Canada's regional innovation systems: the science-based industries* (McGill-Queen's University Press, 2005) 45.

9 K.E. Maskus, n 7 above, 484.

10 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 40. See also G. Asher, The development of the patent system in Canada since 1767 (1965) 43 *Canadian Patent Reporter*, 60.

11 ibid.

12 GATT, 'Proposal by the Nordic Countries for the Negotiations on Standards and Principles for Trade-related Aspects of IPRs', Document MTN.GNG/NG11/W/36 (10 July 1989) 1-2.

13 GATT, 'Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles', Document MTN/GNG/NG11/W/32/Rev.2 (2 February 1990) 86.

Signatories should conduct risk assessments concerning the implications of LMOs.[14] It is already identified in chapter 1 that this obligation covers transgenic livestock animals and their products.[15] Canada is not a party to the Protocol,[16] and, therefore has no legal obligation to implement the various provisions of the document relating to 'the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on human health and environment'.[17] Nevertheless, it is worthy of note that the Canadian Biotechnology Strategy 1998[18] (the Strategy) was formed with a similar aim, namely 'to ensure that the benefits of biotechnology are realised in a way that protects health, safety, and the environment'.[19] This is meant to be achieved through high regulatory standards.[20]

As regards the regulation of livestock animals produced through modern biotechnology and their products, the Strategy underlines that the country's existing legislative and regulatory bodies are to regulate the subject matter.[21] Therefore, the animals and products, which are considered as 'novel',[22] come under the purview of Environment Canada (EC) and Health

[14] See discussion in sub-section 3.2 of chapter 1.
[15] ibid.
[16] However, Canada ratified the CBD on 4 December 1994. See CBD: List of parties, http://www.cbd.int/convention/parties/list/ (Accessed: 13 February 2012).
[17] Article 1 (Objective) of the Cartagena Protocol.
[18] The Strategy broadens the 1983 initial Canadian Biotechnology Strategy by framing general framework and various broad goals to develop the biotechnology industry, and is meant to be implemented by main departments of the federal government. See Government of Canada, Biostrategy: the 1998 Canadian Biotechnology Strategy, http://www.biostrategy.gc.ca/english/View.asp?pmiid=520&x=535 (Accessed: 15 February 2012) 15; Canadian Biotechnology Advisory Committee (CBAC), Toward a Canadian action agenda for biotechnology: a report from the CBAC (CBAC, 2006).
[19] ibid.
[20] ibid.
[21] ibid.; CFIA, Regulating agricultural biotechnology in Canada: an overview, http://www.inspection.gc.ca/english/sci/biotech/reg/bioage.shtml (Accessed: 15 February 2012).
[22] CFIA, Animal biotechnology, http://www.inspection.gc.ca/english/anima/biotech/bioteche.shtml (Accessed: 15 February 2012). 'Novel food' means: (a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. See HC, Division 28, Part B.28.001, of the Food and Drug Regulations (Novel

Canada (HC), with support from the Canadian Food Inspection Agency (CFIA). In Canada, livestock animals produced through modern biotechnology need to undergo a two-tier assessment.[23] First, developers who intend to manufacture, import or sell the animals in Canada need to apply for approval to the EC and HC which are jointly responsible for assessing the impact of the animals on the environment and human health (including the safety of people working with the animals).[24] Then, the products are assessed on the basis of the products' intended end use. For example, if the transgenic livestock animals or fish are intended to be used as food, the HC will be in charge of the assessment relating to food safety.[25] In these assessments, the CFIA assists in matters pertaining to animal health.[26] Except for the detailed procedures for assessment, it is observed that the regulatory framework which is applicable in Canada is similar (in terms of aspects which are regulated

---

Foods) http://www.hc-sc.gc.ca/fn-an/consult/_novel_foods/consultation_appendix-annexe1-eng.php (Accessed: 15 February 2012).

[23] CFIA, Animals and animal products derived through modern biotechnology: roles and responsibilities of the Government of Canada, http://inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/animal-biotechnology/eng/1334783323017/1334783436055 (Accessed: 15 February 2012); H.P.S. Kochhar and B.R. Evans, Current status of regulating biotechnology-derived animals in Canada – animal health and food safety considerations (2007) *Theriogenology*, 67, 194.

[24] ibid. HC co-administers the Canadian Environmental Protection Act (CEPA) 1999 with respect to human health. The Department of Fisheries and Oceans (DFO) is involved in the environmental assessment and notification involving requests to develop fish using modern technology for commercial purposes under the New Substances Notification Regulations (Organisms). Notification is to be sent to the EC for full assessment of potential impacts on the environment. The EC administers the assessments under the CEPA and the New Substances Notification Regulations (Organisms) 2005. Both the Act and Regulations are available at: Department of Justice, http://laws-lois.justice.gc.ca/PDF/C-15.31.pdf and http://laws-lois.justice.gc.ca/PDF/SOR-2005-248.pdf, respectively (Accessed: 7 March 2012). The Regulations provide for notification and assessment of processes for living organisms. The scope includes 'certain new livestock animals (and their progeny)' such as cattle modified to increase milk or meat production and fish modified for growth enhancement. Nevertheless, the 2005 Regulations only provide broad aspects of information required in respect of the organisms (such as taxonomic name of the species and description of modification made to the organisms). Efforts on the details of notification and assessment involving organisms other than micro-organisms for confined or full release in the environment has not been finalised. See EC, Review of the New Substances Notification Regulations (Organisms), http://www.ec.gc.ca/subsnouvelles-newsubs/B59FB284-AC16-448C-A343-9A5F0E1E57F4/NSNR%28O%29%20Phase%20II%20consultation%20-%20EN.pdf (Accessed: 7 March 2012); EC and HC, New substances: review of the new substances notification regulations (organism) – background and update, http://biosafety.icid.com/en/files/presentations/Review-New-Substances-Notfication-Regulations.pdf (Accessed: 7 March 2012).

[25] ibid.

[26] ibid.

and assessed)[27] to that in the EU,[28] Australia and New Zealand.[29]

Historically, efforts toward developing regulations, risk assessments and guidelines for transgenic animals (including fish and aquatic animals) and animal biotechnology food in Canada started in 2001, where the Royal Society of Canada (RSC)[30] recommended to the HC, EC and CFIA that 'approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for causing harm to the environment and human health.'[31] In an immediate response to the recommendation, the Canadian Government promised that the HC would develop and publish guidelines for the safety assessment of novel foods derived from the animals.[32] Unfortunately, after more than a decade of 'efforts'[33] there is still no clear indication when the document will

---

[27] Which are the safety of the food for human health and environment. See S.J. MacLaughlin, Food for the twenty-first century: an analysis of regulations for genetically engineered food in the United States, Canada and the European Union (2003) 14 *Industrial International and Comparative Law Review*, 1, 375-407; H.P.S. Kochhar, G.A. Gifford and S. Kahn, Regulatory and biosafety issues in relation to transgenic animals in food and agriculture, feeds containing genetically modified organisms (GMO) and veterinary biologics in H.P.S. Makkar and G.J. Viljoen (eds), *Applications of gene-based technologies for improving animal production and health in developing countries* (Springer, 2005) 478-498.

[28] For instance, in the EU, foods produced from cloned animals fall under Regulation (EC) No 258/97, being considered as novel foods. They must be subjected to a safety evaluation before they can be legally marketed. European Commission, Novel foods and novel food ingredients, http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm (Accessed: (12 March 2012).

[29] GM foods derived from animals which are entering the Australian and New Zealand food market must comply with Standard 1.5.2 - Food Produced Using Gene Technology 1998 (a joint standard between the two countries). Section 1 of the Standard imposes a pre-market approval system to ensure that GM food is equally safe to conventionally produced foods. Section 2 provides for labelling requirements. See P. Brent, D. Bittisnich, S. Brooke-Taylor, N. Galway, L. Graf, M. Healey and L. Kelly, Regulation of genetically modified foods in Australia and New Zealand (2003) 14 *Food Control*, 409-416.

[30] RSC, Elements of precaution: recommendations for the regulation of food biotechnology in Canada, January 2001, http://www.rsc.ca//files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf (Accessed: 15 February 2012).

[31] ibid. x, paragraph 7.1.

[32] HC, Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, titled 'Elements of precaution: recommendations for the regulation of food biotechnology in Canada', 23 November 2001, http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/RSC_response-reponse_SRC-eng.php (Accessed: 15 February 2012).

[33] This includes: (1) obtaining inputs from national experts consultations; and (2) considering the FAO/WHO Expert Consultation on Genetically Modified Animals which include advice on making GM animals safer from the outset by wise selection of breeding goals and the use of post-market surveillance to gather information relating to the beneficial and adverse effects of GM food. The latter consultation document is available at: FAO, ftp://ftp.fao.org/docrep/fao/006/y5316E/y5316E00.pdf (Accessed: 15 February 2012). See also Progress Reports, in response to the Royal Society of Canada Expert Panel Report, from January 2002 to June 2005, which are available at HC, Reports and publications: biotechnology, http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/index-eng.php (Accessed: 15 February 2012).

be ready for implementation. The latest Progress Report published by the HC states that the relevant agencies are still working on the guidelines.[34] In this respect, it can be observed that, while the Guidelines for the Safety Assessment of Novel Foods[35] have already provided information required for novel foods derived from plants and micro-organisms, so far, only the remark 'under development' appears under the heading of 'Novel Foods Derived from Animals' of the Guidelines.[36]

The HC's seemingly continued commitment conflicts with an important policy[37] published by the authority itself. As early as 2003, the authority explicitly prohibited the sale of cloned animals derived from the somatic cell nuclear transfer (SCNT) technique through the Food Directorate Interim Policy on Foods from Cloned Animals. The Policy states:

> [f]oods produced from livestock developed using SCNT and the progeny of such livestock to be captured under the definition of 'novel food' in the Food and Drug Regulations in that they have been obtained by a reproductive technology which has not previously been applied to generate animals that would be used to manufacture foods (meat, eggs, milk, etc) and which may result in a major change in these foods.
>
> …
>
> Developers producing cloned animals through SCNT must, therefore, not sell the products or by-products of any cloned animals or their progeny in the human food supply in Canada unless they have been subjected to the pre-market safety assessment required of novel foods.[38]

---

[34] HC, Progress Report: June 2005 - Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/prog-rep-rap_06_2005-eng.php (Accessed: 15 February 2012).

[35] HC, Guidelines for the Safety Assessment of Novel Foods, June 2006, http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php (Accessed: 15 February 2012).

[36] ibid.

[37] HC, Food Directorate Interim Policy on Foods from Cloned Animals, http://www.hc-sc.gc.ca/fn-an/legislation/pol/pol-cloned_animal-clones_animaux-eng.php (Accessed: 15 February 2012).

[38] ibid.

In addition, the Policy states:

> As there is currently insufficient data to guide the pre-market safety assessment of these products, developers who wish to use SCNT technology for producing livestock are requested to withhold novel food notification until requirements are determined and guidance is available.[39]

The Interim Policy appears to cover only food from cloned animals. A question may arise as to whether the Policy similarly covers transgenic livestock animals and their products which are meant for human consumption. Cloning is not genetic engineering *per se* as it does not involve direct manipulation of DNA[40] (thus has been described as 'an indirect means of creating biotechnological products').[41] However, the process offers the opportunity to create genetically engineered (or transgenic) animals such as the production of cattle from cells lacking the gene for the prion protein responsible for BSE disease.[42] Therefore, it can be concluded that the Policy also covers genetically engineered (transgenic) livestock animals and their products.

The Policy demonstrates the unequal treatment given by the Canadian Government to animal biotechnology food compared to their conventional counterparts. To date the Interim Policy has not been revised. It should be noted that Canada has been involved in international forums such as CODEX Alimentarius[43] where issues of animal biotechnology food are involved. Nevertheless, the country refrains from taking an official position on the regulation

---

39 ibid.; A.L. van Eenennaam, Is livestock cloning another form of genetic engineering? http://agribiotech.info/details/Alison%20-%20cloning%20March%208%20-%2003.pdf (Accessed: 26 April 2012) 4-5.

40 ibid.

41 A. Warren-Jones, *Patenting rDNA: human and animal biotechnology in the United Kingdom and Europe* (Oxford: Lawtext Publishing, 2001) 11-16.

42 A.L. van Eenennaam, n 39 above, ibid.

43 An international organisation established by the FAO and WHO, which develops food standards and guidelines.

of animal biotechnology food, due to the absence of any definitive and comprehensive stance on the regulation of the products.[44]

Some public surveys prepared for, or undertaken by, the Canadian Government disclose consumers' pessimism toward GM animals and fish as food products. In a recent survey undertaken for Industry Canada,[45] it was reported that Canadians are most supportive of the development of GM animals for medical purposes (such as cloned animals for bio-medical research). However they are less supportive of non-health applications such as animals with uniform quality of meat or dairy products. Of paramount concern are the risks from consuming the products. As regards the impact of some applications of technology, 58% of the respondents were opposed to the genetic modification of animals; 54% to fish and 50% to food.[46] The public survey also identified that genetic modification of fish is not an area of technology that many Canadians are aware of, leading to significant concerns with the idea that GM fish are being imported to Canada.[47] In an earlier survey,[48] while consumers generally accepted that patent protection was necessary in the field of biotechnology to encourage innovations, different perceptions were discovered in terms of the purpose and object of patents. Patenting is more acceptable to the consumers in the context of human health and environmental applications compared to agricultural applications (including altered cows with increased milk production).[49] While similar concern has also been observed

---

[44] USDA Foreign Agricultural Service, Canada biotechnology – GE plants and animals: agricultural biotechnology annual report, Global Agricultural Information Network (GAIN) Report, 8 August 2010, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Plants%20and%20Animals_Ottawa_Canada_08-05-2010.pdf (Accessed: 15 December 2011) 22.

[45] Industry Canada, Emerging technologies tracking research, June 2006, http://www.ic.gc.ca/eic/site/ic1.nsf/eng/04275.html (Accessed: 22 December 2011).

[46] ibid. 8.

[47] ibid. 16.

[48] E.F. Einsiedel and J.A. Smith, Canadian views on patenting biotechnology: report prepared for the Canadian Biotechnology Advisory Committee (CBAC) (Ottawa, 2005).

[49] ibid. 4.

among European consumers,[50] it should be noted that the HC has explicitly underlined that one of the aspects that it will consider, in reaching a final policy decision concerning the foods derived from cloned animals and their progeny, is public opinion.[51] Therefore, in the case of Canada, the negative views of consumers have largely influenced the regulatory agencies' attitude. This eventually causes the minimal progression of the relevant guidelines.

This section has shown that animal inventions could be patentable in Canada in two aspects: (1) the general meaning for the term 'invention' under s2 of the Canadian Patent Act 1985; and (2) the absence of statutory exclusion under the legislation. Yet this is not the case. The country has adopted the view that animal inventions are not patentable subject matter since the TRIPs Agreement was negotiated. This negative attitude corresponds with the country's lack of interest in developing the regulatory framework for biotechnology-driven livestock animals, and their products. Consumer reluctance to support the products contributes to the situation.

The next section assesses the approach to animal patenting within Canada's patent law. For this purpose, the section is divided into two sub-sections. The first part analyses pertinent legal principles in the *Harvard Mouse* decision which adopted a restrictive interpretation to the term 'invention'. The reasoning of the Supreme Court's decision will be compared and contrasted with: (1) the patent authorities'[52] and lower courts'[53] decisions; and (2) the decisions in the cases of *Abitibi* and *Pioneer Hi-Bred Ltd. v Canada (Commissioner of*

[50] See discussion in section 4 of chapter 4.

[51] HC, Report of stakeholder comments on proposed revisions to Health Canada's guidelines for the safety assessment of novel foods derived from plants, microorganisms and Health Canada's responses to these comments, http://www.hc-sc.gc.ca/fn-an/consult/novel-nouveaux/index-eng.php (Accessed: 16 February 2012); A. Singh, Proceed with precaution: the statutory, legal, and consumer influence on genetically modified foods in Canada (2005) *Canadian Journal of Law and Technology*, 190.

[52] The Commissioner of Patents and the Patent Office examiner.

[53] The Federal Court (Appeal Division) and the Federal Court (Trial Division).

Patents) (*Pioneer-Hi Bred).*[54] The two are leading cases on biotechnological patents within Canadian jurisprudence, which involve a micro-organism and a plant, respectively. It will be argued that the Supreme Court decision to refuse a patent to the GM mouse for not being an invention lacks legal reasoning. This part will also demonstrate that the restrictive approach adopted by the judicial authority conforms to the country's pessimistic policy toward animal inventions as earlier shown in this section. The second part is devoted to an analysis of the case of *Percy Schmeiser and Schmeiser Ltd v Monsanto Canada Inc. and Monsanto Company (Percy Schmeiser*).[55] The case is particularly important in identifying whether there has been any change in approach to animal patenting in Canada. It will be contended that notwithstanding the *Percy Schmeiser* decision, the Supreme Court is consistent in its restrictive approach where animal inventions are unpatentable. Nevertheless, as a result of the decision, patented genes and cells contained in the animal gives the patentee the right to exclude others from dealing with the transgenic animal. The latter principle represents a puzzling aspect of Canadian patent law. The analysis is important to the research questions for two reasons: (1) it identifies, and informs Malaysia about the restrictive approach adopted by Canada; and (2) it further identifies whether or not the decision to hold a GM animal as a non-invention is legally justified in the context of the broad meaning of the term 'invention'.

3. The legal approach to animal patenting in Canada

In chapter 4 it was demonstrated that the European-wide permissive approach relies on whether or not an animal invention falls within the term 'animal varieties' under Article 53(b) of the EPC. The discussion in this section will demonstrate that the invention faces a more fundamental hurdle under Canadian patent law, by first having to qualify as an 'invention'

[54] [1989] 1 SCR 1623; [1987] 3 FC 8.
[55] [2004] 1SCR 902; [2004] SCC 34; [2003] 2 F.C. 165; [2002] FCA 309; [2001] FCT 256.

under s2. The facts of the *Harvard Mouse* in Canada are similar to those discussed in sub-section 3.1 of chapter 4, and thus will not be reprised here. As for the position in Europe, various claims for process patents, cell cultures and plasmids were allowed in the first instance by the Commissioner of Patents.[56] Therefore, the question which was the subject of appeal to the Supreme Court was whether a transgenic mouse is an invention under s2.

3.1 The Harvard Mouse in Canada: an analysis of the Supreme Court's decision

For the purpose of analysis, the following sub-sections deal with two pertinent aspects which formed the refusal of the Supreme Court to grant patent protection to the Harvard Mouse: (1) the words, scheme and object of the Patent Act, versus the intention of the legislature; and (2) the non-qualification of the GM mouse as an 'invention' under any of the categories under s2.

3.1.1 The words, scheme and object of the Canadian Patent Act 1985, versus the intention of the legislature

Section 2 and its relation to the intention of the legislature were perceived differently by the majority and minority (of the panel of judges) in the *Harvard Mouse*. In the US case of *Diamond v Chakrabarty*, the majority advocated the principle that the term 'invention' within the context of patent law should be broadly interpreted to cover any invention that fulfilled the patentability criteria. The majority in the *Harvard Mouse* refused to adopt this view in interpreting the same term under s2. In the US, the principle was achieved based on the interpretation of the Congressional Committee Reports accompanying the US Patent Act

[56] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 123.

1952.[57] The majority in the *Harvard Mouse* argued that the adoption of the five categories under s2 clearly indicates that a certain limit was intended by Parliament.[58] Otherwise, the term would have been defined as 'anything new and useful made by man'.[59] The majority was not convinced that the existing Canadian Patent Act 1985 is broad enough to cover higher life forms within the patent scheme, since there was no indication of such an intention from Parliament.[60] Moreover, the patenting of higher life forms raises unique concerns and involves public interest issues which require explicit direction from the legislature.[61] Conversely, the minority argued that due consideration should be given to the central purpose of patent law. Since the law aims to encourage innovation, any invention which fulfils the patent qualification criteria should be patentable, irrespective of the fact that it may be a living being. The fact that an invention involves a living being should not *per se* exclude it from patent protection, as this would undermine the aim of the creation of the patent law itself which is meant to encourage human ingenuity.[62] It will be shown in the following analysis that the majority's restrictive interpretation of the intention of Parliament and the term 'invention' shows a lack of legal reasoning.

Firstly, while refusing to adopt the broad meaning of the term 'invention', the majority recognised that the purpose of patent law and the broad intention of Parliament are to encourage innovation by the grant of patent.[63] This explicit recognition should have led to a view that the term is to be broadly construed, and hence a patent should be allowed to a subject matter which could meet the relevant prerequisites. There are two other reasons which

[57] ibid. paragraph 157.
[58] ibid. paragraph 158.
[59] ibid.
[60] ibid. paragraph 155.
[61] ibid.
[62] ibid. paragraph 1(iii).
[63] ibid. paragraph 158. N. Siebrasse, Comment on *Monsanto Canada Inc. v Schmeiser* (2004) *Canadian Bar Review*, 3.

support this contention: (1) the Canadian courts have tended to consider UK cases when interpreting Canada's patent law, due to the fact that Canada was once a colony of the UK.[64] Therefore, being a commonwealth country, Canada has a system of law derived from English law. While the EPO decisions are not binding upon national courts, the UK courts are, in principle, constrained to adopt the permissive interpretation adopted by the EPO (through the decision of the *Harvard/Onco-mouse* case)[65] when construing the exclusion of animal inventions contained in the UK Patents Act 1977.[66] In evidence, the UK highest courts have recently stressed the importance of the UK courts following the decisions of the EPO (on the same issues) so as to ensure parity of interpretation of the EPC among the Member States.[67] Consequently, based on the principle of precedence, the EPO cases (which would be indicative of UK jurisprudence) would have persuasive value to Canada; and (2) the definition of what constitutes an 'invention' under the Canadian patent statute was modelled upon the US Patent Act 1793.[68] Notably, the majority in the *Harvard Mouse* conceded this

---

64 P. Krishna and M. Perry, Making sense of mouse tales: Canada life form patents topsy-turvy (2001) 23 *European Intellectual Property Review*, 4, 199; M. Kamber, Coming out of the maze: Canada grants the Harvard Mouse Patent (2003) *Washington International Law Review*, 779.

65 The decision was discussed in section 3 of chapter 4.

66 For the UK provision, see Appendix 9.

67 The House of Lords in the case of *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9; [2004] UKHL 46 (which involved product-by-process claims) held that the UK courts should follow the EPO decision. Later, in the case of *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] RPC 28; [2008] UKHL 49, the same court held that the UK courts should follow on general principles, but will diverge in application. Lord Hoffmann, delivering the court's judgement, notably held at page 720: 'A European patent takes effect as a bundle of national patents over which the national courts have jurisdiction. It is therefore inevitable that they will occasionally give inconsistent decisions about the same patent. Sometimes this is because the evidence is different. In most continental jurisdictions, including the EPO, cross-examination is limited or unknown . . . But when the question is one of principle, it is desirable that so far as possible there should be uniformity in the way the national courts and the EPO interpret the EPC.' In the recent case of *Human Genome Sciences Inc v Eli Lilly and Company Limited* [2012] RPC 6; [2011] UKSC 51, the Supreme Court held that the UK courts could decline the EPO decisions only where they considered that the decisions had taken the law in an inappropriate direction, misapplied previous EPO jurisprudence or failed to take a relevant argument into account.

68 J.D. Morrow, Patentable subject matter: emerging technologies in G.F. Henderson (ed), *Patent law of Canada* (Toronto: Carswell, 1994) 24. Despite being a colony of France and the UK (until its confederation on 1 July 1867), the country's patent legislation has, since the first statute dealing with patents in 1823, been modelled upon the US law. This was due to the availability of the US patent statute which was enacted in 1790, in comparison to the UK's patent statute which was only codified in statutory form in 1852 (even though the Statute of Monopolies was enacted much earlier in 1624). See H. Fisher and R.S. Smart, *Canadian patent law and practice* (Toronto: Canada Law Book Company Limited, 1914) 3. For detailed discussion about the development of the Canadian Patent Act, see O.M. Biggar, *Canadian patent law and practice: with special reference to the differences between the law and practice in Canada and in Great*

fact.[69] It is pertinent to note that apart from the dropping of the words 'or discovers' which still remain in the US Patent Act, the meaning of the term 'invention' under the current Canadian Patent Act 1985 is essentially the same as that of the country's Patent Act 1869.[70] This legislative background explains the similarity between s2 of the Canadian Patent Act 1985 and §101 35 USC.[71] Therefore, in view of: (1) the alleged inexplicit direction from the Canadian Parliament; (2) the influence which the UK permissive approach would have on Canada; and (3) the adoption of the meaning 'invention' from the US Patent Act,[72] it is difficult to appreciate the distinctive approach adopted by the majority in the *Harvard Mouse* in interpreting the term 'invention' narrowly.

The different view adopted by the Supreme Courts, in the US and Canada, to interpret the meaning of the term 'invention', demonstrates that the decision whether to allow a patent for animal inventions largely depends on how judicial authorities perceive the issue.[73] The majority[74] in the *Harvard Mouse* notably stated that: (1) 'patenting higher life forms would involve a radical departure from the traditional patent regime'; and (2) 'it is unlikely that Parliament would choose the Patent Act as it currently exists as the appropriate vehicle to protect the rights of investors in this type of subject matter'.[75] In the alleged absence of clear intention from the legislature, this statement inevitably reflects the different attitude toward animal patenting adopted by the Canadian judicial authorities.

Britain and the United States (Toronto: Burroughs & Company (Eastern) Limited Law Publishers, 1927) 2-3; Gordon Asher, n 10 above, 60-63.

69 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 158.

70 J. Bochnovic, Invention/Inventive Step/Obviousness in G.F. Henderson, n 68 above, 43.

71 For §101 35 USC, see footnote 52 of chapter 2.

72 J.A. Lèger, Patent infringement: back to good sense in G.F. Henderson, n 68 above, 263.

73 T. Scassa, A mouse is a mouse is a mouse: a comment on the Supreme Court of Canada's decision on the Harvard Mouse patent (Harvard College v Canada (Comr of Patents)) (2003) 3 *Oxford University Commonwealth Law Journal*, 1, 117.

74 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 1.

75 ibid.

Secondly, the majority's reasoning amounts to requiring Parliament to state precisely that, animal inventions are included in the definition. Arguably a patent legislation would not be able to provide a detailed list of all subject matter which would amount to inventions, thus covered by the statute. The legislation is meant to lay down substantive provisions for the purpose of encouraging innovation and rewarding an inventor,[76] rather than dealing with the minute details. It is the duty of the Court to interpret the relevant provision based on applicable legal principles. It is important at this juncture to reiterate the fact that Article 27.3(b) of the TRIPs Agreement only allows Signatories to exclude 'animals' and 'essentially biological processes' from the patent regime.[77] However, products of microbiological process are to be patentable. [78] Similar principles are provided in Article 8(2) of the EU Biotechnology Directive. Notably, Article 8(1) of the Directive provides that offspring of transgenic animals (which inherit the relevant novel traits) fall within the scope of protection of the European patents.[79] These leading patent law texts do not prevent an animal obtained through technical intervention from being an 'invention'. Moreover, as already highlighted in chapter 2, even in the absence of explicit provision on the patentability of animal inventions, the inventions have been held to be patentable in many countries (such as the US and Japan).[80]

Thirdly, it is pertinent to note that the rules under Article 27.3(b) of the TRIPs Agreement, that only an 'essentially biological process' is not to be protected whereas products of microbiological process are to be granted patents are similarly provided under Article 1709 of

[76] ibid. 6.
[77] See Appendix 4.
[78] ibid.
[79] See detailed discussion of Article 8 in A. Warren-Jones, n 41 above, 124-125.
[80] See discussion in sub-section 2.2.1 of chapter 2.

the North American Free Trade Agreement (NAFTA),[81] to which Canada is a Signatory. Therefore, it must fulfil its international obligation under both Agreements. It is already identified in chapter 4 that the EPO cases (including the *Harvard/Onco-mouse*) have been decided along these principles of Article 27.3(b). In contrast, arguably Canada has failed to observe its international obligation, both under Article 27.3(b) and Article 1709, by refusing a patent to the Harvard Mouse (which is a product of microbiological process).

This contention finds further support from the inconsistency of the Canadian Supreme Court decisions. In *Pioneer-Hi Bred*, the appellant (Pioneer Hi-Bred) claimed a patent for a new line of soybean variety which was achieved through: (1) selection and crossing of the parent plants; and (2) development of a pure line by selective reproduction.[82] The Supreme Court recognised two types of genetic engineering, hence highlighting the difference between them in the case. In essence, the Court was of the view that while hybridisation (crossing different species or varieties) involves human intervention, the process does not alter the actual rules of reproduction, which remains to follow the laws of nature. This first type of genetic engineering falls short of patent protection. Conversely, patent law only grants protection to the second type of genetic engineering which involves an alteration made by human at the molecular level, where the modification to the sequence of the genes affects all the hereditary material.[83] Following this distinction, the processes involved in *Pioneer Hi-Bred* had been classified by the Supreme Court under the first category. Therefore, while the Court did not

---

[81] NAFTA is an agreement signed by the governments of Canada, Mexico and the US, creating a trilateral trade bloc in the North America. The agreement came into force on 1 January 1994. Article 1709(3) provides: A Party may also exclude from patentability: (b) plants and animals other than microorganisms; and (c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production. Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.' See P.C.M. da Costa, NAFTA – The Canadian response or why does the Canadian Patent Act keep changing? (1994) 22 *AIPLA Quarterly Journal*, 66.

[82] *Pioneer Hi-Bred*, n 54 above, 6.

[83] ibid. 11-12.

decide on the unpatentability of the new soybean variety based on the processes involved,[84] the distinction could have been part of the reasons for the refusal. In contrast, the process to obtain the Harvard Mouse explicitly involved the processes described in the second category. Consequently, for the majority in the *Harvard Mouse* to refuse patent protection to the transgenic mouse is anomalous.

Related to this, the majority[85] in its judgement also commented on the Federal Court of Appeal which argued that 'the language of patent law is to be given wide scope as the inventions are necessarily unanticipated and unforeseeable'.[86] Nevertheless, this has been countered by an argument of the majority[87] that while 'Parliament would not have foreseen the genetically engineered mouse and the modern genetic engineering process to produce it, the legislature was well aware of the animal husbandry or breeding which similarly produces animals with a new or several new features'.[88] The Supreme Court further observed, that 'Parliament chose to define the categories of invention using language that does not, in common usage, refer to higher life forms'.[89] There is no clarification as to what the Court meant by 'animals with a new or several new features'. Bearing in mind that the Canadian Patent Act 1985 was passed in the 19th century when the second type of genetic engineering (as categorised by the *Pioneer Hi-Bred* case) was unknown, it is only possible to conclude that the 'new features' referred to by the Court are the result of genetic enhancement through traditional cross-breeding. Therefore, the reason why Parliament did not explicitly include the resulting animals under the Act is obvious - being the product of traditional cross-breeding,

---

84 Rather, the plants were decided to be unpatentable due to the issue of insufficiency of disclosure, ibid. 13.
85 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 164.
86 ibid.
87 ibid.
88 ibid.
89 ibid. Similar argument has been made by Marceau J in the case of *Pioneer Hi-Bred*. In interpreting the limited intention of Parliament he argued that in view of the well established plant breeding when the Patent Act was passed, had the legislature intended to include plants within the Act, the words 'strain', 'variety' or 'hybrid' should have appeared in the Patent Act.

they will eventually fail the qualification requirement under patent law. For this reason, it is more probable that the definition of the term 'invention' has been intentionally left open by the Canadian legislature to allow the Court to interpret the patentability of a subject matter accordingly, based on relevant legal principles as technology develops.

Fourthly, one of the arguments of the majority[90] was that the current form of the Canadian Patent Act 1985 is unprepared to cover animal inventions, and thus necessary protection should come from special legislation.[91] The argument is underpinned by the passage of the Plant Breeders' Rights Act 1990[92] (subsequent to *Pioneer Hi-Bred*) which grants *sui generis* rights to plants that fulfil the requirements of the UPOV Convention.[93] The majority[94] further contended that this development showed that the Canadian Patent Act 1985 was not tailored to protect plants due to their unique characteristics.[95] Eventually, the majority[96] averred that if Parliament intends to include animal inventions in the realm of the patent system it has to make this explicit by two options: (1) introducing a separate Act which would be more suitable to the complex nature of living and sentient beings; or (2) amending the current Canadian Patent Act 1985.[97]

It is argued that, while the proposed methods of implementation are in accordance with the procedural legal requirements, the refusal of the majority to allow patent to the *Harvard Mouse* based on the development of *sui generis* protection for plant varieties, shows a lack of legal reasoning. The majority should have been able to appreciate that when they formed

---

90 ibid. paragraph 192.
91 ibid.
92 Available at: WIPO, http://www.wipo.int/wipolex/en/text.jsp?file_id=207967 (Accessed: 29 November 2011).
93 That has been argued as a response of Parliament to the refusal of the Supreme Court to allow patent protection to a variety of plant in the case of *Pioneer Hi-Bred*.
94 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 188.
95 ibid.
96 ibid. paragraph 189.
97 ibid.

their decision, there was not yet any legal development toward the establishment of a *sui generis* system of protection for animal inventions in Canada.[98] Although the two options are available to the Canadian Parliament, it is not obliged to adopt them.[99] As identified by the appellant in the *Harvard Mouse*, Parliament has not made any move toward either of the options.[100] Notably, this has been the position so far in Canada.

Nevertheless, the decision of the majority to refuse patent protection to the Harvard Mouse because Parliament has not given its express 'blessing', cannot be said to be anomalous as it corresponds with the principle of separation of power between legislature and judiciary.[101] This principle requires that judicial authorities merely interpret and apply the law without interfering with policy decisions which fall within the responsibility of the legislature.[102] In fact, the majority[103] and the minority[104] had constantly reminded themselves of this judicial function in their decision. At this juncture, it is also important to note that the Canadian Biotechnology Advisory Committee (CBAC)[105] had earlier recommended to the Canadian Government two things: (1) that higher life forms (including animal inventions) which meet the patent qualification criteria should be patentable; and (2) so as to safeguard the public interest, three aspects should be included in the Canadian Patent Act 1985: farmers' privilege, innocent bystanders, and research and experimental use.[106]

---

98 This is one of the reasons which motivate the EPO to allow patent protection to the Harvard Mouse. See discussion in section 3.3 of chapter 4.

99 N. Siebrasse, n 63 above, 6.

100 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 189.

101 K. Kanani, Transgenic animal patents: The Harvard mouse on the Canadian frontier (2002) *Canadian Intellectual Property Review*, 555. The author addresses this approach as judicial minimalism, the problem of which, while the court settles cases before it, it leaves many things undecided, thus inviting Parliament to deal with the relevant issue through public debate.

102 ibid.

103 *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 150.

104 ibid. paragraph 1(iii).

105 The CBAC is a special committee appointed to advise the Government of Canada on issues relating to biotechnology. See CBAC, Patenting of higher life forms and related issues: report to the Government of Canada Biotechnology Ministerial Coordinating Committee, June 2002, x.

106 ibid. As regards 'farmer's privilege', the report recommended that 'farmers are permitted to breed patented animals, as long as the progeny are not sold as commercial propagating material or in a manner that

The majority[107] was well aware of these recommendations while deciding the *Harvard Mouse* case. However, in view of the complexity of the three aspects involved in the second recommendation, and also of concern about the patentability of human life,[108] all of which require public debate, the majority (as the decision is explicit) chose to leave the issue for Parliament to decide. The majority's 'dormant' reaction to the CBAC recommendation is not unusual as it has no binding effect on the Court.[109] In fact, a similar situation is observed where the opinion of the European Group on Ethics in Science and New Technologies (EGE) that embryonic stem cell lines are patentable (if modified to allow a specific industrial application and that the modification process is also patentable) was refused by the OD in the case of *Edinburgh Patent case*.[110] Nevertheless, refusing legal protection to the transgenic mouse, in the absence of special legislation dealing with animal inventions, is not a neutral act. Granting a patent to the transgenic mouse is a more neutral act as the Supreme Court did not raise any question about its ability to fulfil the patent qualification criteria. In this way, the technology will be retained for Parliament to consider before it becomes marketable.

---

undermines the commercial value to its creator of a genetically engineered animals'. 'Innocent bystander' means 'the potential liability of farmers who discover genetically modified biological material in their land'. The report recommended that innocent bystanders are protected from claims of patent infringement with respect to 'adventitious insemination of an animal by a patented animal'. The issue of innocent bystander will be further dealt with in sub-section 3.2 below. As regards 'research and experimental use', the report recommended that for private and non-commercial use, and study, of a patented product or process be protected from infringement claims.

[107] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraphs 169-183.

[108] This issue is beyond the scope of this thesis.

[109] M. Perry, Life forms patents: the high and the low (2004) 1 *Journal of International Biotechnology Law*, 22.

[110] European patent (EP) no 0695351. For instance, the role of the opinion by the EGE on the governance of commercial cord blood banking has been studied recently. It was concluded that the expert bioethics advisory body has played an important function in influencing policies relating to the matter. Their opinion has been included in policies and guidelines issued by such bodies as the national ethics committees of some EU Member States. However, among other issues, it was identified that the body's working methods failed to involve public participation which is one of the pertinent aspects in the decision of the EU policy. See A. Mohr, H. Busby, T. Hervey, and R. Dingwall, Mapping the role of official bioethics advice in the governance of biotechnologies in the EU: the European Group on Ethics opinion on commercial cord blood banking (2012) 39 *Science and Public Policy*, 105-117.

Finally, one of the implications of the majority's argument is that it requires the Canadian Patent Act 1985 to be amended as technology develops. Arguably this would impose an unnecessary burden on the legislature as technology advances so rapidly.[111] It has been contended[112] that this is not how technology-specific regulation is introduced in any area such as nuclear power or firearms.[113] Other than that, the argument of the majority can be read as requiring the law to precede the technology.[114] This is detrimental to the development of the latter as it would not be possible for law to evolve at, or faster than, the pace of technology.[115] In this regard, the minority's[116] argument that specific indication from Parliament to include inventions involving living organisms within the Canadian Patent Act 1985 was not necessary since the term 'invention' is broad enough to cover unanticipated inventions (including higher life forms), is more reasonable. Intrinsically, this can be supported by the phrase 'any new and useful' preceding the five categories of inventions in s2.

3.1.2 The non-qualification of a GM animal as an 'invention' under any of the categories under s2 of the Canadian Patent Act 1985

Both the majority and minority in the *Harvard Mouse* argued that the transgenic mouse could only potentially come into the categories of 'manufacture' or 'composition of matter' under s2. Thus, the reasoning rendered by the Court focussed on these two categories. This contention is arguable as it is clear from the wording of s2 that an animal invention can come within any of the five categories for it to constitute an 'invention'. For this reason, the

[111] J.D. Morrow, n 68 above, ibid.
[112] N. Siebrasse, n 63 above, 6.
[113] ibid.
[114] ibid.
[115] ibid.
[116] ibid.; *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 1 (iii).

following analysis considers the potential of the transgenic mouse to fall within any of the categories.

As the majority did not consider the terms 'art', 'process' and 'machine' in their judgement, the analysis looks into the meaning of the terms discussed elsewhere. The term 'art' has been construed as 'a mode, or method, or manner of accomplishing a certain result as distinct from the result'[117] whereas the term 'process' means 'a mode, method or operation, by which a result or effect is produced by chemical action, by the operation or application of some element or power of nature or of one substance to another.'[118] While these constructions align the term 'art' with the term 'process', it has been emphasised[119] that the former term is 'broader than (but embraces) the latter'.[120]

The term 'art' was given an even broader meaning by the Canadian Supreme Court itself, in a leading case prior to the *Harvard Mouse*, where the meaning of the term 'invention' was in question.[121] In the case of *Shell Oil Company v The Commissioner of Patents,*[122] the appellant claimed patents to the discovery of a new use for chemical compounds which he patented earlier. In other words, the claim was for a new use of an old compound. In interpreting the term 'invention' broadly, Wilson J stated:

> [w]hat then is the 'invention' under section 2? I believe it is the application of this new knowledge to effect a desired result which has an undisputed commercial value and that it falls within the words 'any new and useful art. I think *the word 'art'* in the context of the definition *must be given its general connotation of*

[117] H.G. Fox, *The Canadian patent law and practice relating to letters patent for inventions* (Toronto: Carswell Co, 1969) 16-17.
[118] ibid.
[119] ibid.
[120] ibid.
[121] N. Siebrasse, n 63 above, 10.
[122] [1982] 2 SCR 536.

> *'learning' or 'knowledge'* as commonly used in expressions such as 'the state of the art' or 'the prior art'.[123] (emphasis added)

The Court[124] decided the new use is patentable because the appellant's new discovery amounted to 'new and useful art' for adding new knowledge of the compound which was not known before. While the claims were being opposed for failing the condition of inventive step,[125] the approach adopted by the Court demonstrates the understanding of judicial authorities (long before the *Harvard Mouse*) of the importance of patent protection so as to acknowledge the contribution of inventors to the promotion of innovation.

Arguably the Harvard Mouse can be covered by the term 'art' if the majority appreciates the value it contributes to knowledge. Intrinsically, inventions (such as the Harvard Mouse) bring with them a breakthrough of knowledge. It should be reiterated that the novelty, inventiveness and industrial applicability of the transgenic mouse was not disputed by the majority.[126] This demonstrates an acknowledgement of additional new and useful information to the field of invention. In this respect, it has been argued by critics[127] that the Court has a legal duty to 'fit the subject matter within the definition of invention by breathing life into the bare and sometimes dated, words of patent statutes.'[128] It has also been identified[129] that the exclusion of animal inventions from protection under the Canadian patent law is judicially created.[130] Therefore, in order to give effect to the purpose of patent law which includes the promotion or disclosure of information and investments, the court has

[123] ibid. 549.
[124] ibid.
[125] ibid. 539.
[126] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 203.
[127] E.A. Crowne-Mohammed, Can you patent that? a review of subject matter eligibility in Canada and the United States (2009) *Temple International and Comparative Law Journal*, 269.
[128] ibid.
[129] ibid.; N. Siebrasse, n 63 above, 9-10.
[130] N. Siebrasse, ibid.

to construe the exclusion 'narrowly and strictly'.[131] Otherwise the progress of innovation is 'foreclosed *ab initio'*.[132] The majority in the *Harvard Mouse* failed to consider the ability of the transgenic mouse to constitute an invention under the term 'art' (which the same court found to be broad enough to be construed as 'learning' or 'knowledge'). This inevitably demonstrates the failure of the majority in the *Harvard Mouse* to appreciate the function and uphold the purpose, of patent law. As regards the process of creating the transgenic mouse, it easily falls under the term 'process', or 'art' (as defined above), and hence is expected to be allowed by the CIPO patent examiner in the first instance of the application.

Moving on to the term 'machine', it has been defined as 'the embodiment in mechanism of any function or mode of operation designed to accomplish a particular effect.'[133] It includes 'every mechanical device or combination of mechanical powers and devices that perform some function and produce a new result'.[134] This meaning apparently covers inanimate inventions which are mechanical in nature, and therefore, it is appropriate for the majority not to consider how the transgenic mouse could fall under the term.

As regards the term 'manufacture', three definitions had been referred to by the majority in the *Harvard Mouse*:

(1) The term is defined by the Oxford English Dictionary as:

> [t]he action or process of making by hand… The action or process of making articles or material (in modern use, on a large scale) by the application of physical labour or mechanical power.

[131] E.A. Crowne-Mohammed, n 127 above, 269.
[132] ibid. *'Ab initio'* is a Latin expression which means: 'from the beginning'. See http://www.thefreedictionary.com/ab+initio (Accessed: 30 May 2012).
[133] H.G. Fox, n 117 above, 17.
[134] ibid.

(2) The *Le Grand Robert de la langue francaise* defines the term 'fabrication' as:

> [Translation] Art or action of manufacturing … The manufacture of a technical object (by someone). Manufacturing by artisans, by hand, by machine, industrially, by mass production…

(3) In the *Chakrabarty's* case the term was defined as:

> [t]he production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labour or by machinery.[135]

Based on these definitions, the majority[136] concluded that 'the term was commonly understood to denote a non-living mechanistic product or process, and that in its vernacular sense the term does not include animal inventions'.[137]

The argument demonstrates the majority's stance that patent protection could only be considered for chemical, mechanical and technical inventions. This is inconsistent with the ethos of a patent, which is a commercial tool designed to reward an inventor for creating any invention (which meets the required criteria) for the benefit of the public. Further, looking closely at the definitions of 'manufacture' referred to by the majority, arguably their conclusion has not been precisely achieved. The definitions taken together require three things: (1) the process to produce the relevant object should be by hand or the application of physical labour or mechanical power; (2) the process should produce a technical object; and (3) the object should be produced from raw or prepared materials which have been given new forms, qualities, properties or combinations of these. It is argued that the transgenic mouse had fulfilled these elements; it has been produced by human intervention when the onco-gene was injected into its genome, resulting in a mouse which is predisposed to develop cancer, thus making it useful in cancer research.

---

[135] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 159.
[136] ibid.
[137] ibid.

The assessment based on the vernacular meaning of the term demonstrates the Court's literal interpretation. While this approach accords with the established rule of statutory construction, arguably it was not appropriately exercised by looking at the subject matter and modern genetic engineering technology, which is at issue. Additionally, it is difficult to appreciate the contradicting views of the majority when two facts had been explicitly recognised in their decision: (1) that the term 'manufacture' may be considered to have a very broad meaning; and (2) that the mouse may be considered as a 'manufacture' in an industrial setting.[138]

With respect to the phrase 'composition of matter', the majority[139] argued that the definition of: '… all compositions of two or more substances and … all composite articles', as adopted in the *Chakrabarty* case and by the majority in the Federal Court of Appeal, was too broad and would cause redundancy to the words 'machine' and 'manufacture' which also appear in s2.[140] Therefore, the majority argued that the phrase 'composition of matter' must be limited in some way, and does not include animal inventions such as the transgenic mouse.[141] The majority supported their contention with the principle of statutory interpretation where they concluded that the five terms: art, process, machine, manufacture, and composition of matter, if read collectively, should be restricted to the same genus.[142] The majority was of the view that animal inventions could not fall within any of the five categories, because the terms 'machine' and 'manufacture' do not imply a conscious, sentient living matter. Consequently, the category of 'composition of matter' did not cover the transgenic mouse.[143]

---

[138] ibid.
[139] ibid. paragraph 160.
[140] ibid.
[141] ibid.
[142] ibid. paragraph 161. The term 'genus' is used herewith the meaning 'of the same kind'. It does not mean one of the taxonomic classifications of biological materials which is the context used in the analysis in sub-section 3.2 of chapter 4. Under the rule of statutory construction known as 'the *ejusdem generis* rule', general words following particular and specific words are to be construed as confined to things of the same kind. See S.G.G. Edgar, *Craies on statute law* (London: Sweet and Maxwell, 1971) 177-189; R. Cross, *Statutory interpretati*on (London: Butterworths, 1995) 135-137.
[143] ibid.

The reasoning of the majority for the redundancy of the relevant categories and necessary restriction to the same genus is debatable for three reasons. Firstly, patent legislation is designed to be as broad as possible precisely because it is meant to catch inventions which could not be conceived of when the legislation was put in place. This is what makes patent legislation so different from any other type of law where it must regulate what cannot been thought of. Consequently, all scientific, engineering, and other advances must fall within one category or another because the provision is designed to describe all possible advances. Exclusion thereafter relies upon compliance with the patent qualification criteria. In other words, it is not justifiable to simply exclude innovation on the basis that it is not a form of advancement that the law protects. Secondly, the fact that there may be an overlap between the categories does not warrant an argument that a particular category should be understood in a restrictive way. It is difficult to appreciate that an invention which may fall into more than one category is legally penalised as there is no condition to this effect in the Canadian Patent Act 1985. Thirdly, the argument that because the terms 'machine' or 'manufacture' do not imply living matter, the category of 'composition of matter' should not cover a genetically engineered mouse is problematic. This is because it amounts to suggesting that all the terms should cover the same type of inventions. Arguably it undermines the need and importance of each category under s2.

Another pertinent issue which led to the majority's conclusion that the transgenic mouse was not qualified as 'composition of matter' arises from the decision of the Commissioner of Patents who separated the relevant product patents claim into two phases: (1) the preparation of the genetically altered egg; and (2) the development of the embryo in the host mother's

womb.[144] The Commissioner held the embryo to be patentable as the inventor had full control over the production, whereas, the transgenic mouse (the end product) was unpatentable because laws of nature took control. Underpinning the distinction was the idea that the inventor could only consistently reproduce the result of the first, but not the second, phase.[145] On appeal, the majority[146] in the Supreme Court referred to two sources for the definitions of the terms 'composition' and 'matter', to determine whether or not the transgenic mouse could come within the meaning of 'composition of matter'.

According to the Oxford English Dictionary:

> 'composition' means:
>
> [a] substance or preparation formed by combination or mixture of various ingredients; and
>
> 'Matter' means:
>
> [p]hysical or corporeal substance in general... contradistinguishing from immaterial or incorporeal substance (spirit, soul, mind), and from qualities, actions, or conditions.

In addition, the *Le Grand Robert de la langue francaise* defines :

> 'Composition' as:
>
> [a]ction or manner of forming a whole, a set by assembling several parts, several elements; and
>
> 'Matiére' (matter) as:
>
> [Translation] corporeal substance that is perceptible in space and has mechanical mass.[147]

[144] ibid. paragraph 130.
[145] ibid.
[146] ibid. paragraph 159.
[147] ibid.

Based on the definitions, the majority held that the genetically altered egg would satisfy the definition, but the transgenic mouse fails to be covered.[148] As regards the former, the majority[149] contended that human intervention (through the injecting process) has a direct effect on the egg, making it susceptible to cancer, and thus warranted its patentability. Conversely, the transgenic mouse was unpatentable because the process for the creation of the transgenic mouse involved a complex process of the laws of nature where human intervention is no longer required to obtain it.[150] The decision confirmed the Commissioner of Patents' findings. Notably, the majority[151] asserted that while 'the body of the mouse is composed of various ingredients or substances, it does not consist of ingredients or substances that have been combined or mixed together by a person'.

Although the majority's decision was based on appropriate sources, the wrong decision appears to have been reached for a number of reasons. Firstly, it is reasonable that dictionaries or linguistic sources give definitions which are broad. It is the duty of the court to fit the definitions to the issue at hand. The majority's focus on the requirement that the end product 'should be combined or mixed together by a person' demonstrates that the Court's assessment is addressed to subject matter which is chemical, technical and mechanical in nature. Literal application of the definitions to the transgenic animal, with novel characteristics obtained through genetic engineering technique, is inappropriate. This is because it would be impossible for the transgenic mouse (or even any animal inventions) to have been obtained through combining or mixing of ingredients or substances in the way chemical, technical and mechanical products are produced. In the context of the transgenic mouse, it is argued that the focus of the majority should address a broader meaning that can

[148] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 162.
[149] ibid.
[150] ibid.
[151] ibid.

be achieved from the definitions, such as: a physical matter composed of characteristics which are obtained through human effort or technical process. If this more general meaning had been the basis of the Court's decision, it can be surmised that the transgenic mouse could constitute a 'composition of matter' because it is comprised of the novel trait which was developed through human effort and ingenuity.

Secondly, the dividing line between the patentable genetically altered egg, but unpatentable end result, is problematic. It is important to be reminded that in the *Harvard Mouse* the alteration to the mouse's genome was made no later than its 8-cell stage. This is a very early stage of cell division where subsequent cells which develop from the egg (and ultimately form the transgenic mouse) would contain the inserted onco-gene. In other words, the composition of the egg and the mouse (in terms of the novel traits) is the same. The assessment of the majority of the Federal Court of Appeal was that the 'onco-gene and the fertilised mouse egg are forms of biological matter, which, when combined, constitute a 'composition of matter'. When this matter is transferred to the host mother, it produces the transgenic mouse. That these constituents remain a 'composition of matter' within the transgenic mouse, and are thus patentable',[152] appears a convincing argument. Consequently, if the majority held that the inventor has full control over the production of the egg, it would only be reasonable if they decided that the transgenic mouse is patentable due to the biological cycle of life involved.[153]

The fact that the laws of nature are involved in the second phase should not warrant the refusal of a patent to the end result. The reasoning of the majority appears inconsistent with its own decision to hold the genetically altered egg as patentable. This is because, once the

[152] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 137.
[153] N. Siebrasse, n 63 above, 12.

onco-gene is inserted, the egg will further develop to other stages through the biological process of cell division which is also outside the control of the inventor.[154] In addition, the distinction made by the majority leads to another difficult question of: where would the validity of patent protection of the genetically altered egg cease to take effect? Arguably this is a difficult issue which the majority itself failed to address and unnecessarily blurred the distinction of the subject matter protected.[155] Another issue is that the transgenic mouse is the product of a process (the microbiological process) which the majority agreed as patentable. This reiterates the requirement under Article 27.3(b) of the TRIPs Agreement where the resulting product is to be patentable. While the patent law in Canada relies on the broad meaning of 'invention' to determine the patentability of animal inventions (rather than adopting the wording of Article 27.3(b)), arguably the majority must give effect to the key principle underlined by the TRIPs Agreement.

One of the arguments of the Trial Division of the Federal Court[156] against the claims for the Harvard Mouse was the failure of the inventors to control other characteristics of the transgenic mouse including the length of a tail, colour of eyes and texture of fur.[157] In essence, it was averred that the inventors failed the reproducibility test to produce uniform products. This is because, unlike the creation of chemical products where the process involved and resulting products are known and constant, the creation of transgenic animals relies on

[154] The majority in the case of *Percy Schmeiser* made a specific observation of the fact that many inventions make use of natural processes in order to work, by citing with favour the case of *Abitibi* in which the modified yeast culture (which it held to be patentable) utilised its natural operation to purify waste from pulp plants. See *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraphs 88 to 91.

[155] A.D. Morrow and C.B. Ingram, Of transgenic mice and roundup ready canola: the decisions of the Supreme Court of Canada in *Harvard College v Canada* and *Monsanto v Schmeiser* (2005) 38 *University of British Colombia Law Review*, 1, 211; M. Perry, From Pasteur to *Monsanto*: approaches to patenting life in Canada in Y. Gendreau (ed), *An emerging intellectual property paradigm: perspective from Canada* (Edward Elgar: 2008) 79.

[156] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 138.

[157] ibid.

unknown and uncertain factors.[158] It is pertinent to note that the requirement of reproducibility (enablement) under patent law originates from the principle that an invention is to be sufficiently disclosed for a person skilled in the art to obtain the invention where the described methods are repeated.[159] The principle aims at ensuring that an inventor is commercially rewarded only for the disclosed information which is useful and would work to achieve the relevant invention. The robustness of scientific advances relies on this requirement as a crucial justifying factor for the monopoly.[160] There is little doubt that the genetic engineering process is not able to produce animal inventions of uniform character as chemical products are produced. Nor is this requirement of the principle of reproducibility applicable to living matter. The crux of the patent's claim for the Harvard Mouse arises from the novel traits that it has, namely the susceptibility to develop cancer. In other words, the disclosed processes did not promise the attainment of mice with the same length of a tail, colour of eyes and texture of fur. Therefore, provided that the relevant characteristic is achieved from the disclosed process, the reproducibility criterion can be deemed to have been fulfilled.[161]

While the issue of the patentability of lower life forms was not before the Supreme Court in the *Harvard Mouse*, the respondents had questioned the justifiability for the CIPO and courts in Canada of allowing patents to lower life forms, but not to higher life forms. The terms 'lower life forms' and 'higher life forms' are not defined in the Canadian Patent Act 1985. Nevertheless, two sources specify what is covered by each term. According to the Canadian

[158] ibid. paragraph 133.
[159] Section 27.1 of the Canadian Patent Act 1985; S.J.R. Bostyn, A European perspective on the ideal scope of protection and disclosure requirement for biotechnological inventions in a harmonised patent system: the quest for the holy grail? (2002) *The Journal of World Intellectual Property*, 1017.
[160] ibid.
[161] Rothstein JA in the Federal court of Appeal (majority) decision argued that the inability of the inventor to control other named characteristics was irrelevant to the patentability of the transgenic mouse, and otherwise highlighted that the sufficiency of disclosure was not an issue in the *Harvard Mouse*. *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 139.

Manual of Patent Office Practice,[162] 'higher life forms' cover 'animals, plants, seeds, mushrooms, fertilised eggs and totipotent stem cells', whereas 'lower life forms' include microscopic algae, unicellular fungi (including moulds and yeasts), bacteria, protozoa, viruses, transformed cell lines, hybridomas and embryonic pluripotent and multipotent stem cells'.[163] The CBAC Report[164] defined the former term to include 'plants and animals (other than single-celled organisms)'.

The majority approved the distinction between 'lower life forms' and 'higher life forms' and their distinctive nature of patentability. In response to the arguments of the respondents, the majority[165] stated: 'it is easier to conceptualise a lower life form as a 'composition of matter' or 'manufacture' than it is to conceptualise a 'higher life form' in these terms'.[166] This statement is inconsistent with some principles in the case of *Abitibi*. In that case, the Patent Appeal Board[167] adopted the decision of the majority in the case of *Chakrabarty*, and held that a mixed yeast fungal culture (which was modified to digest and purify a certain waste product from pulp mills) is patentable.[168] The Appeal Board underlined an important principle, which was not refuted by the majority in the *Harvard Mouse*, hence arguably demonstrating the majority's approval of the same. The Appeal Board[169] stated:

> [i]ts decision will extend to micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced *en masse*[170] as chemical compounds are prepared, and are

[162] Paragraph 17.02.01a of the Manual of Patent Office Practice. Available at: CIPO, http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/vwapj/2009-01-01chapitre17-chapter17-eng.pdf/$file/2009-01-01chapitre17-chapter17-eng.pdf, (Accessed: 28 November 2011).
[163] ibid.
[164] CBAC, n 105 above, 6.
[165] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 201.
[166] ibid.
[167] *Re Application of Abitibi Co.* n 3 above.
[168] The patentability of micro-organisms has not been litigated in Canada since.
[169] *Re Application of Abitibi Co.*, n 3 above.
[170] A French term which means: 'in one group or body; all together'. See http://www.thefreedictionary.com/en+masse (Accessed: 30 May 2012).

> formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.[171]

While uncertain if its decision could be further extended to higher life forms due to their more complex nature, the Appeal Board acknowledged that the possibility of them being patentable could not be denied. This is provided that the uniformity of characteristics could be attained and the prerequisites of patent protection are met.[172]

In this respect, the majority[173] in the *Harvard Mouse* agreed with the view of the majority in the Federal Court of Appeal that the requirement of being new, useful and non-obvious is sufficiently met so long as the transgenic mouse contains the desired feature. In evidence, the majority stated that: 'If the onco-mouse contains the oncogene, it does not make any difference whether its fur is brown or grey'.[174] From this statement, it is possible to argue that the majority has accepted that the genetic engineering process (adopted to produce the transgenic mouse) is capable of producing results with uniform characteristics as underlined by the *Abitibi* case. Therefore, for the majority to: (1) differentiate between the ability of lower and higher life forms to come within the terms 'manufacture' or 'composition of matter'; and (2) argue that it is 'far easier to analogise a micro-organism to a chemical compound of another inanimate object than it is to analogise a plant or an animal to an inanimate object', is lack of legal reasoning and contradictory.[175]

---

[171] ibid.
[172] ibid.
[173] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 203.
[174] ibid.
[175] M. Perry, n 155 above, 76. Garland and Smordin argued that while the majority made some effort to justify the division between the lower life forms which are patentable and higher life forms which are unpatentable, they avoided placing a strict line between the two, leaving the task to the Patent Office. S.B. Garland and S. Smordin, The Harvard Mouse decision and its future implications (2003) 39 *Canadian Business Law Journal*, 2, 174.

This sub-section has challenged the decision of the majority of the Supreme Court. It has been shown that the decision to refuse a patent to the Harvard Mouse without express direction from Parliament, and the failure to decide that the animal is an 'invention', was achieved with a lack of legal reasoning. It has also been demonstrated that the transgenic mouse can constitute an 'invention' under the categories of 'art' or 'manufacture' or 'composition of matter' under s2 of the Canadian Patent Act 1985. More broadly, the analysis shows that the decision of the majority corresponds to the restrictive policy adopted by the Canadian Government in respect to animal biotechnology food (as identified in section 1).

In the next sub-section, the Supreme Court decision of *Percy Schmeiser* will be assessed. Central to this is an analysis of the *ratio* of the decision, so as to gauge its implications for animal inventions.[176] It will be argued that, *Percy Schmeiser* does not change the *Harvard Mouse*. Thus, animal inventions remain unpatentable. However, as transgenic animals can be protected through patents of genes and cells contained in the animals, the interests of inventors would be adequately protected. Nevertheless, in the instance where the genes and cells cannot be patented, the animals are not legally protected. In terms of the research questions, the discussion is important to facilitate an understanding of Canada's current legal approach to animal patenting.

[176] The relevance of the *ratio* to animal inventions is due to the broad consideration of the majority to the patentability of higher life forms in the *Harvard Mouse*, where the term 'higher life forms' has been accepted to cover animals and plants. See S.B. Garland et al, ibid. 173; A.D. Morrow et al, n 155 above, 217.

3.2 Animal patenting from Harvard Mouse to Percy Schmeiser: Status quo maintained or a wind of change?

It is necessary to consider the facts of the *Percy Schmeiser* case in some details. Monsanto is the patent holder of chimeric genes[177] which confer tolerance of glyphosate herbicides such as Roundup and plant cells containing those genes.[178] Monsanto's patents also contained claims to: (1) an expression vector;[179] (2) a plant transformation vector;[180] and (3) a method of regenerating a glyphosate-resistant plant.[181] Canola seed containing the patented gene and cell is marketed in Canada by Monsanto under the trade name 'Roundup Ready Canola'.[182] Schmeiser is a 'seed saver' where he routinely saves part of his canola harvest for planting in future seasons. He never purchased the plants or entered into a licence agreement with Monsanto to cultivate the plants.[183] As his usual practice, he used his 1996 canola seed to plant the 1997 crops. While Schmeiser was not a routine user of Roundup in his field, he used the herbicide in 1997 and discovered that about 60% of canola survived it.[184] He kept the seed, and used it to plant his entire (1030 acres) crop in 1998.[185] Through chemical tests of the crops in the same year, Monsanto discovered 95-98% of canola in Schmeiser's farm was Roundup Ready Canola.[186] Monsanto brought an action against Schmeiser for patent infringement. Schmeiser did not deny the presence of the Roundup Ready Canola but argued that he never intended to grow the plants.[187] He also contended that he is an innocent

[177] Means: 'a gene that does not exist in nature and is constructed from different species'. See *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraph 20.
[178] ibid. page 2.
[179] Means: 'a DNA molecule into which another DNA segment has been integrated so as to be useful as a research tool'. ibid. paragraph 20.
[180] Which is 'used to permanently insert a chimeric gene into a plant's own DNA'. ibid. 19.
[181] ibid. paragraph 20.
[182] ibid. page 2.
[183] Unlike other five farmers whose farms are adjacent to his farms. ibid. paragraph 60.
[184] ibid. paragraph 61.
[185] ibid. paragraph 87.
[186] ibid. paragraph 64.
[187] *Percy Schmeiser* [2001] FCT 256, n 55 above, paragraph 11.

bystander as the presence of the patented seed in his farms was due to various possible reasons (in 1996). This include cross-field breeding by wind or insects from adjacent farms (where Roundup Ready Canola was planted by farmers who were licensees to Monsanto), or seed blown from passing trucks, or dropping from farm equipment.[188]

Both the majority[189] and the minority[190] concurred that Monsanto's patents were valid. Therefore, one of the issues[191] before the Supreme Court was whether Schmeiser had infringed Monsanto's patent rights under s42 of the Canadian Patent Act 1985[192] through the 'use' of the patented genes and cells by planting the Roundup Ready Canola. Schmeiser's two main defences to the infringement claim were that: (1) the presence of Roundup Ready Canola in his crop was not intended;[193] and (2) he had not sprayed his crop with Roundup, thus the invention claimed was not 'used'.[194] In a 5-4 decision, the Supreme Court held that:

> [t]he appellants' saving and planting seed, then harvesting and selling plants that contained the patented cells and genes appears, on a common sense view, to constitute 'utilisation' of the patented material for production and advantage, within the meaning of section 42 of the Patent Act.[195]

It was further held that: 'by cultivating a plant containing the patented gene and composed of the cells without licence, the appellants deprived the respondents of the full enjoyment of monopoly,'[196] thus infringed the patent rights of the latter.[197] The decision is dealt with more fully below.

---

188 ibid. paragraph 117.
189 *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraph 24.
190 ibid. paragraph 29 to 131.
191 Another issue being the amount of damages to which the respondent was entitled to. ibid. paragraph 7.
192 Section 42 states: 'A patent grants to the patentee the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used.'
193 ibid. paragraph 49.
194 ibid. paragraph 81.
195 ibid. page 4.
196 ibid.
197 ibid. page 5.

While not the focus of this thesis, some discussion on how plants are protected in Canada would be useful in order to identify whether, other than patent protection, there is other protection for animal varieties and animal inventions in Canada. It is already identified that the Plant Breeders' Rights Act 1990 grants a *sui generis* protection to plant varieties which fulfil the requirements (of new, distinct, homogenous and stable) under the UPOV Convention. Intrinsically, the legislation does not protect plant inventions produced through genetic engineering as the Roundup Ready Canola. Equal Animal Breeders' Rights Act is not available in Canada. Therefore, as the *Harvard Mouse* decided that higher life forms are unpatentable, both animal varieties and animal inventions have no legal protection in Canada.[198]

In terms of animal inventions, critics[199] have asserted that the *Harvard Mouse* has left Canada at odds with its business counterparts, such as the US, Japan and Europe which allow patent protection to animal inventions. Intrinsically this is because inventors are not able to obtain the same protection in Canada. Nevertheless, it has also been pointed out[200] that the result of *Percy Schmeiser* is that 'the gap' between Canada and its trading partners mentioned here 'has been minimised'. Arguably, 'the minimisation of gap' as identified by the critics is reasonable only if one appreciates the issue in terms of practical protection to animal inventions *per se*, rather than legal protection. This contention is elaborated here.

[198] For a comparative analysis of protection of plants and plant variety rights in the US, Europe and Canada, see N. Siebrasse, Intellectual property protection for higher life forms: current law and policy (2010) 10 *The Integrated Assessment Journal*, 1, 23-39.

[199] A.D. Morrow et al, n 155 above, 189; K. Sechley, Schmeiser versus Monsanto (2004) 22 *Nature Biotechnology*, 7, 804; C.L. Tape and C.D.M. McCourt, Supreme Court kills Harvard's Mouse, 2003 *Bio Business*, 18.

[200] A.D. Morrow et al, ibid, 222.

The US and Japan recognise animal inventions as patentable subject matter. Therefore, strict comparison between the legal protection of animal inventions in Canada and these countries' will lead to the conclusion that the gap remains. In terms of Europe, animal inventions are patentable notwithstanding the exclusion of 'animal varieties' under Article 53(b) of the EPC. This is because (according to the *Onco-mouse II*) they are classified as sub-species which are not barred from the exclusionary provision.[201] Animal inventions do not have the privilege of being classified in this manner in Canada. Therefore, the assessment similarly refutes the suggestion of minimisation of the gap between the legal protection of animal inventions *per se* in Canada and Europe.

The combination of the *Harvard Mouse* and *Percy Schmeiser* has created a unique but puzzling principle of patent law relating to animal inventions.[202] This is because, while according to the former, animal inventions *per se* are unpatentable, the latter decided that patents to genes and cells give rights to the patentee to exclude others from dealing with the transgenic animals. One of the arguments of Schmeiser[203] was that by deciding infringement in favour of Monsanto, the Court implicitly decided that the plants are patentable subject matter. This, according to him, runs contrary to the decision in the *Harvard Mouse*.[204] Some critics[205] have also argued that the practical result of the Court's decision is that 'plants (and animals) are patentable in Canada provided the genes and cells are claimed.'[206] As these contentions revolve around the issue of the subject matter protected, it is important to assess the distinctive view of the minority and majority in *Percy Schmeiser*.

[201] See discussion in sub-sub-section 3.2.2 of chapter 4.
[202] K. Sechley, n 199 above, 804.
[203] *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraph 21.
[204] ibid.; W.A. Adams, Confronting the patentability line in biotechnological innovation: Monsanto Canada Inc v Schmeiser (2005) *Canadian Business Law Journal*, 294.
[205] N. Siebrasse, n 198 above, 27.
[206] ibid.

Monsanto only claims patents to the genes and cells. Upholding the *Harvard Mouse* decision, the minority gave a narrow construction to the claim which is 'solely for GM genes and cells in the laboratory prior to regeneration'.[207] Therefore, as the protection does not extend to the plants, the minority held the view that Schmieser's cultivation of the plants containing the patented gene and cell does not constitute an infringement.[208] Conversely, according to the majority, the purposeful construction of patent claims in the light of the disclosure and specification of the claim 'recognises that the invention will be practised in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory'.[209] The majority further states that: 'whether or not patent protection for the gene and cell extends to activities involving the plant is not relevant to the patent's validity'.[210] As to the right of the patentee to the effective control over the plant, the majority states: 'according to case law, it is no bar to a finding of infringement that the patented object or process is part of or composes a broader unpatented structure or process, provided the patented invention is significant or important to the defendant's activities that involve the unpatented structure.'[211]

Some arguments and conclusions can be made based on these opposing views. Firstly, the claims made in the *Harvard Mouse* and *Percy Schmeiser* are distinct. In the former, the claim was to the resulting mouse where the Court had to decide whether or not animal inventions *per se* are patentable. The Court answered this in the negative. In the latter, only genes and cells of the canola plants were subject to Monsanto's patent claims, hence, the issue of infringement of these patented materials. It is an accepted fact that higher life forms consist

[207] *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraph 139.
[208] ibid. paragraph 160.
[209] ibid. paragraph 19.
[210] ibid. paragraph 24.
[211] *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, page 4.

of cells. Thus, it is not surprising that critics[212] have argued that it is anomalous for the majority to decide that only cells are patentable subject matter. Nevertheless, as the patentability of plants *per se* was not in issue in *Percy Schmeiser*, the critics' suggestion that plants *per se* are patentable based on the *ratio* of the majority is arguable. This is because, intrinsically, infringement can only arise against valid patents (which are the genes and the cells).[213] The absence of a ruling on the patentability of plants *per se* in *Percy Schmeiser* renders the principle underlined by the *Harvard Mouse* as the law in Canada, namely that plant and animal inventions *per se* are unpatentable. Accordingly, an applicant is unable to claim patents to these inventions. Secondly, it is clear from Monsanto's claim that the genes and cells are to be used in the creation of glyphosate resistance plants.[214] Confining the subject matter of protection, which can be obtained by an inventor, to the patented genes and cells in a laboratory setting is problematic, as it fails to appreciate the intended function of the genes. Only a broad construction of the claims will meet the purpose of the invention. Consequently, the construction by the majority appears more reasonable in this respect.

In comparison with the European legal position, the principle underlined by *Percy Schmeiser* resembles Article 9 of the EU Biotechnology Directive which states:

> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.[215]

[212] N. Siebrasse, n 198 above, 12; E.A. Crowne-Mohammed, n 127 above, 294.
[213] Sections 54 and 55 of the Canadian Patent Act 1985.
[214] *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, paragraph 16-18.
[215] Article 5(1) states: The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. See also K. Sechley, n 199 above, 804.

This provision explicitly extends the protection of (for example) a patented cell which contains a gene to the product which contains the cell. Therefore, while animal inventions *per se* remain not legally protected by patents in Canada, *Percy Schmeiser* has brought Canada in line with Europe in terms of practical protection which may be obtained by an inventor. Eventually, as contended earlier, the gap between Canada and its other main trading countries (including Europe) is practically minimised.

The *Percy Schmeiser* decision notably defines what has been characterised as the 'innocent bystander' issue. In this regard, the majority[216] underlined four important principles relating to infringement of patent rights. Firstly, possession of a patented object or an object incorporating a patented feature may constitute 'use' of the object and thus constitute infringement. Secondly, possession, at least in commercial circumstances, raises a rebuttable presumption of 'use'. Thirdly, while intention is generally irrelevant to determine the 'use' and hence, infringement, the absence of intention to employ or gain any advantage from the invention may be relevant to rebut the presumption of use raised by possession. Finally, a patentee cannot obtain any remedy against a non-benefitting infringer.[217] In the context of *Percy Schmeiser*, by saving, planting and selling canola seed which he knew or should have known to be Roundup Ready Canola,[218] Schmeiser was not an innocent bystander. Moreover, the Court found no evidence that Schmeiser had taken any action to remove the 'unwanted seed', once it was discovered in his farm, to rebut the presumption of use.[219] Thus, it is right for the Supreme Court to find infringement in favour of Monsanto. On appeal, the factor which 'saved' Schmeiser from having to pay the compensation due to Monsanto (as awarded

[216] *Percy Schmeiser* [2004] 1 SCR 902, n 55 above, page 4.
[217] ibid.
[218] ibid. paragraph 87.
[219] ibid.

by the trial Court)[220] was the fact that he was a non-benefitting infringer. The Supreme Court held that there must be a causal connection between the use of the invention and profits identified by the trial Court.[221] The Court found that the profits that Schmeiser made from his sale of the 1998 crops were the same as if he had planted and harvested ordinary canola. This is because, there was no evidence that he sprayed the crops with Roundup herbicide to reduce weed during that period.[222]

The *ratio* of *Percy Schmeiser* is applicable to animal inventions which are equally vulnerable of trans-boundary movement from one place to another (as plant inventions). Therefore, notwithstanding the puzzling decisions shown earlier, arguably the principles underlined by the case would sufficiently protect the interests of an inventor or patentee. In a simple illustration, a transgenic bull (containing patented genes which increase milk production, belonging to a patentee) may stray from a licensee's farm and mate with a non-transgenic cow from an adjacent farm, producing a transgenic offspring. Applying the *Percy Schmeiser* decision, the patentee will be entitled to protect his commercial interest against the innocent bystander, yet only if the infringer gains any monetary benefit from the use of the offspring. Otherwise, while infringement can be established, the patentee will not be able to obtain any remedy. In this regard, it appears that through the judgement, *Percy Schmesier* has preceded the Canadian Government in 'putting in place' the long-recommendation of the CBAC that a provision relating to an innocent bystander should be included in the Canadian Patent Act 1985.

Nevertheless, *Percy Schmeiser* is not without problems. The decision may create difficulties for a patentee to monitor and protect his commercial interests as in the case of trans-boundary

[220] ibid. paragraph 98.
[221] ibid. paragraph 104.
[222] ibid.

movement of animal inventions out of the jurisdiction where patents are granted. As already identified in chapter 1, movement of animal inventions may take place for various purposes. This includes the movement of transgenic animals for research purposes and from one country to another so as to catch up with a sudden decline of local livestock production due to disease.[223] Others include movement for marketing and slaughtering,[224] and livestock auction. In any of these instances a patentee would need to have detailed knowledge of the movement, as without it, he will not be able to enforce his commercial rights against the infringers. A similar implication arises in the case of change of ownership of the transgenic animals without the knowledge of the patentee. In this regard, it is important to note that (for example) while the DEFRA of UK[225] requires keepers of livestock to keep a record of the movement of livestock, there have been complaints[226] that the movement recording system for sheep is flawed. This includes the problem with data supplied by farmers to local authorities which are in-charge of uploading the data into the Animal Movement Licensing System (AMLS), where it took too long, or was no longer being uploaded.[227] This is because the process is done manually, causing extra work.[228] A more important ramification with the finding of infringement (instead of animal inventions *per se* are held to be patentable) will be where claims cannot be made for the genes and cells for lack of complying with the patent qualification criteria.[229] In this instance, inventors may feel insecure in developing animal inventions, and investors may refuse to invest in the Canadian animal biotechnology industry. This is because the inventions are at risk for being not legally protected.

---

[223] See discussion in sub-section 5.1 of chapter 1.
[224] FAO, Transport of livestock, http://www.fao.org/docrep/003/x6909e/x6909e08.htm (Accessed: 3 March 2012).
[225] DEFRA, Report of sheep and goat movement made under a general licence, http://www.defra.gov.uk/forms/2011/03/30/aml1-animal-move-licensing/ (Accessed: 3 March 2012).
[226] The Livestock Auctioneers Association Limited, Time for industry to act, http://www.laa.co.uk/news_details.php?RID=69 (Accessed: 3 March 2012).
[227] ibid.
[228] ibid.
[229] C.L.Tape et al, n 199 above, 18.

This section has shown that the restrictive approach to animal patenting adopted by the Supreme Court in the *Harvard Mouse* stands as the law in Canada. The latter decision of *Percy Schmeiser* held that patents to genes and cells contained in animal inventions confer legal rights to the patentee to control activities relating to the inventions. Nevertheless, it is not possible to conclude that there is a wind of change in the Canadian patent law in respect of the patent protection available for animal inventions *per se*. It is because they remain non-inventions, hence, unpatentable. The decision of the Supreme Court not to allow a patent to the Harvard Mouse is arguable because the term 'invention' under s2 of the Canadian Patent Act 1985 is broad enough to cover animal inventions as such. *Percy Schmeiser* may adequately protect a patentee's commercial interests through infringement of valid patents to genes and cells. However, the decision potentially deters inventors and investors from developing animal inventions in Canada, in particular where patent claims to genes and cells cannot be guaranteed.

The next section assesses the implications of Canada's restrictive approach on the livestock industry. Towards this end, the development of animal biotechnology applications in Canada is overviewed and put into context. It will be argued that the livestock industry will be adversely affected by the approach. The discussion is important to the research questions as it identifies two things: (1) the impact of the restrictive approach; and (2) the importance of patent protection, in view of a particular country's objective to meet the explosion of demand of animal-protein based food from the inhabitants.

4. The implications of Canada's restrictive approach on the livestock industry

Canada is one of the industrialised countries which has been actively pursuing its biotechnology sector.[230] According to the OECD, in 2005, Canada's total biotechnology R&D expenditure was US$1.4 billion, third after the US (US$25.1 billion) and Germany (US$2.35 billion).[231] Two of the sectors where biotechnology is actively applied in Canada are agriculture and aquaculture.[232] Among the OECD Member Countries, Canada has the highest share of biotechnology R&D investment (9%) of agricultural applications.[233] Agricultural biotechnology in Canada has been the focus of the province of Saskatchewan.[234] Within the Saskatoon Science City,[235] where the R&D activities on agricultural biotechnology are mostly located, molecular techniques have being applied and developed by genomics researchers. Nevertheless, it has been identified (in section 2) that the Canadian Government remained uncertain of the safety of animal biotechnology food, even after more than a decade of efforts to develop the assessment criteria for the products.[236] As a result, unlike plant biotechnology which has been the focus of the Canadian Government (with the aim to develop novel crops),[237] it is observed that less emphasis is given to the animal

[230] T. Munn-Venn and P. Mitchell, The Conference Board of Canada, Biotechnology in Canada: a technology platform for growth, Report December 2005, http://www.agwest.sk.ca/biotech/documents (Accessed: 19 December 2011).

[231] OECD, Biotechnology Statistics 2009, http://www.oecd.org/dataoecd/4/23/42833898.pdf (Accessed: 19 December 2011) 24.

[232] Other sectors include human health, food processing and environment. See T. Munn-Venn et al, n 230 above, 16-21.

[233] OECD, n 231 above, 58. Other OECD Member Countries are Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the UK, and the US.

[234] J. Niosi, n 8 above, 51; Ag-West Bio Incorporation, Saskatoon: Canada's science city, http://www.agwest.sk.ca/upload_mce_image/file/SaskatoonScienceCity.pdf (Accessed: 19 December 2011).

[235] Which is the host to the University of Saskatchewan and the Plant Biotechnology Institute of the National Research Council. Ag-West Bio Incorporation, ibid.

[236] See the wording of the Food Directorate Interim Policy on Foods from Cloned Animals in section 1.

[237] 'Novel crops' falls under the meaning of 'novel foods' which HC defines to include: (a) Foods resulting from a process not previously used for food; (b) Products that do not have a history of safe use as a food; and (c) Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods. See HC, Genetically modified (GM)

biotechnology industry.[238] In evidence, (for example) the R&D activities by Ag-West Biotech, a non-profit organisation funded by the province of Saskatchewan whose mandate is 'to initiate, promote and support the growth of the province's agriculture and biotechnology industry'[239] focus on plants, pharmaceutical, medical and therapeutic products.[240]

Yet it cannot be denied that there are some R&D activities relating to livestock animals which have been carried out in academic and government institutions in the country. Of note is the Enviropig, the GM pig which has been developed by the University of Guelph at Ontario. The pig produces the enzyme phytase in its saliva. When the pig consumes animal feed, the food mixes with the enzyme, which degrades the phytates which are otherwise not digestable in feed grains.[241] Other than that, the Fisheries and Oceans Canada (DFO)'s[242] transgenic fish research has produced GM salmon, the strain of which is used to obtain information on performance characteristics, fitness parameters and food safety characteristics. The information is utilised to assess the impact of transgenic fish on the environment and human health.[243] In addition, animal biotechnology R&D in the Saskatoon Science City focuses on: (1) the development of vaccines for livestock animals; (2) genetic services for

---

foods and other novel foods, http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php (Accessed: 9 March 2012).

238 There are ninety-six products of genetic modifications involving crops which have been approved for sale by HC, including GM corn, maize, soybean and tomato. See HC, Novel food regulation in Canada, http://www.ciphi.nl.ca/Novel%20Foods.pdf; HC, Food and nutrition: approved products, http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php (both Accessed: 19 December 2011). The products are altered to have useful agricultural benefits such as herbicide-resistance, insect-pest-resistance and slow ripening rate. In terms of the importance of GM crops to the Canadian economy, Canada was reported to have the highest agricultural sales (25% of total biotechnology sales) among the OECD countries in 2005. In 2008, the area planted with GM crops in the US and Canada accounted for 99.2% of the OECD countries. See OECD, n 231 above, 62 and 76.

239 J. Niosi, n 8 above, 51.

240 Ag-West Bio Incorporation, The path to success: 2010-2011 Annual report, http://www.agwest.sk.ca/upload_mce_image/file/AnnualReports/AWB2011AnnualReport-web.pdf (Accessed: 19 December 2011).

241 University of Guelph, Enviropig, http://www.uoguelph.ca/enviropig/index.shtml (Accessed: 19 December 2011).

242 The Canadian Government department which is responsible for maintaining sustainable fisheries and aquaculture. See DFO, http://www.dfo-mpo.gc.ca/about-notre-sujet-eng.htm (Accessed: 21 December 2011).

243 Government of Canada, Biotechnology transforming society: creating an innovative economy and a higher quality of life, http://www.bioportal.gc.ca/CMFiles/11865_CAN_BIO_REP_Ev949SFJ-922004-3421.pdf (Accessed: 21 December 2011).

pure-bred parentage certifications and genetic disease; (3) the development of DNA microsatellite markers for parentage testing of llamas, alpacas, elk, sheep, goats and swine; and (4) the use of both micro satellites and single nucleotide polymorphisms to assist the Canadian livestock industry to improve product lines and gain access to new markets.[244]

The use of the above biotechnology applications relating to livestock animals may demonstrate the commitment of the Canadian Government to develop its livestock industry in the light of the various factors which may easily influence sustainable production of livestock products. In this respect, it is worth noting that similar to the EU (and other countries worldwide), the Canadian livestock and fisheries industry was adversely affected by problems such as BSE and ISA.[245] Nevertheless, contrary conclusions can equally be made where the animal biotechnology applications (so far adopted by the country) are put into context. None is directed toward the addition of benefit to the food that the animal produces (such as leaner meat or high quality milk). A more fundamental challenge comes from the government policy itself (which explicitly restricts the development and marketing of animal biotechnology food) and the undeveloped regulatory framework. So far, no food from biotechnology-derived animals have been approved or authorised for sale in Canada.[246] This is not strange given that other countries around the globe (including the European countries) have not approved any such products. However, (for example) in Europe the absence of an explicit policy which restricts the development and marketing of products obtained from

[244] Ag-West Bio Incorporation, n 234 above.

[245] In early 2004, the total direct economic cost to the livestock industry (caused by the BSE) was reported to be CDN$6.3 billion. In addition, the disease had caused a CDN$2 billion loss in GDP and a $5.7 billion decline in total output of the Canadian economy. Statistics Canada, Canada's beef cattle sector and the impact of BSE on farm family income 2000-2003, http://publications.gc.ca/collections/Collection/Statcan/21-601-MIE/21-601-MIE2004069.pdf (Accessed: 28 December 2011) 4-5. As regards salmon, the production which peaked in 2002 (126,321 tonnes) has fallen drastically in 2003 (99,961 tonnes) due to an outbreak of ISA. While the production has been improving since 2005 (93,470 tonnes), the amount of production remained low up to 2008 (104,075). FAO, Regional review on status and trends in aquaculture development in North America: Canada and the United States of America – 2010, http://www.fao.org/docrep/014/i2163e/i2163e00.pdf (Accessed: 29 December 2011) 13-15.

[246] HC, n 238 above.

animal biotechnology allows active progression of R&D activities in the field. This is already evidenced where the growth of the animal biotechnology industry is supported by clear objectives and concerted regional strategies.[247] Moreover, two aspects will particularly support the marketing of the potential products in Europe: (1) the regulatory framework relating to the assessment and approval of novel foods derived from animal biotechnology which is already in place;[248] and (2) the EFSA repeated statements that meat and milk from cloned animals are just as safe for consumption as their traditionally bred counterparts.[249] In contrast, it is argued that the strict Canadian Government policy and undeveloped regulatory framework will hamper the investment which has been spent in animal biotechnology industry as the products are not marketable. Consequently, (for example) while an application for Enviropig to be approved for food products in Canada has been filed since 2009,[250] the chances of the products reaching the domestic market are negligible. This is because it is doubtful that the necessary guidelines for approval will be ready, at least not in the near future.

Moving on to the restrictive approach adopted by the Canadian Supreme Court, it pertinent to note that the *Harvard Mouse* decision produced divided criticisms. On the one hand, for stakeholders such as scientists, investors and biotechnology companies, the decision has failed to uphold what patent law is expected to do: (1) to protect intellectual efforts directed at the improvement of the quality of human life through science; (2) to allow biotechnology companies to recoup investments spent on the development of an invention; and (3) to generate a country's economic growth through domestic and international financial

[247] See discussion in section 4 of chapter 4.
[248] See details of the EU Regulations of GMOs in footnote 200 of chapter 4.
[249] ibid.
[250] University of Guelph, Enviropig: technology http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).

support. [251] In evidence, subsequent to the *Harvard Mouse*, there have been some biotechnological companies which asserted that they had had difficulty in raising funds abroad because investors were puzzled by the ruling.[252] On the other hand, while agreeing with the expected ramifications for the life-science research and biotechnology in Canada, some critics[253] are doubtful that the industry will be adversely affected by the *Harvard Mouse* decision. This is because Canada has not totally shut its door to allowing patent protection to inventions involving animals. This contention was supported by the fact that in the *Harvard Mouse*, claims other than the end product were allowed by the CIPO in the first instance.[254]

In order to assess the weight of these opposing arguments, it is useful to appreciate the importance of patent protection to the biotechnology industry. The Canadian biotechnology industry is made up of small biotechnology companies[255] and at the development stage.[256] Of the 470 biotechnology companies in 2007, approximately two-thirds have fewer than twenty employees, and one-third have fewer than five employees.[257] In a survey[258] involving the Canadian biotechnology companies, it has been identified that earlier (start ups) and later stage biotechnology companies have different priorities. Start ups companies are generating little of product-related revenues and are highly likely to focus on the domestic market.[259]

---

[251] Letter to Minister Rock, John Reid, President of the Canadian Advanced Technology Alliance to the Minister of Industry dated 9 December 2002, http://wwwcata.ca?Advocacy/Industry_Canada/MinRockHarMouse.html (Accessed: 4 January 2010); J.B. White, Higher life forms are not patentable in Canada – for now, http://www.osler.com/uploadedFiles/Resources/up-423.pdf, (Accessed: 4 January 2010); BIOTECanada, BIOTECanada responds to Supreme Court decision on Harvard Mouse case, http://www.community-online.com/communityarticle.cfm?ArticleID=494 (Accessed: 4 January 2010).

[252] Organic Consumers Association, Harvard Mouse patent denied in Canada: biotech industry hard hit http://www.purefood.org/Patent/041903_mouse_patent.cfm, (Accessed: 10 December 2011).

[253] E. Check, Canada stops Harvard's oncomouse in its tracks, 420 *Nature*, 593 (12 December 2002) http://www.nature.com/nature/journal/v420/n6916/full/420593b.html (Accessed: 4 January 2010).

[254] J.B. White, n 251 above.

[255] K. Sechley, n 199 above, 804.

[256] S. Vanderbyl and S. Kobelak, Critical success factors for biotechnology industry in Canada (2007) 13 *Journal of Commercial Biotechnology*, 68.

[257] Survey conducted by Ernst and Young. K. Sechley, n 199 above, 804.

[258] S. Vanderbyl et al, n 256 above, 68-77.

[259] ibid, 75; T. Munn-Venn et al, n 230 above, ii.

Consequently, these companies concentrate on funding aspects. Later stage companies which were equipped with internal resources converge on retaining and educating employees. Nevertheless, notably the survey found that irrespective of the diverse interests, the companies at both stages identified protection of patent rights as a key element for success in the biotechnology industry where the R&D is known to involve huge investments.[260] Start ups companies require huge investments to develop technology and secure intellectual property rights.[261] Yet the companies struggle to attract investors.[262]

The fact that some transgenic livestock animals have been developed and animal biotechnological applications are utilised in Canada will require patent law to support the development of the R&D activities which is intrinsically time-consuming and expensive.[263] For instance, the R&D on Enviropig has been carried out since 1995[264] with funding from various public and private institutions such as the Agriculture and Agri-food Canada, Ontario Ministry of Agriculture, Food and Rural Affairs, Natural Sciences and Engineering Research Council of Canada, Rural Economic Development Program of the Ontario Government and

[260] S. Vanderbyl et al, n 256 above, 75. See also P. Krisha et al, n 64 above, 197; T. Munn-Venn et al, n 230 above, 35.

[261] S. Vanderbyl et al, ibid. 68.

[262] T. Munn-Venn et al, n 230 above, iii. While the survey involves companies with a variety of interests such as an agricultural basis; diagnostics and health; and waste and the environment, arguably the findings similarly represent the requirements of animal biotechnology companies. This is because in Canada the companies are classified within the agricultural biotechnology sector. J. Niosi, n 8 above, 30. There were only 17.9% of agricultural biotechnology firms in 2003, second after the human health sector (52.7%). See T. Munn-Venn et al, n 230 above, 16. While no details are provided for the number of animal biotechnology companies, bearing in mind that plant biotechnology is Canada's main focus, it can be concluded that the number of animal biotechnology companies is negligible.

[263] Warren-Jones asserted that patent protection underwrites the innovative process. The importance of the protection lies in the exclusivity that it grants to an inventor which eventually ensures monopoly and confers marketability of an invention. The effect of this could be the relocation of an industry into a country which has a more friendly patent system than the other. Therefore, if the biotechnology industry is to be developed, 'each patent system is constrained at least to some degree to have in mind the global effect of decisions regarding granting protection'. A. Warren-Jones, Patenting DNA: a lot of controversy over a little intangibility (2004) 12, *Medical Law Review*, 1, 102.

[264] University of Guelph, Enviropig: history, http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).

Ontario Pork.[265] Joint funding of animal biotechnology R&D from public institutions and private companies as seen here is not exclusive to Canada. The same trend has been identified in Europe.[266] This is not unusual as it has been emphasised[267] that R&D involving the development of products of animal biotechnology cannot be left solely to public funding.[268] Two reasons which have been identified are: (1) public funding is often underfunded, intrinsically because there are many competing claims; and (2) private research is more directly market-based than public research.[269] Therefore, as private investments are also required if the pace of innovation is to accelerate, it has been contended that intellectual property protection is necessary.[270] In the light of these principles, the reaction of investors to the *Harvard Mouse* decision is not surprising.

While patents are territorial in nature (being limited to enforcement in the country of grant), the development of a technology often comes down to the broader regulatory environment. Nevertheless, critics[271] have contended that insufficient patent protection in Canada should not necessarily have an adverse effect on users' willingness to seek patents elsewhere. This is because there is a tendency for the Canadians to seek protection in the US because of its relative economic size and geographic proximity.[272] The lack of patent protection in a particular country should not be perceived in this way because most stakeholders agree that patent protection affects trade in most sectors.[273] Overly restrictive policies could result in an

[265] University of Guelph, Enviropig: financial contributors to Enviropig research, http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).
[266] See discussion in section 4 of chapter 4.
[267] N. Siebrasse, n 198 above, 33.
[268] ibid.
[269] ibid. 32.
[270] ibid. 34.
[271] See Answer of the Canadian Group of International Association for the Protection of Intellectual Property (AIPPI), https://www.aippi.org/download/commitees/180/QS180canada06.pdf (Accessed: 10 December 2011).
[272] ibid.
[273] T. Munn-Venn et al, n 230 above, 32.

outflow of both funds and expertise.[274] In the long term, the lack of patent protection would cause domestic biotechnology companies to suffer due to increased international competition for funding and human resource skills.[275] This could have a dampening effect on the R&D activities, [276] and, eventually, 'would leave the country behind in terms of global competitiveness in the effort to be an innovative jurisdiction'.[277] Arguably any country which lacks patent protection (such as Canada) cannot be immune to this effect.[278]

The contention that the *Harvard Mouse* adequately protects inventors' interest by allowing patents to other claims than the resulting animals *per se* is arguable. The granting of patent protection to the end product is important to secure an inventor's commercial interest from damage by competitors. This is because without any kind of protection to the end product, a competitor could simply buy, breed and commercialise a relevant animal invention[279] while leaving the inventor without any remedy. The decision of *Percy Schmeiser* has responded to the reaction of the stakeholders in this respect. Therefore, while animal inventions *per se* remain unpatentable in Canada, the extent of legal protection recognised by the Supreme Court through patents of genes and cells would benefit the animal biotechnology, and livestock, industry in Canada. Nevertheless, there is a possibility that patent claims to genes and cells cannot be made. In this instance, the decision not to allow a patent to animal inventions *per se* where they can: (1) fulfil the patent qualification criteria; and (2) come within the broad definition of the term 'invention' in s2 of the Canadian Patent Act 1985, will adversely affect the development of the livestock industry.

[274] ibid.; AIPPI, n 271 above.
[275] K. Sechley, n 199 above, 804.
[276] AIPPI, n 271 above.
[277] T. Munn-Venn et al, n 230 above, 32; BIOTECanada, n 251 above.
[278] AIPPI, n 271 above.
[279] *Harvard College v Canada (Commissioner of Patents)*, n 5 above, paragraph 139.

5. Conclusion

This chapter has shown how Canada deals with the issue of animal patenting in the absence of a statutory provision prohibiting the patentability of animal inventions under its patent law. Under s2 of the Canadian Patent Act 1985, 'any new and useful art, process, machine, manufacture or composition of matter' may constitute an 'invention'. The patentability of animal inventions is seemingly easier to achieve by these broad categories, compared to the specific exclusion of animal varieties under Article 53(b) of the EPC. Nevertheless, ironically, the Canadian Supreme Court in the precedent case of *Harvard Mouse*, has adopted a restrictive approach where the transgenic mouse (and animal inventions, generally) was held to be unpatentable subject matter. Two reasons underpinned this restrictive approach. Firstly, that the words and scheme of the current Canadian Patent Act 1985 do not reflect Parliament's intention to allow patent protection to animal inventions. Secondly, animal inventions fail to come within the meaning of the term 'manufacture' or 'composition of matter' under s2.

In order for the Supreme Court's decision to stand, the reasoning should be firmly defended according to patent law principles governing the patentability of animal inventions. Through various arguments, this chapter has shown that this, unfortunately, is not the case. Section 2 of the Canadian Patent Act 1985 is modelled from §101 35 USC. There is little doubt that it is not necessary that the interpretation of the provisions should reach the same conclusion. However, in the light of the alleged inexplicit direction from the Canadian Parliament on the patentability of animal inventions, the majority decision in the *Chakrabarty* case (which decided that living matter that fulfils patent prerequisites is an invention within the meaning of the term 'invention' under §101 35 USC) should have been the most persuasive for

adoption by the majority in the *Harvard Mouse*. From another perspective, Canada is a commonwealth country whose system of law is derived from English law. As the UK (being a Member State of the EPC) would adopt the permissive approach on animal patenting as decided by the EPO in the *Harvard/Onco-mouse* case, it is anomalous that the Canadian Supreme Court interpreted the term 'invention' narrowly and excluded animal inventions from the definition. Specifically, this chapter contends that the term 'invention' under s2 of the Canadian Patent Act 1985 is broad enough to cover animal inventions which are capable of qualifying as either 'manufacture' or 'composition of matter'. Underpinning this contention is their ability to fulfil the patent qualification criteria (which notably has not been refuted by the Supreme Court). In an alternative, while not at all considered by the Supreme Court, it has been shown that animal inventions could fall under the term 'art' under s2 which denotes an extensive meaning of 'learning' or 'knowledge'.

Article 27.3(b) of the TRIPs Agreement allows Signatories to exclude 'animals' and 'essentially biological processes' from the patent regime. Nevertheless, 'microbiological processes and products' derived from it are patentable. Underpinning this division is the aspiration of patent law to protect animal inventions which involve technical intervention and meet patent prerequisites. It aims at recognising the inventive effort of inventors in promoting innovation. Conversely, products of nature are to be left out of the regime due to the absence of human ingenuity. The European-wide permissive approach to animal patenting adopted through the case of *Harvard/Onco-mouse* gives effect to the patent law principles underlined by Article 27.3(b). In that, patent protection was allowed to the relevant transgenic mouse which was held not to be an animal variety. This chapter has shown that while Canada is also a Signatory to the TRIPs Agreement, the decision of the Supreme Court not to allow patent to the transgenic mouse (notwithstanding being able to fulfil the patentability criteria, and

qualify as a product of microbiological process) runs contrary to the requirement of Article 27.3(b). Eventually, Canada fails to meet its international obligations.

The restrictive approach to animal patenting adopted by the Canadian Supreme Court conforms to government policies. Politically, a strong view was raised during the Uruguay Round Meeting of the TRIPs Agreement that animal inventions should not be patentable. The pessimistic political view is consistent with the slow development of regulatory framework for the assessment and approval of animal biotechnology food which is underpinned by the Food Directorate Interim Policy on Foods from Cloned Animals. The Policy restricts the development and use of the food due to the absence of pre-market safety assessment of the products. To date, the assessment guidelines for novel animal food remained unavailable notwithstanding the long period and various seeming efforts undertaken by the government to develop the system and documentation. This reflects the government's lack of interest to promote the use and marketing of the products. Consumers' negative perspective towards animal biotechnology food has been identified as playing a major role in the strict policy adopted by the government. This scenario in Canada is immensely different from the position in Europe where the progression of the animal biotechnology sector and the potential marketing of livestock products derived from it is supported by many aspects. The absence of any restriction allows active R&D activities (including genomics research to improve the quantity and quality of livestock products) with huge investment from the EU, public institutions and private companies. In addition, the availability of pre-market safety assessment facilitates the marketing of the potential products. Of equal importance, the decision of the EPO to allow patent protection to animal inventions will enhance innovation and investment in the sector. As regards public opinion, it is widely accepted that it is pertinent in policy-making decision. However, in terms of whether or not animal

biotechnology applications are to be utilised in full for the creation of animal biotechnology food so as to ensure sustainable production of livestock products for the population, the European-wide permissive approach rightly demonstrates that the opinion should not be the decisive factor. Rather, the decision is to be grounded on the myriad of challenges underpinning the problem to secure the food supply, which eventually necessitates the technology's intensive use.

The *Harvard Mouse* decision has raised divided responses from stakeholders of the Canadian biotechnology industry. On the one hand, for the proponents of patent, the decision would have a chilling effect on the development of the industry, in particular the R&D activities. On the other hand, there have been arguments that the decision would not adversely affect the industry as sufficient patent protection could be secured by inventors. This is because, claims other than the end product (the transgenic mouse) have been allowed. In this regard, *Percy Schmeiser* appears to be a quick legal response to the criticisms against the *Harvard Mouse* and 'remedy' the predicted negative implications. However, it should be noted that the decision does not change the restrictive approach to animal patenting adopted by the *Harvard Mouse*. Notwithstanding this, the case has underlined an important patent law principle where, the use of patented genes and cells embodied in animal inventions amounts to infringement of the patent rights of the patentee. Therefore, while animal inventions *per se* are unpatentable in Canada, the findings of the *Percy Schmeiser* may adequately protect the commercial interests of a patentee and investors. Nevertheless, in the event where patents to genes and cells cannot be claimed (for not being able to meet the patent qualification criteria) animal inventions which are otherwise able to meet patent prerequisites will not be legally protected. Consequently, this will hinder inventors from developing animal inventions, and, investors from investing, in the animal biotechnology industry. Therefore, unlike the European-wide

permissive approach, the restrictive approach is not able to maximise the potential of animal biotechnology applications. As a result, it remains challenging for the livestock industry to meet the growing demand from the population. The next chapter will conclude the thesis where, in the light of the findings, of this chapter, and the four previous core chapters, an assessment of both the permissive and restrictive approaches will be made in the context of Malaysia. This eventually answers the research questions.

DISCUSSION AND CONCLUSION:
A WAY FORWARD FOR MALAYSIA

Discussion

A patent is meant to recognise the intellectual contribution of an inventor for creating an invention which benefits society. However, animals have been explicitly recognised to be excluded from the patent regime. As a result, their exclusion is contained in Article 27.3(b) of the TRIPs Agreement and other national patent laws (discussed in chapter 2). Nevertheless, the meaning of terms used to represent the excluded matter (for example, 'animals' or 'animal varieties') is not explicit. This creates uncertainty for one of the most pertinent aspects of patent law, namely the nature of the patent protection which an applicant is entitled to. This thesis focuses on the exclusion of animal varieties in s13(1)(b) of the Malaysian Patents Act 1983 which experiences the same ambiguity, and aims to suggest how it can be resolved. Towards this end, two research questions were formed at the beginning of the thesis (Introduction). In this discussion section the questions are revisited and an assessment is made in the context of Malaysia, based on the arguments and conclusions from the previous chapters. In essence, the chapter aims to answer the research questions and to suggest a way forward for Malaysia, in terms of how it should interpret its exclusionary provision.

The first research question is: how can the exclusion of animal varieties under s13(1)(b) of the Malaysian Patents Act 1983 be interpreted? This thesis has shown that the exclusion can be construed either narrowly or broadly. Underpinning the options are two models of interpretation which so far have been adopted by countries which are Signatories to the TRIPs Agreement, namely the permissive approach (of the European-wide, discussed in chapter 4) and the restrictive approach (of Canada, discussed in chapter 5). The TRIPs

Agreement plays an important role in the existence of these approaches. Being the 'umbrella' international patent law text, the exclusion of matters relating to animals under Article 27.3(b) was formed in a flexible manner (chapter 2). Fundamentally, the provision allows Signatories to exclude 'animals' and 'essentially biological processes' from patentability. Nevertheless, 'microbiological processes and products' derived from it are patentable. The flexibility is the result of negotiations among the Member States of the WTO which have different levels of economic and technological development. Most developed countries with strong economic and scientific advancement (such as the US, Japan and Australia) urged that the TRIPs Agreement provides that animal inventions be explicitly patentable. Intrinsically it aims to ensure that the commercial interests of their inventors are secured globally. Conversely, many developing countries (for instance, Argentina and Brazil) perceived the inventions as products of nature (discoveries), and so argued that they cannot be patented.[1] Underpinning this argument is their lack of ability to benefit from the strengthened patent protection, which would eventually benefit their developed counterparts, hence widening the economic gap between them.

The flexibility accorded by Article 27.3(b) is pertinent in the context of the international obligations imposed by the TRIPs Agreement on its Signatories. Only through flexibility on such a contentious issue would negotiating countries agree to the provision, hence securing the conclusion of the TRIPs Agreement. Most notably, the flexibility demonstrates that each Signatory has the right to determine how the exclusion of animal inventions is to be construed and utilised. Yet this thesis argues that for a developing country which includes the

[1] See for instance, GATT, 'Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay', Document MTN.GNG/NG11/W/71 (14 May 1990) Article 4(1), 8; WTO, 'Review of the provisions of Article 27.3(b): Summary of issues raised and points made', Document IP/C/W/369/Rev.1 (9 March 2006) 4; J. Carr, Agreements that divide: TRIPs vs CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications (2008) 18 *Journal of Transnational Law and Policy*, 1, 131-154.

exclusion in its national patent law, there are some pertinent aspects and issues which must be considered in interpreting the provision (chapter 2). This is because any interpretation will have broader social and economic implications. This contention is further elaborated here in the context of Malaysia.

Section 13(1)(b) of the Malaysian Patents Act 1983 and Article 53(b) of the EPC share a similar legislative background (chapters 3 and 4). Animal varieties are excluded under both patent law texts without clear intention or direction from the framers as to what is the meaning of the term 'animal varieties' itself and, therefore, the subject matter of the exclusion. An important lesson that Malaysia can learn from Europe is that, notwithstanding the 'deficiencies', the exclusion has to be construed so as to promote national interests. This is precisely the principle which Malaysia should pursue in the light of the flexibility granted by Article 27.3(b). While the country can either construe the exclusion of animal varieties under s13(1)(b) narrowly or broadly, putting the legal provision in the context of its key national interest will assist the country to achieve the interpretation which works in practice.

Similar to other developing countries, food security is a pertinent issue for Malaysia (chapter 1). In this respect, notwithstanding the shift of economic focus toward industry in the 1980s and the mid-1990s, agriculture remains one of the country's key economic drivers. Livestock animals and fish, and their products, have been an important animal-protein based source for Malaysians. The demand for the products from the population is growing as their income increases. This trend of consumption differs from that of the population of developed countries which focuses on the quality of the products (such as leaner meat and their environmental impact). Notwithstanding this, there has been evidence that the population in developing countries (including Malaysia) is venturing into the quality aspects of animal-

protein based food as their knowledge, in particular of health-related issues, advances. The production of food in Malaysia has been increasing in tandem with demand. Nevertheless, a self-sufficiency level in main livestock products has been identified as Malaysia's long-term challenge, despite the continued efforts adopted by the government (chapter 1). These include the increase of grazing reserves, promotion of good husbandry practice and improvement of marketing strategies. The main factors, which have been identified as causing the problem and have proved difficult to manage, are the shortage of breeding stock and fish seed; risk of livestock and aquatic diseases; and constraints of animal and fish feed.

Animal biotechnology can create products which are not achievable through traditional breeding techniques (chapter 1). Most notable are genetic engineering and cloning methods which produce optimum yields through the sustainable creation of livestock animals and fish (for example), which grow faster and are disease resistant.[2] The benefits of these scientific methods cannot be doubted, but consumers have been very cautious about animal biotechnology food.[3] Concerns relating to the products are mostly associated with the implications arising from their consumption for human health and the environment. While consumers have the right to be cautious, due to the non-traditional procedures which are involved in creating the food, there is ample scientific evidence that they are safe for human consumption and for the environment. Most convincing are the views published by the international food authorities including the USFDA, EFSA and UKFSA about their safety for human consumption, which are underpinned by years of rigorous scientific research (chapter

[2] Other qualities of the animals which have been the focus of the populations of developed countries, and would inevitably be followed by Malaysians in the future include: high quality meat; good taste; high nutrients; and protection of the environment.

[3] As a response to animal biotechnology, opponents have argued that consumers should avoid animal products altogether, but as identified, it is not clear how many people will feel strongly enough to adopt a vegetarian diet in response to the developments in technology. See A. Bruce, Regulation of cloned farm livestock, Economic and Social Research Council, 2007, http://www.genomicsnetwork.ac.uk/media/Regulation%20of%20Cloned%20Farm%20Livestock.pdf (Accessed: 13 March 2012).

1). In this respect, the thesis argues that consumers' pessimism toward animal biotechnology food can be managed through appropriate information and knowledge about the benefits of the products. Malaysians' perception can also be improved in similar ways (chapter 1).

One of the practices within livestock breeding is the trans-boundary movement of the animals for reasons such as to meet a sudden decline of breeding stock in neighbouring countries due to livestock diseases, and livestock auction (chapters 1 and 5). A similar practice is relevant for their transgenic counterparts, and it causes concern to consumers. The thesis asserts that any implications for human health and the environment which arise from the trans-boundary movement of the LMOs (including transgenic animals for food) are adequately covered by the Cartagena Protocol (chapter 1). The aspect of the Protocol which contributes to this is the requirement to subject intended trans-boundary movement of the LMOs to obtaining the prior informed consent of the importing Party or notification procedures, and their identification in international shipment (chapter 1). Another important feature of the Protocol is that Parties to the Protocol may fully utilise the right to impose relevant conditions in national biosafety laws so as to reduce potential risks arising from the movement (chapter 1). In addition, patent law principle as underlined by the Canadian Supreme Court in the *Schmeiser* case, which holds a benefiting infringer as liable for infringing a patentee's right (chapter 5) should have also alleviated the consumers' unease mentioned here. While the rule stems from a case which involves the trans-boundary movement of plant invention, it is similarly applicable to animal biotechnology food.

Due to the continued problem of self-sufficiency levels faced by the Malaysian livestock industry, it becomes clear that the country cannot continue to depend on current efforts to supply animal-protein based food to its population. Assistance is required from animal

biotechnology. The promises of the technology have led to the strong aspiration of the Malaysian Government to fully utilise the technology to enhance the country's food production (chapter 1). It aims at the country's dependence to imported products, which are increasing significantly every year, to be reduced (chapter 1). Broadly, various efforts have been made, and incentives offered, by the government in order to support the biotechnology sectors. Mainly, it is the increase in government investment, allocated to the industry, which amounts to MYR2,021.3 billion in the Ninth Malaysia Plan (2006-2010) compared to Malaysian Ringgit MYR574.4 million in the Eighth Malaysia Plan (2001-2005).[4] There are also some other pertinent efforts which are worth mentioning here. One of them is the creation of the Agro-Biotechnology Institute Malaysia which 'undertakes research, development and commercialisation projects pertaining to agriculture biotechnology in co-operation with various research and higher leaning institutions and industry players'.[5] Another notable effort is the granting of BioNexus status which aims to attract foreign investments. International and local biotechnology and life science companies which achieve the status are eligible for various incentives under the country's Bionexus Bill of Guarantees.[6] The incentives include freedom to bring in knowledge workers, eligibility for import duty and sales tax exemptions on approved biotechnology equipment and materials, and entitlement to strong intellectual property protection.[7] While these endeavours are not exclusive to the

[4] Biotechnology for Wealth Creation, Chapter 6, The Ninth Malaysia Plan (2006-2010), http://www.digitallibrary.my (Accessed: 9 October 2009) 168. MYR is the abbreviation for 'Malaysian Ringgit' which is the currency of Malaysia.

[5] National Biotechnology Division, Ministry of Science, Technology and Innovation, Malaysia http://www.biotek.gov.my/index.php?option=com_content&view=article&id=64&Itemid=63 (Accessed: 21 April 2012).

[6] Available at: Malaysian Biotechnology Corporation, Bionexus: A special award for an exceptional group http://www.biotechcorp.com.my/bionexus-new/ (Accessed: 21 April 2012). For full details of the Malaysian Bill of Guarantees, see Appendix 2.

[7] ibid. Starting with only seven BioNexus companies in 2006, there were one hundred and thirty five companies comprising local and international companies at the end of 2009. Speech of the 5th Prime Minister of Malaysia, His Excellency Datuk Seri Abdullah bin Haji Ahmad Badawi, at the official launch of BioMalaysia 2006, 6 December 2006, http://www.pmo.gov.my (Accessed: 20 November 2009); *New Straits Times*, 50 more BioNexus firms in 2 years, 17 November 2009. This BioNexus status has so far continued to attract international investment such as from the UK, the US, France, Germany, Italy, Belgium, India, China, Japan, Taiwan, Hong Kong, Singapore, Thailand, Australia and New Zealand. It has been reported that the

animal biotechnology sector, they are of utmost relevance and important to it, being a pertinent sector intended for development in Malaysia and identifying a general commitment to this technology.

In the light of the problems which the Malaysian livestock industry is facing and the explicit commitment of the government 'to provide strong intellectual property protection regime to support R&D and commercialisation efforts',[8] s13(1)(b) has to be construed in a way which will ensure that what is expected from the animal biotechnology sector is achieved. In other words, the exclusionary provision must play its role in supporting the technology and livestock industry. Otherwise, the aspirations, efforts and investment of the government will be hampered. This relates to the second research question: which of the permissive or restrictive approaches is the most practical for Malaysia to adopt? This thesis argues that Malaysia has to adopt the permissive approach if its livestock industry is to be enhanced so as to assist the country in meeting the growing demand for animal-protein based products from the population. This contention is further supported here.

The permissive approach is underpinned by the importance of patents of animal inventions for the development of biotechnology and the economy.[9] R&D activities for the purpose of creating animal biotechnology food are known to be expensive and time-consuming because they involve highly skilled workers, modern facilities, and extensive and rigorous research to achieve the required output. Within this, investment and technology transfer are two pertinent

---

Bionexus companies, as a group, have substantially contributed to the creation of knowledge workers in Malaysia. In 2008, there was a 382% increase of knowledge workers to 1,851 from only 384, in 2007. Malaysian Biotechnology Corporation, BiotechCorp Annual Report 2008, http://www.biotechcorp.com.my (Accessed: 21 December 2009) 12.

8 Which is explicitly underlined in Thrust 7 of the Malaysian National Biotechnology Policy. See Appendix 1.

9 The UK Supreme Court has explicitly recognised the importance of patents as an incentive to innovation in any sector (not limited to the pharmaceutical industry which is relevant to the case). See *Human Genome Sciences Inc v Eli Lilly and Company Limited* [2012] RPC 6, paragraph 98-99.

aspects which are closely related to patents. There has been evidence which shows that patents are able to attract FDI (chapter 2), and are being used as a principal criterion by venture capital firms to funding requests from biotechnology firms (chapter 5). Intrinsically, this is because patents demonstrate the research activities of a given firm. Active research would generate more patents, which leads to commercial gain due to their licensing. In the context of the thesis, this rule underpins the reluctance of developed countries to invest in the R&D activities of countries which lack patent protection for animal inventions (including developing countries) (chapter 2). Nevertheless, it has been identified that developing countries need to have the relevant technological capacity to adapt the technology to local interests (chapter 2).

This thesis contends that allowing patents to animal inventions in accordance with the permissive approach will benefit the Malaysian livestock industry, because the country has the technological ability in animal biotechnology. In evidence, to date, while only artificial insemination is widely applied, other more advanced applications such as gamete and gene manipulation for the production of sexed embryos, embryo transfer and embryo cryopreservation are already at the research stage in various research and higher learning institutions in the country (chapter 1). Although Malaysia has the necessary expertise to use the applications, it appears that much knowledge and technologies are still required by local scientists to enhance their technological knowledge before they can work independently to fully develop the industry. This can be achieved through research collaboration with experts from developed countries.

Another important point which has been identified by the thesis is that R&D activities involving animal biotechnology also require investment from private companies, as public

funding has many competing claims (chapter 5).[10] Allowing patents to animal inventions under the Malaysian Patents Act 1983 will encourage the collaboration which brings together the transfer of technology from the technologically developed (which are mostly developed) countries to Malaysia and investment from private companies. Strengthened patent protection is not to be perceived as only benefiting foreign scientists. Malaysian scientists will similarly benefit from it. In this respect, so as to safeguard the sharing of technology of foreign origin with local scientists in R&D activities relating to animal biotechnology, and to encourage the competition between local scientists and foreign scientists in terms of patent applications, conditions similar to those stipulated by § 204 of the USC Bayh-Dole Act 1980[11] (pertaining to the preference of local industry) should be introduced into the Malaysian Patents Act 1983. Mainly, the provision stipulates that an invention must be manufactured in the US unless there is lack of local capacity.[12] In this respect, it should be noted that the Malaysian Government has been encouraging local scientists and researchers to obtain patents for newly developed biotechnological inventions (chapter 1). As a result, many have protected their commercial interests through patents for products such as DNA sequence coding for various proteins and vaccines and animal feed (chapter 1). Patent protection for animal inventions *per se* widens the subject of patentable matter, and hence encourages them to be more innovative in creating animal biotechnology food to fulfil the demand from the population.

---

[10] Some of the pertinent proposals made by the OECD to boost research of agricultural biotechnology are by increasing public research investment, reducing regulatory burdens and encouraging private-public partnerships. OECD, The Bioeconomy to 2030: Designing a Policy Agenda, 2009, http://www.oecd.org/dataoecd/5/24/42837897.pdf (Accessed: 6 May 2012) 6.

[11] The Act is chapter 18 of 35 USC (the US Patent Act). Available at: USPTO, United States Code Title 35 – Patents, http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf (Accessed: 21 June 2012). The Act was introduced so as to allow universities and other research institutions to own and control patents for inventions which arise from their scientific research that is funded by the US Government. This incentive aims at attracting the private sector to invest in biotechnological inventions, hence, rigorously developing and commercialising the relevant inventions.

[12] ibid.

In Europe, the active animal biotechnology R&D activities which are carried out throughout the region stems from the optimism that the technology can relieve the region of dependence on imported feed, and assist in the sustainable development of its livestock industry (chapter 4). The activities are funded by both public and private organisations. In addition, the regulatory framework to assess the safety of the products derived from the technology is already in place. These aspects facilitate the growth of the technology, and ultimately, the marketability of the products. The patentability of animal inventions through the permissive approach further supports technological development, as the creation of the inventors can be legally protected. Conversely, Canada's pessimistic view toward animal patenting which has been explicit since the issue of animal patenting and was discussed during the Uruguay Round Meeting, has a stalling effect on the development of animal biotechnology applications in the country (chapter 5). Consequently, in comparison to Europe, the animal biotechnology industry has not been the focus of the Canadian Government. It is pertinent to note that the country's later policies relating to animal biotechnology appear to be consistent with its earlier political view. Most notable is the Food Directorate Interim Policy of Foods from Cloned Animals which remains in place to date. The Policy contains the specific restriction that manufacturers of cloned animals must not sell the products or by-products of any cloned animals or their progeny in the human food supply in Canada unless they have been subjected to the pre-market safety assessment. Subjecting the production to the assessment is most logical given the concerns which consumers may have. However, the failure of the Canadian Government to come up with the necessary assessment guidelines after more than a decade of planning, demonstrates their reluctance to govern and promote animal biotechnology food and relevant technology. Therefore, it is doubted if the products of this technology will ever reach the market.

It can be concluded from this thesis that the two approaches toward animal patenting correspond with a region's or a country's broader policies and perceptions of animal biotechnology. The permissive approach is in line with Europe's optimistic policy toward animal biotechnology, whereas the restrictive approach is equivalent to Canada's pessimistic view of the technology. It has been shown that Malaysia has a clear expectation from, and direction for, its animal biotechnology industry. Arguably, this corresponds with Europe's, rather than Canada's policies. Consequently, it is only reasonable that Malaysia should adopt the permissive approach in order to ensure that the objective it sets forth is achieved. In terms of the regulatory framework for assessing the pre-market safety of animal biotechnology food, while being an area which has not yet been tested in Malaysia, it should have been covered by the existing Biosafety (Approval and Notification) Regulation 2010.[13]

In tandem with this, another marked contrast between the permissive and restrictive approaches is the role of consumers' opinion towards animal biotechnology food in the adoption of each approach. In contrast to the European-wide permissive approach (chapter 4), the restrictive approach is also underpinned by the pessimistic attitude of Canadians to the use of the products (chapter 5). There is little doubt that public opinion is pertinent in policy-making decisions, given that the public are the end-users of the technology. However, it has been identified by this thesis that the pessimistic view of the public is not necessarily informed by scientific evidence (chapter 1). As a matter of fact, opinion could become positive if consumers are appropriately and adequately educated about the benefits of the

[13] Section 3 of the Malaysian Biosafety Act 2007 defines 'living modified organism' 'as: 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. In turn, 'modern biotechnology' is defined as: 'the application of (a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection.' These definitions resemble Articles 3(g) and (i), respectively, of the Cartagena Protocol.

technology.[14] It is argued that in the light of the myriad of challenges underpinning the effort to attain food security for Malaysians, the permissive approach has rightly demonstrated that the decision to either adopt or to reject the technology and products derived from it should be based on the potential of animal biotechnology applications to meet expectations, rather than be decisively based on opinion of consumers. In addition, as animal biotechnology food is subject to a range of regulation[15] before its use is allowed (chapters 4 and 5), the safety of the product cannot be a valid argument for their exclusion from patenting.

The permissive approach aims to ensure that an inventor, whose invention fulfils the patent qualification criteria, can be granted patent protection. This rule is the crux of innovation. The pertinent aspects of the review of Article 27.3(b) and restrictive approach require assessment at this juncture. This thesis asserts that animal inventions are able to fulfil the patent qualification criteria. It should be noted that even the Canadian Supreme Court which denied patents to the Harvard Mouse did not refute the ability of the transgenic mouse to fulfil the criteria (chapter 5). Therefore, there is no doubt that the inventions could be patentable. The argument by some developing countries during the review, that animal inventions are discoveries (thus should not be patentable) (chapter 2), neglects the basis of patent law which only grants protection to animals which do not occur naturally. This rule underpins the distinction between the patentable and unpatentable matter under Article 27.3(b), which recognises that products of nature are not to be patentable, but requires a Signatory to grant patents to products of human ingenuity.

---

[14] See for instance, L.J. Butler, M.M. Wolf and S. Bandoni, Consumer attitudes toward milk products produced from cloned cows (2008) 39 *Journal of Food Distribution Research*, 1, 35; L. Amin, J. Md Jahi, A.R. Md Nor, M. Osman and N.M. Mahadi, Uncovering factors influencing Malaysian public attitude towards modern biotechnology (2006) 14 *Asia-Pacific Journal of Molecular Biology and Biotechnology*, 2, 36.

[15] For instance, Regulation (EC) No 1829/2003 on the placing on the market of GMO food and feed or food and feed products containing or consisting of GMO (EU); Directive 2001/18/EC on the deliberate release into the environment of GMOs (EU); Standard 1.5.2 - Food Produced Using Gene Technology 1998 (Australia and New Zealand); and the Biosafety (Approval and Notification) Regulations 2010 (Malaysia).

Modern biotechnology applications such as genetic engineering are able to create novel animals within patent law. Therefore, animals which fulfil patent qualification requirements should be protected. The restrictive approach adopted by the Canadian Supreme Court in not allowing patent to animal inventions and the meaning of the term 'invention', lacks legal reasoning and fails the required obligation imposed by Article 27.3(b) (chapter 5). The terms 'art' or 'composition of matter' or 'manufacture' under s2 of the Canadian Patent Act 1985 are broad enough to cover the inventions (chapter 5). In this, so as to give effect to Article 27.3(b) the Supreme Court had to determine that the transgenic mouse is patentable. Alternatively, being a product of a microbiological process (genetic engineering), the transgenic mouse should be eligible for patent protection. In the context of Malaysia, the adoption of the permissive approach would ensure that the country fulfils its international obligation which falls short of the restrictive approach. These are other reasons why the permissive approach is advocated for Malaysia.

Malaysia has taken various stances during the review process of Article 27.3(b). Among others, that: (1) the flexibility under Article 27.3(b) should be maintained;[16] (2) the flexibility is to be exercised with conditions. Signatories which allow patents on plants and animals, should strictly fulfil the criteria under Article 27.1, whereas Signatories which have chosen to exclude plants and animals are justified in doing so on the basis that they are discoveries rather than inventions;[17] and (3) Signatories could demonstrate the importance of the CBD concepts by enacting national legislation that incorporates the relevant provisions of the

[16] WTO, 'Council for Trade-related Aspects of IPRs Minutes of Meeting', Document IP/C/M/29 (6 March 2001) para 204-205.

[17] WTO, 'Council for Trade-related Aspects of IPRs Minutes of Meeting', Document IP/C/M/30 (1 June 2001) para 179.

Convention in order to achieve wider international recognition.[18] Nevertheless, it is also notable that Malaysia has explicitly recognised that patents are important in encouraging R&D in biotechnology.[19] These principles represent the country's policies where, while intending to utilise animal biotechnology applications to the fullest for its livestock industry, the country (being a Signatory to the CBD)[20] puts equal emphasis on the importance of the conservation of biodiversity (including animal resources) for its sustainable development. In this respect, the requirement for mandatory disclosure of the source and country of origin of animal genetic resources involved in animal inventions is an issue which has also been advocated by developing countries during the review of Article 27.3(b) (chapter 2). Underpinning the requirement is the prior informed consent of developing countries which are widely accepted as producers of genetic resources, and benefit-sharing of profits from an invention developed using the genetic resources.

It is pertinent for Malaysia to assess the implications of the proposed mandatory disclosure requirements for the progression of animal biotechnology, and its livestock industry. This thesis contends that the requirements should be encouraged rather than be made mandatory (chapter 2). Underpinning this proposal is the intrinsic problem of identifying the country of origin (where the animal genetic resource is indigenous) precisely. It can be too burdensome for an applicant (including local innovators) if the granting of patents is conditional upon fulfilling this requirement (chapter 2). In the context of the thesis, as farm animals have been subject to trans-boundary movement for thousands of years, precise identification appears to be almost impossible. The problem in identifying the true providers of the genetic resources poses other challenges for an applicant, namely to obtain prior informed consent and ensure

[18] WTO, n 16 above, ibid.
[19] ibid.
[20] Malaysia signed the CBD on 12 June 1992, and has ratified the same on 24 June 1994. See CBD, http://www.cbd.int/convention/parties/list/ (Accessed: 31 March 2011).

that commercial benefits arising from the inventions are equally shared. These hurdles to obtaining patents will unnecessarily discourage investment in R&D activities relating to livestock animals, and ultimately adversely affect the livestock industry in Malaysia. As an alternative, it is proposed that Malaysia considers attaching the disclosure requirements as a condition for the enforcement of the granted national patents (in accordance with Article 62 of the TRIPs Agreement) rather than a prerequisite to obtain patent protection (chapter 2). Apart from serving the interests of the country under the CBD (where the obtaining of local genetic resources by foreign inventors can be appropriately monitored), it would ensure that Malaysia fulfils its obligation to grant patents to animal inventions under Article 27.3(b). Similarly, the option would encourage the flow of investment and progress of innovation.

In terms of plant varieties which are similarly excluded under s13(1)(b), it is notable that Malaysia has already in place the New Plant Varieties Protection Act 2004[21] which gives intellectual property rights to breeders of a new plant variety. In essence, the Act protects the rights of the breeders of plant varieties which fulfil the requirements under the UPOV Convention. It is worthy of note that there is not yet a statute which gives *sui generis* rights to animal varieties in Malaysia. Intrinsically this is because the concept of animal varieties (equivalent to plant varieties) has not yet been established (not only in the country, but also worldwide).[22] In this regard, the argument which underpins the restrictive approach, that it is open for the legislature to enact tailor-made legislation for animal inventions (chapter 5) has little foundation. The creation of animal inventions for food purposes is proceeding, and as already argued, the inventions are able to fulfil the patentability criteria. Without patent protection, they will be left without any legal protection and this will eventually bring social

[21] Act 634. The Act came into force on 1 January 2007, and is available at: WIPO, http://www.wipo.int/clea/docs_new/pdf/en/my/my040en.pdf (Accessed: 16 April 2012).

[22] Although some countries such as India and the Czech Republic have extended the plant varieties concept to establish *sui generis* systems for animal breeders in the countries. See discussion in section 3.3 of chapter 4.

and economic repercussions to Malaysia due to the problem of adequately supplying the population with animal-protein based food. Conversely, allowing patent protection to animal inventions ensures that they are legally protected before any alternative protection (such as the *sui generis* systems) can be established and more importantly, proven to be efficiently enforced. The permissive approach explicitly recognises the importance of patents to animal inventions and precisely anticipates the implications for its absence, which the restrictive approach fails to do.

Another issue relating to the restrictive approach which needs discussion is why patents are pertinent to animal inventions *per se* where process, and other claims relating to the inventions (such as cell cultures, plasmids and vectors) have been allowed by the CIPO. Patent claims (and protection) need to be broad enough so as to fully cover an inventor's interests and prevent a competitor from claiming that he does not infringe the patents of the original inventor through trivial improvement to the invention.[23] In this way, patents solve the 'free-riding' problem, and allow the original inventor to recoup the cost of the invention.[24] While patents to process and other claims pertaining to animal inventions give an applicant the required protection, the whole end-product is not necessarily protected from trivial improvement by competitors. This is unless a provision in national patent law explicitly extends the patents granted (for instance) to genetic material for the animals in which it is placed.[25] It is on this basis that patents to animal inventions *per se* are pertinent. A concern with too broad patent protection is that monopoly rights will be concentrated in only a few hands, causing a stifling effect on technological development as competitors refuse to

[23] S.J.R. Bostyn, A European perspective on the ideal scope of protection and disclosure requirement for biotechnological inventions in a harmonised patent system: The quest for the holy grail? (2002) *The Journal of World Intellectual Property*, 1013.

[24] ibid.

[25] For instance, as explicitly provided under Article 8(1) of the EU Biotechnology Directive. For the full provision, see footnote 153 in sub-section 3.2.3 of chapter 4.

improve the technology.[26] It is argued that the permissive approach, which allows patent protection to animal inventions *per* se, cannot be taken as allowing too broad a scope of protection to an inventor. This is because patent law has already anticipated and safeguarded this potential problem through the enablement requirement, which limits an applicant to obtaining patents only for claims which can be supported by sufficient disclosure.[27] It is worth noting that this was the fundamental problem with patenting the Harvard Onco-mouse in Europe.

The thesis discussed the argument by critics that licensing of patents will cause a barrier for technology transfer to developing countries (chapter 2). It is pertinent to put this contention in the context of the thesis. As the livestock industry in developing countries is mainly dominated by small-scale farmers (generally with limited financial resources), a question which may be raised is: how can the breeders benefit from the expensive cost of biotechnology? This question is particularly relevant to Malaysia. For instance, in 2008, cattle breeders in Malaysia were estimated at 41,838 persons.[28] The majority of them are small-scale breeders, with only 478 commercial and 675 semi-commercial breeders.[29] Due to the nature of their breeding activities, intrinsically small-scale breeders may not be able to independently utilise the technology discussed here. Nevertheless, it is premature to conclude that the costs of licensing will hinder the utilisation of this technology, and adversely affect small-scale breeders in Malaysia. This is because (apart from the widely applied artificial

---

[26] ibid.

[27] This is a requirement (for instance) under Article 84 of the EPC; s14(5) of the UK Patents Act 1977.

[28] Department of Veterinary Services Malaysia, Annual Report 2008, http://www.dvs.gov.my/web/guest/penerbitan (Accessed: 25 October 2010). 'Commercial' and 'semi-commercial' breeders are terms generally used in reference to the number and category of livestock breeds. For instance, a commercial breeder of poultry breeds 50,000 birds, whereas semi-commercial breeders breed fewer than 50,000 but more than 5,000 birds. For cattle breeders, a commercial breeder has 100 cattle, and those who have fewer than 100 but more than 40 cattle are considered as semi-commercial breeders. Breeders below the semi-commercial category are considered small-scale breeders. Personal communication with an official of the Department of Veterinary Services Malaysia dated 1 March 2011.

[29] ibid.

insemination) the more advanced applications (such as embryo transfer and embryo cryopreservation) are still in the research stage which is currently undertaken by various public research and higher learning institutions (chapter 1). Consequently, the aspect of the licensing cost of this technology should be within the management of the institutions (where the Malaysian Government has to play its role), rather than becoming the concern of the individual breeders. Therefore, any decision not to allow patent protection to animal inventions in view of the assumption that licensing impedes the use of the technology is unsupportable.

This thesis has shown that the Malaysian Patents Act 1983 comes in two versions, namely English and Malay, where each, is a translated version of the other (chapter 3). The Malaysian Patents Act 1983 is unique in the sense that the provisions where the patentability of animal inventions can be covered, 'combines' the scheme of Article 53(b) of the EPC and s2 of the Canadian Patent Act 1985. Unlike Article 53(b) and s2 which are the sole provisions within which the patentability of animal inventions are to be decided (respectively, in Europe and Canada), the Malaysian Patents Act 1983 contains both the definition of the term 'invention' (as in the Canadian Patent Act 1985) and the list of 'exceptions to patentability' (as in the EPC). The reproduction of the relevant provisions of the Malaysian Patents Act 1983 assists to crystallise this point.

Section 12 on the 'Meaning of invention' states:

> An invention means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.

In turn, s13 on 'Non-patentable inventions' provides:

> (1) Notwithstanding the fact that they may be inventions *within the meaning of section 12*, the following shall not be patentable:
> . . .
> (b) plant or *animal varieties* or essentially biological processes for the production of plants or animals, other than manmade living micro-organisms, micro-biological processes and the products of such micro-organism processes;
> . . .
> Provided that this paragraph shall not apply to products used in any such methods. *(emphasis added)*

Based on the foregoing reasons and arguments in this discussion section, the permissive approach requires that s13(1)(b) be construed narrowly where patents are to be granted to animal inventions (provided they fulfil the patent qualification criteria). In this respect, it is useful to assess the role which can be played by s12. In comparison with the term 'invention' under s2 of the Canadian Patent Act 1985, s12 appears to be broader as no restriction is imposed on the nature of the inventions involved; either animate or inanimate. Under s12, an invention does not have to qualify under any specific category of 'art, process, machine, composition of matter, or manufacture' which have been decided by the Canadian Supreme Court to exclude animal inventions (chapter 5). In the context of the thesis, animal biotechnology food can fit squarely within the term 'invention' under the provision, as its creation is intrinsically the idea of an inventor and is meant to solve the problems of the livestock industry. It is thus capable of industrial application in the patent law sense.[30]

From another perspective, the permissive approach appears to be underpinned by the purposive interpretation of patent law which intends to encourage innovation. This legal principle of interpretation of statutory provision is not foreign or new in the context of the Malaysian legal system. It is a principle of law which is clearly provided by the Malaysian

[30] L. Bently and B. Sherman, *Intellectual Property Law* (Oxford University Press, 2009) 393.

Interpretation Acts 1948 and 1967 (Consolidated and Revised 1989)[31] and has been established by the highest court in Malaysia in many cases over time. Section 17A of the Interpretation Act explicitly provides:

> In the interpretation of a provision of an Act, a construction that would promote the purpose or object underlying the Act (whether that purpose or object is expressly stated in the Act of not) shall be preferred to a construction that would not promote the purpose or object.

This principle has been recently upheld by the Federal Court in case of *Tenaga Nasional Berhad v Ong See Teong and Anor*,[32] which, referring to s17A stated:

> It is thus abundantly clear that what must prevail is a construction that will promote the purpose of an Act. ... The literal rule of construction, whatever the qualifications with which it is expressed, must give way to a statutory injunction to prefer a construction which would promote the purpose of an Act to one which would not, especially where that purpose is set out in the Act.[33]

Arguably this legal principle is applicable to the exclusionary provision as s13(1)(b) where the meaning of the term 'animal varieties' and, therefore, the subject matter of the exclusion is unclear. The above principle of interpretation makes the purpose of the Malaysian Patents Act 1983 crucial. The objective of the Act has only been generally mentioned as 'An Act to make better provisions in the law relating to patents and for other matters connected therewith'.[34] Notwithstanding this, it is pertinent to note that the Malaysian Patents Act 1983 is enacted to grant protection to inventors in various industries (intrinsically including the livestock industry), and is meant to foster the country's economic development (chapter 3). This objective justifies the adoption of the permissive approach by Malaysia.

---

[31] Act 388. Available at: Commonwealth Legal Information Institute, http://www.commonlii.org/my/legis/consol_act/ia1948a1967ar1989425/ (Accessed: 3 June 2011).

[32] [2010] 2 CLJ 1.

[33] ibid. paragraph 6. See also the case of *Datuk Seri Ahmad Said Hamdan, Ketua Suruhanjaya, Suruhanjaya Pencegahan Rasuah Malaysia & Ors v Tan Boon Wah* [2010] 3 MLJ 193 (Court of Appeal) where the court reiterated the principle of interpretation under s 17A.

[34] The preamble of the Malaysian Patents Act 1983.

Conclusion

In summary, this thesis proposes no amendment to s13(1)(b) of the Malaysian Patents Act 1983. Through the adoption of the permissive approach, the exclusion of 'animal varieties' contained in the exclusionary provision should be construed narrowly (in line with the permissive approach), so as not to exclude transgenic or cloned animals for food purposes. Section 12 of the Malaysian Patents Act 1983 on the meaning of the term 'invention' provides support to this interpretation. The adoption of the permissive approach promises the enhancement of the Malaysian animal biotechnology sector and ultimately the growth of the livestock industry so as to meet the growing demand for animal protein-based food from consumers. Of equal importance, the interpretation ensures that Malaysia fulfils its international obligations under Article 27.3(b) of the TRIPs Agreement which requires that inventions which could fulfil the patent qualification criteria be protected. Nevertheless, so as to further clarify the Malaysian legal position on the issue, it is proposed that, the Guidelines for Patent Examination of MyIPO introduce two provisions. Firstly, a provision to the effect which extends patent protection to an animal invention as a product and not just the process of its production. Secondly, a provision to the effect that 'notwithstanding that animals are involved in an invention it is patentable provided that the patent qualification criteria under s11 of the Malaysian Patents Act 1983 are met'.[35]

[35] For full provision of s11, see Appendix 3.

APPENDIX 1

NATIONAL BIOTECHNOLOGY POLICY (MALAYSIA)

Thrust 1: Agriculture Biotechnology Development
Transform and enhance the value creation of the agricultural sector through biotechnology

Thrust 2: Healthcare Biotechnology Development
Capitalize on the strengths of biodiversity to commercialize discoveries in natural products as well as position Malaysia in the bio-generics market

Thrust 3: Industrial Biotechnology Development
Ensure growth oppoortinities in the application of advanced bio-processing and bio-manufacturing technologies

Thrust 4: R&D and Technology Acquisition
Establish Centres of Excellence, in existing or new institutions, to bring together multidisciplinary research teams in co-ordinated research and commercialization initiatives. Accelerate technology development via strategic acquisitions.

Thrust 5: Human Capital Development
Build the nation's biotech human resource capability in line with market needs through special schemes, programmes and training

Thrust 6: Financial Intrastructure Development
Apply competitive "lab to market" funding and incentives to promote committed participation by academia, the private sector as well as government-linked companies. Implement sufficient exit mechanisms for investments in biotech

Thrust 7: Legislative and Regulatory Framework Development
Create an enabling environment through continuous reviews of the country's regulatory framework and procedures in line with global standards and best practices. Develop a strong intellectual property protection regime to support R&D and commercialization efforts

Thrust 8: Strategic Positioning
Establish a global marketing strategy to build recognition for Malaysian biotech and benchmark progress. Establish Malaysia as a centre for Contract Research Organizations and Contract Manufacturing Organizations

Thrust 9: Government Commitment
Establish a dedicated and professional implementation agency overseeing the development of Malaysia's biotech industry, under the aegis of the Prime Minister and relevant government ministries

APPENDIX 2

BILL OF GUARANTEES (MALAYSIA)

Freedom of ownership

Freedom to source funds globally

Freedom to bring in knowledge workers

Eligibility for competitive incentives and other assistance

Eligibility to receive assistance for international accreditations and standards

Strong intellectual property (IP) regime

Access to supportive information network linking research centres of excellence

Access to shared laboratories and other related facilities

BiotechCorp as the one-stop agency

APPENDIX 3

MALAYSIAN PATENTS ACT 1983 (ACT 291)

Part IV

Patentability

Patentable inventions

11. An invention is patentable if it is new, involves an inventive step and is industrially applicable.

Meaning of "invention"

12. (1) An invention means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.

(2) An invention may be or may relate to a product or process.

Non-patentable inventions

13. (1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable:

(a) discoveries, scientific theories and mathematical methods;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than manmade living micro-organisms, micro-biological processes and the products of such micro-organism processes;

(c) schemes, rules or methods for doing business, performing purely mental acts or playing games;

(d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human and animal body:

Provided that this paragraph shall not apply to products used in any such methods.

(2) For the purpose of subsection (1), in the event of uncertainty as to whether the items specified therein shall be patentable or not, the Registrar may refer the matter to the Examiner for an opinion and the Registrar shall thereafter give a decision as to whether to include or exclude such item as being patentable, as the case may be.

Novelty

14. (1) An invention is new if it is not anticipated by prior art.

(2) Prior art shall consist of –

(a) everything disclosed to the public, anywhere in the world, by written publication, by oral disclosure, by use or in any other way, prior to the priority date of the patent application claiming the invention;

(b) the contents of a domestic patent application having an earlier priority date than the patent application referred to in paragraph (a) to the extent that such contents are included in the patent granted on the basis of the said domestic patent application.

(3) A disclosure made under paragraph (2)(a) shall be disregarded –

(a) if such disclosure occurred within one year preceding the date of the patent application and if such disclosure was by reason or in consequence of acts committed by the applicant or his predecessor in title;

(b) if such disclosure occurred within one year preceding the date of the patent application and if such disclosure was by reason or in consequence of any abuse of the rights of the applicant or his predecessor in title;

(c) if such disclosure is by way of a pending application to register the patent in the United Kingdom Patent Office as at the date of coming into force of this Act.

(4) The provisions of subsection (2) shall not exclude the patentability of any substance or composition, comprised in the prior art, for use in a method referred to in paragraph 13(1)(d) , if its use in any such method is not comprised in the prior art.

Inventive step

15. An invention shall be considered as involving an inventive step if, having regard to any matter which forms part of the prior art under paragraph 14(2)(a), such inventive step would not have been obvious to a person having ordinary skill in the art.

Industrial application

16. An invention shall be considered industrially applicable if it can be made or used in any kind of industry.

(. . .)

Part VI

Application, procedures for grant and duration

(. . .)

Grant of patent

31. (1) The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the performance of any act in respect of the claimed invention is prohibited by any law or regulation, except where the performance of that act would be contrary to public order or morality.

(2) Where the Registrar is satisfied that the application complies with sections 23, 29 and 30, he shall grant the patent and shall forthwith –

(a) issue to the applicant a certificate of grant of the patent and a copy of the patent together with a copy of the Examiner's final report; and

(b) record the patent in the Register.

(2A) Where two or more persons have separately and independently made the same invention and each of them has made an application for a patent having the same priority date, a patent may be granted on each application.

(3) As soon as possible thereafter the Registrar shall -

(a) cause to be published in the Gazette a reference to the grant of the patent; and

(b) make available to the public, on payment of the prescribed fee, copies of the patent.

(4) The patent shall be deemed to be granted on the date that the Registrar performs the acts referred to in subsection (2).

APPENDIX 4

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 1994 (TRIPs Agreement)

PART II

Standards concerning the availability, scope and use of intellectual property rights

Section 5 : Patents

Article 27 : Patentable subject matter

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

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

3. Members may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

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

Article 28: Rights conferred

1. A patent shall confer on its owner the following exclusive rights:

   (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

   (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts

of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29 : Conditions on patent applicants

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

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

Article 30: Exceptions to rights conferred

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

Article 31: Other use without authorization of the right holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32: Revocation/Forfeiture

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

Article 33: Term of protection

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

Article 34: Process patents – burden of proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

(. . .)

PART IV

Acquisition and maintenance of intellectual property rights and related *inter-partes* procedures

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

APPENDIX 5

EUROPEAN PATENT CONVENTION 2010

PART II

Substantive patent law

Article 52: Patentable invention

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
(d) presentations of information.

(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Article 53: Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 54: Novelty

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(3) Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 and which were published on or after that date, shall be considered as comprised in the state of the art.

(4) Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.

Article 55: Non-prejudicial disclosures

(1) For the application of Article 54, a disclosure of the invention shall not be taken into consideration if it occurred no earlier than six months preceding the filing of the European patent application and if it was due to, or in consequence of:

(a) an evident abuse in relation to the applicant or his legal predecessor, or

(b) the fact that the applicant or his legal predecessor has displayed the invention at an official, or officially recognised, international exhibition falling within the terms of the Convention on international exhibitions signed at Paris on 22 November 1928 and last revised on 30 November 1972.

(2) In the case of paragraph 1(b), paragraph 1 shall apply only if the applicant states, when filing the European patent application, that the invention has been so displayed and files a supporting certificate within the time limit and under the conditions laid down in the Implementing Regulations.

Article 56: Inventive step

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. If the state of the art also includes documents within the meaning of Article 54, paragraph 3, these documents shall not be considered in deciding whether there has been an inventive step.

Article 57: Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

APPENDIX 6

DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 JULY 1998 ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS (EU Biotechnology Directive)

(. . .)

Recital 29:

Whereas this Directive is without prejudice to the exclusion of plant and animal varieties from patentability; whereas on the other hand inventions which concern plants or animals are patentable provided that the application of the invention is not technically confined to a single plant or animal variety;

(. . .)

CHAPTER I - Patentability

Article 1

1. Member States shall protect biotechnological inventions under national patent law. They shall, if necessary, adjust their national patent law to take account of the provisions of this Directive.

2. This Directive shall be without prejudice to the obligations of the Member States pursuant to international agreements, and in particular the TRIPs Agreement and the Convention on Biological Diversity.

Article 2

1. For the purposes of this Directive,
   (a) 'biological material` means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
   (b) 'microbiological process` means any process involving or performed upon or resulting in microbiological material.

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

3. The concept of 'plant variety` is defined by Article 5 of Regulation (EC) No 2100/94.

Article 3

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 4

1. The following shall not be patentable:

(a) plant and animal varieties;
(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 7

The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

CHAPTER II - Scope of protection

Article 8

1. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

2. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Article 9

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.

APPENDIX 7

IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANT OF EUROPEAN PATENTS (Implementing Regulations to the EPC)

CHAPTER 5 – Biotechnological inventions

Rule 26: General and definitions

(1) For European patent applications and patents concerning biotechnological inventions, the relevant provisions of the Convention shall be applied and interpreted in accordance with the provisions of this Chapter. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions shall be used as a supplementary means of interpretation.

(2) "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(3) "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

(4) "Plant variety" means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
(c) considered as a unit with regard to its suitability for being propagated unchanged.

(5) A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

(6) "Microbiological process" means any process involving or performed upon or resulting in microbiological material.

Rule 27: Patentable biotechnological inventions

Biotechnological inventions shall also be patentable if they concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Rule 28: Exceptions to patentability

Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Rule 29: The human body and its elements

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

APPENDIX 8

CANADIAN PATENT ACT 1985 (PATENT ACT, R.S.C, 1985, c.P-4)

Interpretation

Definitions

2. In this Act, except as otherwise provided,

“invention” means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;

APPENDIX 9

UNITED KINGDOM PATENTS ACT 1977

PART 1

New Domestic Law

Patentability

1. Patentable inventions

(1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

(a) the invention is new;
(b) it involves an inventive step;
(c) it is capable of industrial application;
(d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below;
and references in this Act to a patentable invention shall be construed accordingly.

(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -

(a) a discovery, scientific theory or mathematical method;
(b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
(c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
(d) the presentation of information;

but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

(5) The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

2. Novelty

(1) An invention shall be taken to be new if it does not form part of the state of the art.

(2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

(3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say –

(a) that matter was contained in the application for that other patent both as filed and as published; and

(b) the priority date of that matter is earlier than that of the invention.

(4) For the purposes of this section the disclosure of matter constituting an invention shall be disregarded in the case of a patent or an application for a patent if occurring later than the beginning of the period of six months immediately preceding the date of filing the application for the patent and either -

(a) the disclosure was due to, or made in consequence of, the matter having been obtained unlawfully or in breach of confidence by any person

(i) from the inventor or from any other person to whom the matter was made available in confidence by the inventor or who obtained it from the inventor because he or the inventor believed that he was entitled to obtain it; or

(ii) from any other person to whom the matter was made available in confidence by any person mentioned in sub-paragraph (i) above or in this sub-paragraph or who obtained it from any person so mentioned because he or the person from whom he obtained it believed that he was entitled to obtain it;

(b) the disclosure was made in breach of confidence by any person who obtained the matter in confidence from the inventor or from any other person to whom it was made available, or who obtained it, from the inventor; or

(c) the disclosure was due to, or made in consequence of the inventor displaying the invention at an international exhibition and the applicant states, on filing the application, that the invention has been so displayed and also, within the prescribed period, files written evidence in support of the statement complying with any prescribed conditions.

(5) In this section references to the inventor include references to any proprietor of the invention for the time being.

(6) [repealed]

3. Inventive step

An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above).

4. Industrial application

(1) An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

(2) [repealed]

(3) [repealed]

(. . .)

General provisions as to amendment of patents and applications

(. . .)

76A. Biotechnological inventions

(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.

(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.

(. . .)

SCHEDULE A2 (section 76A)

BIOTECHNOLOGICAL INVENTIONS

1. An invention shall not be considered unpatentable solely on the ground that it concerns-

(a) a product consisting of or containing biological material; or
(b) a process by which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

3. The following are not patentable inventions -

(a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;
(b) processes for cloning human beings;
(c) processes for modifying the germ line genetic identity of human beings;
(d) uses of human embryos for industrial or commercial purposes;
(e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

4. Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

5. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.

7. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

8. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

9. The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided for in paragraph 3(a) above, in which the product is incorporated and in which the genetic information is contained and performs its function.

10. The protection referred to in paragraphs 7, 8 and 9 above shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the proprietor of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

11. In this Schedule:

“essentially biological process” means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;

“microbiological process” means any process involving or performed upon or resulting in microbiological material;

“plant variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes; and

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics; and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

BIBLIOGRAPHY

Abdul Ghani Azmi, I.M. (2003) *Patent law in Malaysia: cases and commentary*, Sweet and Maxwell.

Abdul Ghani Azmi, I.M. (2008) Research on human embryos and stem cells: weaving ethical and religious concerns into the framework of patent law in Malaysia, in Torremans, P.L.C. (ed) *Intellectual property and human rights: enhanced edition of copyright and human rights*, Wolters Kluwer.

Abdul Ghani Azmi, I.M. (2009) Patenting whilst being ethical, *International Islamic University Malaysia (IIUM) Law Review*, 489.

Abler, D. (2010) *Demand growth in developing countries*, OECD Food, Agriculture and Fisheries Working Papers, No 29, United States, OECD Publishing.

Adams, W.A. (2005) Confronting the patentability line in biotechnological innovation: Monsanto Canada Inc v Schmeiser, *Canadian Business Law Journal*, 393.

Adcock, M. and Llewelyn, M. (2000) Micro-organisms, definitions and options under TRIPS, Paper prepared for a discussion meeting hosted by the Quaker UN Office (Geneva) and the International Centre for Trade and Sustainable Development.

Adede, A.O. (2003) Origins and history of the TRIPS negotiations, in Bellmann, C., Dutfield, G., and Melendez-Ortiz, R. (eds) *Trading in knowledge: development perspectives on TRIPS, trade and sustainability*, London, Earthscan.

Adolf, H. (2001) Trade-related aspects of intellectual property rights and developing countries, *The Developing Economies*, 49.

Aerni, P. (2004) Risk, regulation and innovation: the case of aquaculture and transgenic fish, *Aquatic Science*, 66, 327.

Ag-West Bio Incorporation, Saskatoon: Canada's science city, http://www.agwest.sk.ca/upload_mce_image/file/SaskatoonScienceCity.pdf (Accessed: 19 December 2011).

Ag-West Bio Incorporation, The path to success: 2010-2011 Annual report, http://www.agwest.sk.ca/upload_mce_image/file/AnnualReports/AWB2011AnnualReport-web.pdf (Accessed: 19 December 2011).

Allan, G. (2004) Fish for feed vs fish for food, in Brown, A.G. (ed) Fish, aquaculture and food security: sustaining fish as a food supply, Record of a conference conducted by the ATSE Crawford Fund Parliament House, Canberra.

Amin, L., Md Jahi, J., Md Nor, A.R., Osman, M., and Mahadi, N.M. (2006) Uncovering factors influencing Malaysian public attitude towards modern biotechnology, *Asia-Pacific Journal of Molecular Biology and Biotechnology*, 14, 2, 33.

Amin, L., Md Jahi, J., Md Nor, A.R., Osman, M., and Mahadi, N.M. (2008) Malaysian public attitude towards several modern biotechnology applications, Proceedings of the 6th WSEAS International Conference on Environment, Ecosystems and Development, 54.

Answer of the Canadian Group of International Association for the Protection of Intellectual Property (AIPPI), https://www.aippi.org/download/commitees/180/QS180canada06.pdf (Accessed: 10 December 2011).

Anuradha, R.V. (2001) IPRs: Implications for biodiversity and local and indigenous communities, *Review of European Community and International Environmental Law*, 10, 1, 27.

ARK-Genomics, http://www.ark-genomics.org/ (Accessed: 3 October 2011).

Armitage CB, E., and Davis CB, I. (1994) *Patents and morality in perspectives*, London, Common Law Institute of Intellectual Property.

Asher, G. (1965) The development of the patent system in Canada since 1767, *Canadian Patent Reporter*, 43, 56.

Barrett, T., Labhrainn, I.M., and Fallon, H. (eds), *Handbook of enquiry and problem based learning*, http://www.aishe.org/readings/2005-2/contents.html (Accessed: 28 March 2012).

Bentley, L., and Sherman, B. (2009) *Intellectual property law*, Oxford University Press.

Berita Harian, LKIM tambah import ikan sejuk beku dari 4 negara, 1 March 2010.

Beyleveld, D. and Brownsword, R. (1993) *Mice, morality and patents*, London, Common Law Institute of Intellectual Property.

Bièvre, D.D., and Thomann, L., Forum shopping in the global intellectual property regime, Arbeitspapiere - Working Papers, Nr. 132, (Mannheimer Zentrum für Europäische Sozialforschung, 2010).

Biggar, O.M. (1927) *Canadian patent law and practice: with special reference to the differences between the law and practice in Canada and in Great Britain and the United States*, Toronto, Burroughs & Company (Eastern) Limited Law Publishers.

BIOTECanada, BIOTECanada responds to Supreme Court decision on Harvard Mouse case, http://www.community-online.com/communityarticle.cfm?ArticleID=494 (Accessed: 4 January 2010).

Biotechnology for Wealth Creation, Chapter 6, The Ninth Malaysia Plan (2006-2010), http://www.digitallibrary.my (Accessed: 9 October 2009).

Black, R., Push to have GM salmon approved, *BBC News*, 24 March 2004, http://news.bbc.co.uk/1/hi/sci/tech/3565041.stm (Accessed: 18 November 2010).

Blakeney, M. (1996) *Trade related aspects of intellectual property rights: a concise guide to the TRIPs Agreement*, London, Sweet and Maxwell.

Bochnovic, J. (1994) Invention/Inventive Step/Obviousness in Henderson, G.F. (ed) *Patent law of Canada*, Toronto, Carswell.

Bonny, S. (2008) How have opinions about GMOs changed over time? The situation in the European Union and the USA, *CAB Reviews: Perspectives in agriculture, veterinary science, nutrition and natural resources*, 93, 1.

Bostyn, S.J.R. (2002) A European perspective on the ideal scope of protection and disclosure requirement for biotechnological inventions in a harmonised patent system: the quest for the holy grail?, *The Journal of World Intellectual Property*, 1013.

Bouët, A., Gruère, G., and Leroy, L. (2010) From 'may contain' to 'does contain': the price and trade effects of strict information requirements for GM maize under the Cartagena Protocol on Biosafety, Selected paper prepared for presentation at the Agricultural and Applied Economics Association's, 1.

Bragdon, S., Garforth K., and Haapala Jr, J.E., Safeguarding biodiversity: the Convention on Biological Diversity (CBD), http://web.idrc.ca/en/ev-119955-201-1-DO_TOPIC.html (Accessed: 21 January 2012).

Brent, P., Bittisnich, D., Brooke-Taylor, S., Galway, N., Graf, L., Healey M., and Kelly, L. (2003) Regulation of genetically modified foods in Australia and New Zealand, *Food Control*, 14, 409.

Bruce, A. (2007) Regulation of cloned farm livestock, Economic and Social Research Council, http://www.genomicsnetwork.ac.uk/media/Regulation%20of%20Cloned%20Farm%20Livestock.pdf (Accessed: 13 March 2012).

Burgos, S., and Otte, J. (2010) 'Global public health and transboundary animal diseases: issues and options, approaches and concerns', FAO-UN Research Report.

Butler, L.J., Wolf, M.M., and Bandoni, S. (2008) Consumer attitudes toward milk products produced from cloned cows, *Journal of Food Distribution Research*, 39, 1, 31.

Buzz of GM mosquitoes still feared, http://www.asiaone.com (Accessed: 21 December 2010).

Cambray, G., African bees – a solution to North America's bee problems?, http://www.scienceinafrica.co.za/2007/april/africanbees.htm (Accessed 16 March 2011).

Canadian Biotechnology Advisory Committee (CBAC), (2002) Patenting of higher life forms and related issues: report to the Government of Canada Biotechnology Ministerial Coordinating Committee.

Canadian Biotechnology Advisory Committee, (2006) Toward a Canadian action agenda for biotechnology: a report from the CBAC.

Canadian Food Inspection Agency (CFIA), Animals and animal products derived through modern biotechnology: roles and responsibilities of the government of Canada, http://inspection.gc.ca/animals/veterinary-biologics/guidelines-forms/animal-biotechnology/eng/1334783323017/1334783436055 (Accessed: 15 February 2012).

Canadian Food Inspection Agency, Regulating agricultural biotechnology in Canada: an overview, http://www.inspection.gc.ca/english/sci/biotech/reg/bioage.shtml (Accessed: 15 February 2012).

Canavari, M., Tisselli, F., Nayga Jr, R.M., and Scarpa, R. (2009) Italian consumer acceptance of nutritionally enhanced GM food, Paper prepared for presentation at the International Association of Agricultural Economists Conference, 1-16.

Carr, J. (2008) Agreements that divide: TRIPs vs CBD and proposals for mandatory disclosure of source and origin of genetic resources in patent applications, *Journal of Transnational Law and Policy*, 18, 1, 131.

Cassar-Malek, I., Picard, B., Bernard C., and Hocquette, J.F. (2008) Application of gene expression studies in livestock production systems: a European perspective, *Australian Journal of Experimental Agriculture*, 48, 701.

Cataldo, V.D. (2002) From the European patent to a community patent, *Columbia Journal of the European Law*, 8, 19.

Check, E., Canada stops Harvard's oncomouse in its tracks, *Nature* 420, 593 (12 December 2002) http://www.nature.com/nature/journal/v420/n6916/full/420593b.html (Accessed: 4 January 2010).

Chin, F.Y., Palm Kernel Cake (PKC) as a supplement for fattening and dairy cattle in Malaysia, http://www.jpvpk.gov.my (Accessed: 13 December 2010).

Christie, A., and Peace, N. (1996) Intellectual property protection for the products of animal breeding, *European Intellectual Property Review*, 18, 4, 213.

Commission on IPRs, (2002) 'Integrating IPRs and development policy: report of the Commission on IPRs', London.

Committee to Examine the Patent System and Patent Law (1970) *The British patent system: Report of the Committee to Examine the Patent System and Patent Law*, London, Her Majesty's Stationery Office.

Consumers Association of Penang, Revoke and remove approved GM food from our shelves, http://www.consumer.org.my/food/safety/411-revoke-and-remove-approved-gm-food-from-our-shelves (Accessed: 21 December 2010).

Cornish, W., and Llewelyn, D. (2007) *Intellectual property: patents, copyright, trade marks and allied rights*, London, Sweet and Maxwell.

Correa, C.M. (1998) *Implementing the TRIPs Agreement: general context and implications for developing countries*, Third World Network.

Correa, C.M. (1998a) Implementing the TRIPs Agreement in the patents field: options for developing countries, *Journal of World Intellectual Property*, 1, 1, 75.

Correa, C.M. (2008) Patent rights, in Correa, C.M., and A.A. Yusuf (eds) *Intellectual property and international trade: the TRIPS Agreement*, Wolters Kluwer.

Correa, C.M., Review of the TRIPs Agreement: fostering the transfer of technology to developing countries, 946, http://www.twnside.org.sg/title/foster.htm (Accessed: 10 August 2010).

Council of Europe (COE), 'Draft Official Report of the Meeting of 6th July 1951', Document CM/WP/IV (51) PV 8 (7 July 1951).

Council of Europe, 'Draft Minutes of the Fourth Meeting held at Strasbourg on 10th July 1952', Document EXP/Brev (52) PV 10 prov (11 July 1952).

Council of Europe, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe, from the point of view of the German legislation', Document EXP/Brev (53) 1 (12 January 1953).

Council of Europe, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts from the point of view of the French legislation', Document EXP/Brev (53) 4 (10 February 1953).

Council of Europe, 'Reply to questionnaire drawn up by the Bureau of the Committee of Experts of the Council of Europe from the point of view of legislation in Norway', Document EXP/Brev (53) 9 (7 April 1953).

Council of Europe, 'Observations and proposals of the German experts on the unification of general conditions of patentability', Document EXP/Brev (56) 8 (26 October 1956).

Council of Europe, 'Report of the French Delegation on the Unification of European Laws in respect of Patents', Document EXP/Brev (57) 3 (13 May 1957).

Council of Europe, 'Report by the Committee of Experts to the Committee of Ministers on the meeting held at The Hague from 28 November to 2 December 1960', Document CM (60) 150 (2 December 1960).

Council of Europe, 'Report of the meeting on 16 and 17th March 1961', Document EXP/Brev B (61) 3 (24 March 1961).

Council of Europe, 'Proposal by the Working Group', Document EXP/Brev/Misc (61) 13 (8 November 1961).

Council of Europe, 'Proposal of the Drafting Committee', Document EXP/Brev/Misc (61) 14 (9 November 1961).

Council of Europe, 'Memorandum by the Secretariat on the Meeting held at Strasbourg from 7th to 10th November 1961', Document EXP/Brev (61) 8 (13 December 1961).

Council of Europe, 'Report of the Committee of Experts to the Committee of Ministers on the meeting held from Strasbourg from 14th to 17th May 1963', Document CM (63) 101 (27 May 1963).

Council of Europe, 'Criteria of Novelty and Patentability', Document CM/WP/IV (51) 9.

Cressey, D. (2009) Future fish, *Nature*, 458, 398.

Cross, R. (1995) *Statutory interpretati*on, London, Butterworths.

Crowne-Mohammed, E.A. (2009) Can you patent that? a review of subject matter eligibility in Canada and the United States, *Temple International and Comparative Law Journal*, 269.

da Costa, P.C.M. (1994) NAFTA – The Canadian response or why does the Canadian Patent Act keep changing?, *AIPLA Quarterly Journal*, 22, 65.

de Barcellos, M.D., Kügler, J.O., Grunert, K.G., van Wezemael, L., Pérez-Cueto, F.J.A., Ueland, ø., Verbeke, W. (2010) European consumers' acceptance of beef processing technologies: a focus group study, *Innovative Food Science and Emerging Technologies*, 11, 721.

de Carvalho, N.P. (2000) 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, *Washington University Journal Law and Policy*, 371.

Deignan, T. (2009) Enquiry-based learning: perspectives on practice, *Teaching in Higher Education*, 1, 14, 13.

Delgado, C.L. (2003) Rising consumption of meat and milk in developing countries has created a new food revolution, *The Journal of Nutrition*, 133, 3907S.

Department for Environment, Food and Rural Affairs, UK (DEFRA), Report of sheep and goat movement made under a general licence, http://www.defra.gov.uk/forms/2011/03/30/aml1-animal-move-licensing/ (Accessed: 3 March 2012).

Department of Fisheries Malaysia, Annual fisheries statistics 2007 – import/export, http://www.dof.gov.my/642 (Accessed: 3 December 2010).

Department of Fisheries Malaysia, Food fish production, http://www.dof./gov.my (Accessed: 3 December 2010).

Department of Fisheries Malaysia, Performance and achievements of the fisheries sector, http://www.dof.gov.my/18?p_p_id=56_INSTANCE_3Fyn&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&page=1 (Accessed: 10 January 2012).

Department of Fisheries Malaysia, Status of the fisheries sector in Malaysia, 2009, http://www.dof.gov.my/c/document_library/get_file?uuid=4e69ed3d-f8c5-4b68-87be-d904b95ec011&groupId=172176 (Accessed: 10 January 2012).

Department of Veterinary Services Malaysia, Annual Report 2008, http://www.dvs.gov.my/web/guest/penerbitan (Accessed: 25 October 2010).

Department of Veterinary Services Malaysia, http://www.dvs.gov.my/web/guest/penerbitan (Accessed: 23 April 2012).

Devlin, R.H., D'Andrade, M., Uh, M., and Biagi, C.A. (2004) Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions, *Proceedings of the National Academy of Sciences of the United States of America*, 101, 25, 9303.

Dey, M.M., Garcia, Y.T., Kumar, P., Piumsombun, S., Haque, M.S., Li, L., Radam, A., Senaratne, A., Khiem, N.T., and Koeshendrajana, S. (2008) Demand for fish in Asia: a cross-country analysis, *The Australian Journal of Agricultural and Resource Economics*, 52, 321.

Donovan, M.J. (2009) Genetically modified insects: why do we need them and how they will be regulated?, *Missouri Environmental Law & Policy Review*, 17, 62.

Dunham, R.A., Warr, G.W., Nicholas, A., Duncan, P.L., Argue, B., Middleton, D., and Kucuktas, H. (2002) Enhanced bacterial disease resistance of transgenic Channel catfish *Ictalurus puncatus* possessing cecropin genes, *Marine Biotechnology*, 4, 338.

Dutfield, G. (2002) Sharing the benefits of biodiversity: is there a role for the patent system?, *The Journal of World Intellectual Property Law*, 899.

Dutfield, G. (2009) *IPRs and the life science industry: past, present and future*, World Scientific.

Economic Planning Unit Malaysia, First Malaysia Plan (1966-1970) to Tenth Malaysia Plan (2011-2015), http://www.epu.gov.my/previousplan (Accessed: 26 October 2010).

Edgar, S.G.G. (1971) *Craies on statute law*, London, Sweet and Maxwell.

Einsiedel, E.F., and Smith, J.A. (2005) Canadian views on patenting biotechnology: report prepared for the Canadian Biotechnology Advisory Committee (CBAC), Ottawa.

Environment Canada (EC), Review of the New Substances Notification Regulations (Organisms), November 2007, http://www.ec.gc.ca/subsnouvelles-newsubs/B59FB284-AC16-448C-A343-9A5F0E1E57F4/NSNR%28O%29%20Phase%20II%20consultation%20-%20EN.pdf (Accessed: 7 March 2012).

Environment Canada and Health Canada (HC), New substances: review of the new substances notification regulations (organism) – background and update, http://biosafety.icid.com/en/files/presentations/Review-New-Substances-Notfication-Regulations.pdf (Accessed: 7 March 2012).

Europa, Biotechnology and Europe - The speech of Peter Mandelson (Europe Trade Commissioner) on the European biotechnology info day, 14 June 2007, Speech/07/397, http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/397&format=HTML&aged=0&language=EN&guiLanguage=en (Accessed: 19 May 2011).

Europa, Life sciences and biotechnology – a key sector for Europe's competitiveness and sustainability, Press Release, 11 April 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/130&format=HTML&aged=1&language=EN&guiLanguage=en (Accessed: 19 May 2011).

Europa, Questions and answers on the regulation of GMOs in the European Union, MEMO/07/117, 26 March 2007, http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/07/117 (Accessed: 29 September 2011).

Europa, A fisheries policy for the future, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/873&format=HTML&aged=0&language=EN&guiLanguage=en (Accessed: 8 November 2011).

Europa, The Common Fisheries Policy, http://ec.europa.eu/fisheries/documentation/publications/pcp2008_en.pdf (Accessed: 8 November 2011).

Europe scorns "supersalmon" as GM battle widens, http://uk.reuters.com/article/2011/04/22/food-salmon-idUKLDE73K1EU20110422 (Accessed: 10 November 2011).

European Animal Disease Genomics Network of Excellence for Animal Health and Food Safety (EADGENE), http://www.eadgene.info/ (Accessed: 3 October 2011).

European Commission, Agricultural statistics: main results 2008-2009, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-ED-10-001/EN/KS-ED-10-001-EN.PDF (Accessed: 27 September 2011).

European Commission, Europeans and biotechnology in 2010: winds of change?, http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_winds_en.pdf (Accessed: 29 September 2011).

European Commission, Novel foods and novel food ingredients, http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm (Accessed: (12 March 2012).

European Food Safety Authority (EFSA), Scientific opinion of the scientific committee: Food safety, animal health and welfare and environmental impact of animals derived from cloning by somatic cell nucleus transfer (SCNT) and their offspring and products obtained from those animals, 15 July 2008, http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf (Accessed: 12 March 2012).

European Food Safety Authority, Update on the state of play of animal cloning, 14 September 2010, http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf (Accessed: 12 March 2012).

European Patent Office (EPO), India's traditional knowledge digital library (TKDL): a powerful tool for patent examiners, http://www.epo.org/news-issues/issues/traditional.html (Accessed: 31 March 2011).

European Patent Office, Biotechnology in European patents – threat or promise?, http://www.epo.org/news-issues/issues/biotechnology.html (Accessed: 20 April 2011).

Fisher, H., and Smart, R.S. (1914) *Canadian patent law and practice*, Toronto, Canada Law Book Company Limited.

Food and Agriculture Organization of the United Nations (FAO), (1999) The importance of food quality and safety for developing countries, http://www.fao.org/docrep/meeting/x1845e.htm (Accessed: 17 March 2011).

Food and Agriculture Organization of the United Nations, (2000) The state of world fisheries and aquaculture, http://www.fao.org/DOCREP/003/X8002E/x8002e05.htm#P30 (Accessed: 22 March 2011).

Food and Agriculture Organization of the United Nations, (2004) Overfishing on the increase in Asia-Pacific seas, http://www.fao.org/newsroom/en/news/2004/49367/index.html (Accessed: 22 March 2011).

Food and Agriculture Organization of the United Nations, (2007) The state of capacities in animal genetic resources management: reproductive and molecular biotechnology, ftp://ftp.fao.org/docrep/fao/010/a1250e/a1250e.pdf (Accessed: 17 December 2010).

Food and Agriculture Organization of the United Nations, (2008) The state of world fisheries and aquaculture, 2008, http://www.fao.org/docrep/011/i0250e/i0250e00.htm (Accessed: 26 October 2010).

Food and Agriculture Organization of the United Nations, (2008) World watch list for domestic animal diversity, ftp://ftp.fao.org/docrep/fao/009/x8750e/x8750e.pdf (Accessed: 25 February 2011).

Food and Agriculture Organization of the United Nations, (2009) The state of food and agriculture: livestock in the balance, http://www.fao.org/docrep/012/i0680e/i0680e.pdf (26 November 2010).

Food and Agriculture Organization of the United Nations, (2010) Regional review on status and trends in aquaculture development in North America: Canada and the United States of America, http://www.fao.org/docrep/014/i2163e/i2163e00.pdf (Accessed: 29 December 2011).

Food and Agriculture Organization of the United Nations, Global plan of action for animal genetic resources and the Interlaken Declaration, ftp://ftp.fao.org/docrep/fao/010/a1404e/a1404e00.pdf (Accessed: 8 December 2010).

Food and Agriculture Organization of the United Nations, The emergence of Nipah virus, http://www.fao.org/docrep/005/AC449E/ac449e04.htm (Accessed: 9 December 2010).

Food and Agriculture Organization of the United Nations, Transport of livestock, http://www.fao.org/docrep/003/x6909e/x6909e08.htm (Accessed: 3 March 2012).

Food and Agriculture Organization of the United Nations, What should be the role and focus of biotechnology in the agricultural research agendas of developing countries?, http://www.fao.org/biotech/C8doc.htm (Accessed: 28 March 2012).

Fox, H.G. (1969) *The Canadian patent law and practice relating to letters patent for inventions*, Toronto, Carswell Co.

Freeman, R. (1972) *Classification of the animal kingdom*, London, English Universities Press Ltd.

French National Institute for Agricultural Research (INRA), http://www.international.inra.fr/the_institute/a_brief_overview (Accessed: 2 October 2011).

Garcia, J.F., Fortes, M.R.S., Porto-Neto, L.R., and Boettcher, P.J. (2009) Achievement of research in the field of molecular genetics: recent molecular genetics achievements and unfolding applications to livestock, in Rosati, A., Tewolde, A., and Mosconi, C. (eds) *WAAP Book of the year 2007: A review on developments and research in livestock systems*, Wageningen Academic Publishers.

Garland, S.B., and Smordin, S. (2003) The Harvard Mouse decision and its future implications, *Canadian Business Law Journal*, 39, 2, 162.

Garnett, T. (2007) Meat and dairy production and consumption, http://www.miljopunkt-valby.dk/det-gor-vi-old/ressource-forbrug/klimatildes-kokken/tg-fcrn-livestock-final-6-nov.pdf (Accessed: 29 September 2011).

Gaskell, G., and Jackson, J., A Comparative analysis of public opinion: Canada, the USA and the European Union, in First impressions: understanding public views on emerging technologies, prepared by Genome Prairie GE3LS team as the University of Calgary, funded by the Canadian Biotechnology Secretariat, http://epe.lac-bac.gc.ca/100/200/301/cbs-scb/first_impressions-e/Iu199-4-2005E.pdf#page=64 (Accessed: 29 September 2011).

Gaskell, G., Allum, N., Bauer, M., Durant, J., Allansdottir, A., Bonfadelli, H., Boy, D., de Cheveigné, S., Fjaestad, B., Gutteling, J.M., Hampel, J., Jelsøe, E., Jesuino, J.C., Kohring, M., Kronberger, N., Midden, C., Nielsen, T.H., Przestalski, A., Rusanen, T., Sakellaris, G., Torgersen, H., Twardowski, T., and Wagner, W. (2000) Biotechnology and the European public, *Nature Biotechnology*, 18, 935, http://www.ask-force.org/web/Discourse/Gaskell-Biotechnology-European-Public-2000.pdf (Accessed: 29 September 2011).

Gee, L.H. (1997) A study of the historical development of the Malaysian patents system, in Firth, A. (ed) *The prehistory and development of intellectual property systems*, London, Sweet and Maxwell.

General Agreement on Tariffs and Trade (GATT), 'Ministerial Declaration on the Uruguay Round', Document GATT/1396 (25 September 1986).

General Agreement on Tariffs and Trade, 'Guidelines and Objectives Proposed by the EU for the Negotiations on Trade Related Aspects of Substantive Standards of IPRs', Document MTN.GNG/NG11/W/26 (7 July 1988).

General Agreement on Tariffs and Trade, 'Mid Term Meeting', Document MTN.TNC/11 (21 April 1989).

General Agreement on Tariffs and Trade, 'Standards and Norms for Negotiations on Trade-Related Aspects of IPRs: Communication from Australia', Document MTN.GNG/NG11/W/35 (10 July 1989).

General Agreement on Tariffs and Trade, 'Proposal by the Nordic Countries for the Negotiations on Standards and Principles for Trade-related Aspects of IPRs', Document MTN.GNG/NG11/W/36 (10 July 1989).

General Agreement on Tariffs and Trade, 'Standards and Principles Concerning the Availability, Scope and Use of Trade-related Aspects of IPRs: Communication from India', Document MTN.GNG/NG11/W/37 (10 July 1989).

General Agreement on Tariffs and Trade, 'Meeting of Negotiating Group of 12-14 July 1989', Document MTN.GNG/NG11/14 (12 September 1989).

General Agreement on Tariffs and Trade, 'Submission from Canada', Document MTN.GNG/NG11/W/47 (25 October 1989).

General Agreement on Tariffs and Trade, 'Meeting of Negotiating Group of 30 October-2 November 1989', Document MTN.GNG/NG11/16 (4 December 1989).

General Agreement on Tariffs and Trade, 'Communication from Brazil', Document MTN.GNG.NG11/W/57 (11 December 1989).

General Agreement on Tariffs and Trade, 'Synoptic Tables Setting Out Existing International Standards and Proposed Standards and Principles', Document MTN/GNG/NG11/W/32/Rev.2 (2 February 1990).

General Agreement on Tariffs and Trade, 'Draft Agreement on Trade-Related Aspects of IPRs', Document MTN.GNG/NG11/W/68 (29 March 1990).

General Agreement on Tariffs and Trade, 'Draft Agreement on the Trade-Related Aspects of IPRs: Communication from the US', Document MTN.GNG/NG11/W/70 (11 May 1990).

General Agreement on Tariffs and Trade, 'Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay', Document MTN.GNG/NG11/W/71 (14 May 1990).

General Agreement on Tariffs and Trade, 'Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Aspects of IPRs: Communication from the Switzerland', Document MTN.GNG/NG11/W/73 (14 May 1990).

General Agreement on Tariffs and Trade, 'Main Elements of a Legal Text for TRIPS: Communication from Japan', Document MTN.GNG/NG11/W/74 (15 May 1990).

General Agreement on Tariffs and Trade, 'Status of Work in the Negotiation Group: Chairman's Report to the GNG', Document MTN.GNG/NG11/W/76 (23 July1990).

General Agreement on Tariffs and Trade, 'Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', Document MTN.TNC/W/35/Rev. 1 (3 December 1990).

General Agreement on Tariffs and Trade, 'Meeting at Ministerial Level, Brussels, 3-7 December 1990', Document MTN.TNC/18 (MIN) (18 December 1990).

General Agreement on Tariffs and Trade, 'Trade Negotiations Committee 16th Meeting on 25 April 1991', Document MTN.TNC/20 (7 May 1991).

General Agreement on Tariffs and Trade, 'Draft Final Act Embodying the Results of the Uruguay Round on Multilateral Trade Negotiations', Document MTN.TNC/W/FA (20 December 1991).

Geng, K. (2003) Should China provide intellectual property protection for genetically modified animals?, *Northwestern Journal of International Law and Business*, 23, 467.

Gervais, D. (2008) *The TRIPS Agreement: drafting history and analysis*, London, Sweet and Maxwell.

Government of Canada, Biotechnology transforming society: creating an innovative economy and a higher quality of life, http://www.bioportal.gc.ca/CMFiles/11865_CAN_BIO_REP_Ev949SFJ-922004-3421.pdf (Accessed: 21 December 2011).

Government of Canada, Biostrategy: the 1998 Canadian Biotechnology Strategy, http://www.biostrategy.gc.ca/english/View.asp?pmiid=520&x=535 (Accessed: 15 February 2012).

Grubb, P. (1999) *Patents for chemicals, pharmaceuticals and biotechnology: fundamentals of global law, practice and strategy*, Oxford, Oxford University Press.

Haertal, K. (1981) *European Patent Convention: english translation by Volker Vossius*, C.Heymanns.

Harian Metro, Conspiracy to raise price of chicken, 12 January 1998.

Hargreaves, I. Digital opportunity: a review of intellectual property and growth, May 2011, http://www.ipo.gov.uk/ipreview-finalreport.pdf (Accessed: 13 February 2012) 1-130.

Health Canada (HC), Food and nutrition: approved products, http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php (Accessed: 19 December 2011).

Health Canada, Novel food regulation in Canada, http://www.ciphi.nl.ca/Novel%20Foods.pdf (Accessed: 19 December 2011).

Health Canada, Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, titled 'Elements of precaution: recommendations for the regulation of food biotechnology in Canada', 23 November 2001, http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/RSC_response-reponse_SRC-eng.php (Accessed: 15 February 2012).

Health Canada, Division 28, Part B.28.001, of the Food and Drug Regulations (Novel Foods) http://www.hc-sc.gc.ca/fn-an/consult/_novel_foods/consultation_appendix-annexe1-eng.php (Accessed: 15 February 2012).

Health Canada, Food Directorate Interim Policy on Foods from Cloned Animals, http://www.hc-sc.gc.ca/fn-an/legislation/pol/pol-cloned_animal-clones_animaux-eng.php (Accessed: 15 February 2012).

Health Canada, Guidelines for the Safety Assessment of Novel Foods, June 2006, http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php (Accessed: 15 February 2012).

Health Canada, Progress Report: June 2005 - Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report, http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/prog-rep-rap_06_2005-eng.php (Accessed: 15 February 2012).

Health Canada, Reports and publications: biotechnology, http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/index-eng.php (Accessed: 15 February 2012).

Health Canada, Report of stakeholder comments on proposed revisions to Health Canada's guidelines for the safety assessment of novel foods derived from plants, microorganisms and Health Canada's responses to these comments, http://www.hc-sc.gc.ca/fn-an/consult/novel-nouveaux/index-eng.php (Accessed: 16 February 2012).

Health Canada, Genetically modified (GM) foods and other novel foods, http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php (Accessed: 9 March 2012).

Heinemann, A. (1996) Trade-related aspects of IPRs: report on the 9th Ringberg Symposium from July 6 to 8, 1995, in Beier, F.K., and Schricker, G. (eds) *From GATT to TRIPS – The Agreement on Trade-related Aspects of IPRs*, New York, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law.

Holzapfel, H. and Werner, G. (2009) Interpreting exceptions in intellectual property law, in Wolrad Prinz zu Waldeck und Pyrmont, Adelman, M.J., Brauneis, R., Drexl, J., and Nack, R. (eds) *Patents and technological progress in a globalized world*, Berlin, Springer.

Howard, A., and Reinbothe, J. (1991) The state of play in the negotiations on TRIPs (GATT/Uruguay Round), *European Intellectual Property Review*, 13, 5,157.

Huang, J., Zhang, D., Yang, J., Rozelle, S., and Kalaitzandonakes, N. (2008) Will the Biosafety Protocol hinder or protect the developing world: learning from China's experience, *Food Policy*, 33, 1.

Ibrahim, A. and Joned, A. (1995) *The Malaysian legal system*, Kuala Lumpur, Dewan Bahasa dan Pustaka.

Imam, A.M. (2006) How does patent protection help developing countries? *International Review of Intellectual Property and Competition Law*, 37, 3, 245.

Industry Canada, Emerging technologies tracking research, June 2006, http://www.ic.gc.ca/eic/site/ic1.nsf/eng/04275.html (Accessed: 22 December 2011).

Intellectual Property Corporation of Malaysia (MyIPO), Corporate information, http://www.myipo.gov.my/en/about-myipo.html (Accessed: 8 April 2011).

Intergovernmental Conference for the Setting Up of a European System for the Grant of Patents, 'First Preliminary Draft of a Convention Establishing a European System for the Grants of Patents' Document BR/88/71 (15 February 1971).

International Union for Conservation of Nature and Natural Resources (IUCN), Red list of threatened species, http://www.iucnredlist.org/apps/redlist/details/13972/0 (Accessed: 2 November 2011).

Jaafar, J. (2004) Emerging trends of urbanisation in Malaysia, *Journal of the Department of Statistics Malaysia*, 1, 43.

Jaffe, G. (2005) Implementing the Cartagena Biosafety Protocol through national biosafety regulatory systems: an analysis of key unresolved issues, *Journal of Public Affairs*, 5, 299.

Johnson, W.H., Delanney, L.E., Williams E.C., and Cole, T.A. (1969) *Principles of zoology*, Holt, Rinehart and Winston.

Jungcurt, S., and Schabus, N. (2010) Liability and redress in the context of the Cartagena Protocol on Biosafety, *Review of the European Community and International Environmental Law*, 19, 2, 197.

Kabir, S.M.L. (2010) Avian flu (H5N1): threat of 'global pandemic' is growing and it's impact on the developing countries' economy, 4 *African Journal of Microbiology Research*, 4, 12, 1192.

Kamber, M. (2003) Coming out of the maze: Canada grants the Harvard Mouse Patent, *Washington International Law Review*, 761.

Kamstra, G., Döring, M., Scott-Ram, N., Sheard A., and Wixon, H. (2002) *Special report: patents on biotechnological inventions: The E.C Directive*, Sweet and Maxwell.

Kanani, K. (2002) Transgenic animal patents: The Harvard mouse on the Canadian frontier, *Canadian Intellectual Property Review*, 543.

Keong, N.W. (2004) Researching the use of Palm Kernel Cake in aquaculture feeds, *Malaysian Palm Oil Board*, 19.

Kevles, D.J. (2002) *A history of patenting life in the US with comparative attention to Europe and Canada*, Luxembourg, Office for Official Publications of the European Communities.

Khor, M. (1995) ASEAN raises concerns on life patenting at the WTO, *Third World Economics*.

Kinderler, J. (2008) The Cartagena Protocol on Biosafety, *Collection of Biosafety Reviews*, 4, 12.

Kirby, A., Atlantic salmon in short supply, *BBC News*, 31 May 2000, http://news.bbc.co.uk/1/hi/sci/tech/769646.stm (Accessed: 20 December 2010).

Kochhar, H.P.S., and Evans, B.R. (2007) Current status of regulating biotechnology-derived animals in Canada – animal health and food safety considerations, *Theriogenology*, 67, 188.

Kochhar, H.P.S., Gifford, G.A., and Kahn, S. (2005) Regulatory and biosafety issues in relation to transgenic animals in food and agriculture, feeds containing genetically modified organisms (GMO) and veterinary biologics, in Makkar, H.P.S., and Viljoen, G.J. (eds) *Applications of gene-based technologies for improving animal production and health in developing countries*, Springer.

Komen, J., and Persley, G. (1993) 'Agricultural biotechnology in developing countries: a cross-country review', ISNAR Research Report.

Krishna, P., and Perry, M. (2001) Making sense of mouse tales: Canada life form patents topsy-turvy, *European Intellectual Property Review*, 23, 4, 196.

Kuanpoth, J. (2008) Intellectual property protection after TRIPs: an Asian perspective, in Malbon, J., and Lawson, C. (eds) *Interpreting and implementing the TRIPs Agreement: is it fair?*, Edward Elgar.

Lander, S. (2010) Low in fat – high in taste: fat replacement technology, *Food Marketing and Technology*, 16.

Lèger, J.A. (1994) Patent infringement: back to good sense in Henderson, G.F. (ed) *Patent law of Canada*, Toronto, Carswell.

Letter to Minister Rock, John Reid, President of the Canadian Advanced Technology Alliance to the Minister of Industry dated 9 December 2002, http://wwwcata.ca?Advocacy/Industry_Canada/MinRockHarMouse.html (Accessed: 4 January 2010).

Loo, E.V., Caputo, V., Nayga Jr., R.M., Meullenet, J., Crandall, P.G., and Ricke, S.C. (2010) Effect of organic poultry purchase frequency on consumer attitudes toward organic poultry meat, *Journal of Food Science*, 75, 384.

Ludlow, K. (1999) Genetically modified organisms and their products as patentable subject-matter in Australia, *European Intellectual Property Review*, 21, 6, 298.

MacLaughlin, S.J. (2003) Food for the twenty-first century: an analysis of regulations for genetically engineered food in the United States, Canada and the European Union, *Industrial International and Comparative Law Review*, 14, 1, 375.

MacQueen, H., Waelde, C., and Laurie, G. (2007) *Contemporary intellectual property: law and policy*, Oxford University Press.

Malaysian Agricultural Research and Development Institute, IP status, http://www.mardi.my/web/guest/ip-status (Accessed: 9 January 2012).

Malaysian Biotechnology Corporation, BiotechCorp Annual Report 2008, http://www.biotechcorp.com.my (Accessed: 21 December 2009).

Malaysian Biotechnology Corporation, Overview: Malaysian agricultural biotechnology, http://biotechcorp.inventgw.com/wp-content/uploads/2011/11/publications/White_Paper_Agricultural.pdf (Accessed: 17 December 2010).

Malaysian Biotechnology Corporation, Patent protection in Malaysia – a basic information guide, http://www.biotechcorp.com.my/wp-content/uploads/2011/11/downloads_aboutmalaysia/IP_Booklet_Patents_V1.pdf (Accessed: 5 March 2012).

Malaysian Biotechnology Corporation, Bionexus: A special award for an exceptional group http://www.biotechcorp.com.my/bionexus-new/ (Accessed: 21 April 2012).

Malaysian Biotechnology Information Centre, Biotechnology in Malaysia, http://www.bic.org.my/?action=localscenario&do=biotechnology (Accessed: 17 December 2010).

Malaysian Hansard HR vol 1 cols 7767-7768 (25 July 1983).

Malaysian Hansard, HR vol 1cols 7916, 7941, 7943 (26 July 1983).

Marshall, J.M. (2010) The Cartagena Protocol and genetically modified mosquitoes, *Nature Biotechnology*, 28, 9, 896.

Maskus, K.E. (2000) Intellectual property rights and economic development, *Case Western Reserve Journal of International Law*, 32, 471.

Maskus, K.E. (2005) Using the international trading system to foster technology transfer for economic development, *Michigan State Law Review*, 219.

Matsushita, M., Schoenbaum, T.J., and Mavroidis, P.C. (2003) *The World Trade Organization: law, practice and policy*, Oxford, The Oxford International Law Library.

Mayr, E. (1969) *Principles of systematic zoology*, New York, McGraw-Hill Book Company.

Mazzocchi, M., Brasili, C., and Sandri, E. (2007) Trends in dietary patterns and compliance with World Health Organization recommendations: a cross-country analysis, *Public Health Nutrition*, 11, 5, 535.

McCabe, K.W. (1998) The January 1999 review of Article 27 of the TRIPs Agreement: diverging views of developed and developing countries toward the patentability of biotechnology, *Journal of Intellectual Property Law*, 41.

McKelvey, B., and Marshall, G. (2007) Food supply – can we meet the demand?, *Journal of the Royal Agricultural Society of England*, 168, 1.

Meyer, H. (2000) The Cartagena Protocol on Biosafety, *Biotechnology and Development Monitor*, 43, 2.

Mills, O. (2005) *Biotechnological inventions: moral restraints and patent law*, Ashgate.

Ministry of Agriculture and Agro-Based Industry Malaysia, Imports of agriculture sector, http://www.moa.gov.my (Accessed: 25 October 2010).

Ministry of Agriculture and Agro-Based Industry, Malaysia, Kenyataan media: pengimportan daging kerbau dari India, http://www.moa.gov.my/web/guest/siaranakhbar_april3 (Accessed: 3 December 2010).

Ministry of Agriculture and Agro-Based Industry Malaysia, Third National Agricultural Policy (1992-2010), http://moa.gov.my/web/guest/dpn3 (Accessed: 3 December 2010).

Ministry of Health Malaysia, Health facts 2009, http://moh.gov.my/images/gallery/stats/heal_fact/healthfact-P_2009.pdf (Accessed: 29 November 2010).

Ministry of Natural Resources and Environment Malaysia, Permohonan untuk kelulusan uji kaji lapangan untuk tanda-lepas-tangkap semula secara terhad (MRR) nyamuk Aedes aegypti jenis liar dan jenis trangenik OX513A(My1): Rumusan isu-isu dari konsultasi awam, 29 October 2010, http://www.biosafety.nre.gov.my/consultation/Isu-Isu%20Konsultasi%20Awam%20v2.pdf (Accessed: 21 March 2011).

Ministry of Natural Resources and Environment Malaysia, Wild type and aedes aegypti genetically modified mosquitoes OX513A(My1), http://www.biosafety.nre.gov.my/app_field/nbb_decision.shtml (Accessed: 21 March 2011).

Mohr, A., Busby, H., Hervey, T., and Dingwall, R. (2012) Mapping the role of official bioethics advice in the governance of biotechnologies in the EU: the European Group on Ethics opinion on commercial cord blood banking, *Science and Public Policy*, 39, 105.

Morrow, A.D., and Ingram, C.B. (2005) Of transgenic mice and roundup ready canola: the decisions of the Supreme Court of Canada in *Harvard College v Canada* and *Monsanto v Schmeiser*, *University of British Colombia Law Review*, 38, 1, 189.

Morrow, J.D. (1994) Patentable subject matter: emerging technologies in Henderson, G.F. (ed) *Patent law of Canada*, Toronto, Carswell.

Muir, W.M., and Howard, R.D. (2001) Fitness components and ecological risks of transgenic release: a model using Japanese Medaka *(Oryzias latipes) The American Naturalist*, 158, 1, 1.

Munn-Venn, T., and Mitchell, P., The Conference Board of Canada, Biotechnology in Canada: a technology platform for growth, Report December 2005, http://www.agwest.sk.ca/biotech/documents (Accessed: 19 December 2011).

National Biosafety Malaysia Board Decision, Application for approval for limited mark-release-capture of Aedes aegypti wild type and aedes aegypti genetically modified mosquitoes OX513A(My1), http://www.biosafety.nre.gov.my/app_field/nbb_decision.shtml (Accessed: 21 March 2011).

National Bureau of Animal Genetic Resources, India, Guidelines for Registration of Livestock and Poultry Breeds, http://www.nbagr.res.in/guidelines.html (Accessed: 21 May 2011).

Nature, New Zealand's GM cattle under fire, 27 March 2010.

New Straits Times, No reason to increase meat prices, 26 February 1993.

New Straits Times, 50 more BioNexus firms in 2 years, 17 November 2009.

New Straits Times, Government to check on festive price hikes, 14 August 2010.

New Straits Times, Aedes mosquito experiment: too many risks involved, 6 September 2010.

Nijar, G.S., Lawson-Stopps, S., and Fern, G.P. (2008) *Liability and redress under the Cartagena Protocol on Biosafety: a record of the negotiation for developing international rules*, Centre of Excellence for Biodiversity Law.

Niosi, J. (2005) Biotechnology, in Niosi, J. *Canada's regional innovation systems: the science-based industries*, McGill-Queen's University Press.

Noor, M.I. (2002) The nutrition and health transition in Malaysia, *Public Health Nutrition*, 5, 1(A), 191.

North Atlantic Salmon Conservation Organization (NASCO) (2010) 'Focus area report: aquaculture, introductions and transfers, and transgenics, United Kingdom (Scotland)'.

Oh, C. (2003) IPRs and biological resources: implications for developing countries, *Journal of Intellectual Property Rights*, 8, 400.

Organic Consumers Association, Harvard Mouse patent denied in Canada: biotech industry hard hit http://www.purefood.org/Patent/041903_mouse_patent.cfm, (Accessed: 10 December 2011).

Organisation for Economic Co-operation and Development (OECD), (1999) 'Intellectual property practices in the field of biotechnology', Document TD/TC/WP (98) 15/Final (2 February 1999).

Organisation for Economic Co-operation and Development, (2009) The bioeconomy to 2030: designing a policy agenda, http://www.oecd.org/dataoecd/5/24/42837897.pdf (Accessed: 5 April 2011).

Organisation for Economic Co-operation and Development- Food and Agriculture Organization of the United Nations (OECD-FAO), Agricultural Outlook 2010-2019: Highlights, http://www.agri-outlook.org/dataoecd/13/13/45438527.pdf (Accessed: 26 October 2010).

Organisation for Economic Co-operation and Development- Food and Agriculture Organization of the United Nations (OECD-FAO), Agricultural Outlook 2011-2020, http://www.agri-outlook.org/dataoecd/2/36/48184304.pdf (Accessed: 27 September 2011).

Organisation for Economic Co-operation and Development, Biotechnology Statistics 2009, http://www.oecd.org/dataoecd/4/23/42833898.pdf (Accessed: 19 December 2011).

Oudemans, G. (1963) *The draft European Patent Convention: a commentary with english and french texts*, London, Stevens & Sons Limited.

Ozor, N., and Igbokwe, E.M. (2007) Roles of agricultural biotechnology in ensuring food security in developing societies, *African Journal of Biotechnology*, 6, 14, 1597.

Pacon, A.M. (1996) What will TRIPs do for developing countries?, in Beier, F.K., and Schricker, G. (eds) *From GATT to TRIPS – The Agreement on Trade-related Aspects of IPRs*, New York, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law.

Param, S., GM Mosquitoes could help save many lives, *The Star*, http://www.thestar.com.my (Accessed: 21 December 2010).

Patents Working Party (PWP), 'Comments on the First Preliminary Draft Convention Relating to a European Patent Law of 14 March 1961', Document IV/2071/61-E.

Patents Working Party, 'Proceedings of the 1st Meeting of the Patents Working Party held at Brussels from 17-28 April 1961', Document IV/2767/61-E (3 May 1961).

Patents Working Party, 'Proceedings of the 5th Meeting of the Patents Working Party held at Brussels from 2-18 April 1962', Document 3076/IV/62-E (22 May 1962).

Paterson, G. (1992) *The European patent system: the law and practice of the European Patent Convention*, Sweet and Maxwell.

Perry, M. (2004) Lifeforms patents: the high and the low, *Journal of International Biotechnology Law*, 1, 20.

Perry, M. (2008) From Pasteur to *Monsanto*: approaches to patenting life in Canada, in Gendreau, Y. (ed) *An emerging intellectual property paradigm: perspective from Canada*, Edward Elgar.

Phipps, R.H., and Cockburn, A. (2004) GM technology: a tool to benefit livestock production, in Owen, E., Smith, T., Steele, M.A., Anderson, S., Duncan, A.J., Herrero, M., Leaver, J.D., Reynolds, C.K., Richards, J.I., Ku-Vera, J.C. (eds) *Responding to the livestock revolution*, Nottingham University Press.

Pila, J. (2009) Article 53(b) EPC: a challenge to the Novartis theory of European patent history, *The Modern Law Review*, 72, 3, 436.

Pilling, D., Cardellino, R., Zjalic, M., Rischkowsky, B., Tempelman, K.A., and Hoffmann, I. (2007) The use of reproductive and molecular biotechnology in animal genetic resource management – a global overview, *Animal Genetic Resources Information*, 40, 1.

Putra University of Malaysia, Commercialized products, http://www.vet.upm.edu.my/eresearch5.html (Accessed: 17 December 2010).

Putra University of Malaysia, Faculty of Agriculture: facts and figures, http://www.rmc.upm.edu.my/upmip/index.php?content=faculty&fac=1 (Accessed: 9 January 2012).

Rasmussen, R.S., and Morrissey, M.T. (2007) Biotechnology in aquaculture: transgenics and polyploidy, *Comprehensive Reviews in Food Science and Food Safety*, 6, 2.

Reichhardt, T. (2000) Will souped salmon sink or swim?, *Nature*, 406, 10.

Reiss, T., Hinze, S., and Lacasa, I.D. (2004) Performance of European Member States in biotechnology, *Science and Public Policy*, 31, 5, 344.

Rollin, F., Kennedy J., and Wills, J. (2011) Consumers and new food technologies, *Trends in Food Science and Technology*, 99.

Rosendal, G.K. (2006) Balancing access and benefit sharing and legal protection of innovations from bioprospecting: impacts on conservation of biodiversity, *The Journal of Environment and Development*, 15, 4, 428.

Royal Society of Canada (RSC), Elements of precaution: recommendations for the regulation of food biotechnology in Canada, January 2001, http://www.rsc.ca//files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf (Accessed: 15 February 2012).

Scassa, T. (2003) A mouse is a mouse is a mouse: a comment on the Supreme Court of Canada's decision on the Harvard Mouse patent (Harvard College v Canada (Comr of Patents)), *Oxford University Commonwealth Law Journal*, 3, 1, 105.

Schnier, D.J. (2001) Genetically modified organisms and the Cartagena Protocol, *The Fordham Environmental Law Journal*, 12, 377.

Schuh, R.T. (2000) *Biological systematic: principles and applications*, Ithaca, Cornell University Press.

Science University of Malaysia, http://cserver.cs.usm.my/patent/Search_Patent.aspx (Accessed: 17 December 2010).

Sechley, K. (2004) Schmeiser versus Monsanto, *Nature Biotechnology*, 22, 7, 803.

Sell, S.K. (2009) From forum-shifters to shape-shifters: rulemaking and enforcement in intellectual property, Paper presented at the annual meeting of the International Studies Association's (ISA) 50th Annual Convention 'Exploring the past, anticipating the future', New York City, http://www.allacademic.com//meta/p_mla_apa_research_citation/3/1/0/4/2/pages310424/p310424-1.php (Accessed: 29 March 2011).

Sheng, T.Y., Shamsudin, M.N., Alias, R., Zainalabidin, M., and Amin, M.A. (2008) Demand for beef in Malaysia: preference for quantity, quality or lean?, *International Food Research Journal*, 15, 3, 347.

Sheng, T.Y., Shamsudin, M.N., Mohamed, Z., Abdullah, A.M., and Radam, A. (2008) Complete demand systems of food in Malaysia, *Agricultural Economics*, 10, 467.

Shun, G.W.S. (2003) *Mus musculus* and *Homo sapiens*: murine metaphysics and the Canadian Supreme Court, *Singapore Journal of Legal Studies*, 38.

Siebrasse, N. (2004) Comment on *Monsanto Canada Inc. v Schmeiser*, *Canadian Bar Review*, 1.

Siebrasse, N. (2010) Intellectual property protection for higher life forms: current law and policy, *The Integrated Assessment Journal*, 10, 1, 23.

Simpson, G.G. (1961) *Principles of animal taxonomy*, London, Oxford University Press.

Singer, M. and Stauder, D. (2003) *European Patent Convention: a commentary: Vol. I*, Sweet and Maxwell.

Singh, A. (2005) Proceed with precaution: the statutory, legal, and consumer influence on genetically modified foods in Canada, *Canadian Journal of Law and Technology*, 181.

Singh, P.J. (2010) *Sui generis* protection of animal genetic resources: An initiative by the Indian Council of Agricultural Research (ICAR), in Biber-Klemm, S., and Temmerman, M., Rights to animal genetic resources for food and agriculture: notes from an interdisciplinary workshop, Working Paper No 2010/05, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652166 (Accessed: 31 March 2011).

Sinohin, V.O., and Diokno, G.R. (2001) The biosafety protocol: a complement to modern biotechnology, *CANOPY International*, 27, 5, 6.

Smith, C. (2005) A practical guide to Chinese patent law, *Seton Hall Legislative Journal*, 29, 2, 643.

Speech of the 5th Prime Minister of Malaysia, His Excellency Datuk Seri Abdullah bin Haji Ahmad Badawi, at the official launch of BioMalaysia 2006, 6 December 2006, http://www.pmo.gov.my (Accessed: 20 November 2009).

Statistics Canada, Canada's beef cattle sector and the impact of BSE on farm family income 2000-2003, http://publications.gc.ca/collections/Collection/Statcan/21-601-MIE/21-601-MIE2004069.pdf (Accessed: 28 December 2011).

Steinfield, H., and Chilonda, P. (2006) Old players, new players, in Food and Agriculture Organization of the United Nations, Livestock Report, ftp://ftp.fao.org/docrep/fao/009/a0255e/a0255e.pdf (Accessed: 26 October 2010).

Stewart, T.P. (ed) (1993) *The GATT Uruguay Round: a negotiating history (1986-1992), Volume II: commentary*, Deventer, Kluwer Law and Taxation Publishers.

Straus, J. (1997) *The present state of patent systems in the European Union: as compared with the situation in the United States and Japan*, Luxembourg, Office for Official Publications of The European Communities Stationery Office.

Sustainable Animal Breeding (SABRE), http://www.sabre-eu.eu/ (Accessed: 3 October 2011).

Syed Ahmad, S.S. (2007) *Malaysian legal system*, Lexis Nexis.

Tape, C.L., and McCourt, C.D.M. (2003) Supreme Court kills Harvard's Mouse, *Bio Business*, 16.

Taxonomy of the Cephalopods, http://www.molluscs.at/cephalopoda/taxonomy.html (Accessed: 5 October 2011).

Temmerman, M. (2006) The patentability of animal genetic inventions. Pt.1, NCCR International Trade: Stocktaking paper no. 2006/4.

Teschemacher, R. (1987) Patentable subject matter under the European Patent Convention (EPC) in the field of biotechnology and disclosure and manner of claiming of biotechnological inventions before the European Patent Office, Paper presented in the Symposium on the Protection of Biotechnological Inventions, 89-115.

The 2010 Eurobarometer on the life sciences, (2011) *Nature Biotechnology*, 29, 2, 113.

The Joint Scandinavian Patent Committees, (1971) 'The Preliminary Report by the Joint Scandinavian Patent Committees: Draft Patent Law and Extracts from the Explanatory Notes' (25 March 1971).

The Livestock Auctioneers Association Limited, Time for industry to act, http://www.laa.co.uk/news_details.php?RID=69 (Accessed: 3 March 2012).

The Roslin Institute, University of Edinburgh, http://www.roslin.ed.ac.uk/ (Accessed: 3 October 2011).

The Star, Global crisis as food prices soar, 14 April 2008, http://thestar.com.my/news/story.asp?file=/2008/4/14/focus/20942898&sec=focus (Accessed: 22 November 2010).

The Star, More local inventions: scientists and researchers to get good payouts from Government, 23 June 2009, http://thestar.com.my/news/story.asp?file=/2009/6/23/nation/4175423&sec=nation (Accessed: 17 December 2010).

The United Kingdom Halal Food Authorities (HFA), http://www.halalfoodauthority.co.uk/definitionhalal.html (Accessed: 30 November 2010).

Third meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 3) – Meeting decision BS-III/10, 'Handling, transport, packaging and identification of living modified organisms : paragraph 2(a) of Article 18', http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11066 (Accessed : 21 March 2012).

Thompson, D. (1973) The draft Convention for a European Patent, *International and Comparative Law Quarterly*, 22, 51.

Thornton, P.K. (2010) Livestock production: recent trends, future prospects, *Philosophical Transactions of the Royal Society B*, 365, 2853.

Tonukari, N.J., and Omotor, D.G. (2010) Biotechnology and food security in developing countries, *Biotechnology and Molecular Biology Reviews*, 5, 1, 13.

Tritton, G. (1996) *Intellectual property in Europe*, London, Sweet and Maxwell.

Tvedt, M.W. (2007) Patent protection in the field of animal breeding, *Acta Agriculturae Scand Section A*, 57, 105.

Tvedt, M.W., Hiemstra, S.J., Drucker, A.G., Louwaars, N., and Oldenbroek, K. (2007) Legal aspects of exchange, use and conservation of farm animal genetic resources, Fridtjof Nansens Institut (FNI) Report 1/2007.

UNCTAD-ICTSD, (2005) *Resource book on TRIPS and development*, Cambridge University Press.

United Kingdom Food Standard Agency (UKFSA), Meat and milk from cloned animals, 7 December 2010, http://www.food.gov.uk/news/newsarchive/2010/dec/boardcloning (Accessed: 8 April 2012).

United Kingdom Parliament Lords Hansard, 'Genetic Modification in Agriculture: ECC Report', http://www.publications.parliament.uk/pa/ld199899/ldhansrd/vo990527/text/90527-08.htm (Accessed: 19 November 2010).

United Nation, World population prospects: the 2008 revision population database, http://esa.un.org/unpp/p2k0data.asp (Accessed: 26 November 2010).

United States Department of Agriculture (USDA) Foreign Agricultural Service, Animal Biotech Policy and Research in the EU, Global Agricultural Information Network (GAIN) Report, 14 September 2009, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Animals_Berlin_EU-27_9-1-2009.pdf (Accessed: 23 September 2011).

United States Department of Health and Human Services, FDA issues documents on the safety of food from animal clones, 15 January 2008, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116836.htm (Accessed: 12 March 2012).

University of Guelph, Enviropig, http://www.uoguelph.ca/enviropig/index.shtml (Accessed: 19 December 2011).

University of Guelph, Enviropig: financial contributors to Enviropig research, http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).

University of Guelph, Enviropig: history, http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).

University of Guelph, Enviropig: technology http://www.uoguelph.ca/enviropig/technology.shtml (Accessed: 19 December 2011).

USDA Foreign Agricultural Service, Canada biotechnology – GE plants and animals: agricultural biotechnology annual report, Global Agricultural Information Network (GAIN) Report, 8 August 2010, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Plants%20and%20Animals_Ottawa_Canada_08-05-2010.pdf (Accessed: 15 December 2011).

USF-HICOM, http://www.usf-hicom.com.my/about_usf.html (Accessed: 29 July 2010).

Vanderbyl, S., and Kobelak, S. (2007) Critical success factors for biotechnology industry in Canada, *Journal of Commercial Biotechnology*, 13, 68.

van Doorn, J., and Verhoef, P.C. (2011) Willingness to pay for organic products: differences between virtue and vice foods, *International Journal of Research in Marketing*, 28, 167.

van Eenennaam, A.L. (2006) What is the future of animal biotechnology, *California Agriculture*, 60, 3, 132.

van Eenennaam, A.L., Is livestock cloning another form of genetic engineering?, http://agribiotech.info/details/Alison%20-%20cloning%20March%208%20-%2003.pdf (Accessed: 26 April 2012).

van Wezemael, L., Verkebe, W., de Barcellos, M.D., Scholderer, J., and Pérez-Cueto, F.J.A. (2010) Consumer perceptions of beef healthiness: results from a qualitative study in four European countries, *BMC Public Health*, 10, 342, 1.

Verbeke, W., Pérez-Cueto, F.J.A., de Barcellos, M.D., Krystallis, A., and Grunert, K.G. (2010) European citizen and consumer attitudes and preferences regarding beef and pork, *Meat Science*, 84, 284.

Victoria, M. (ed) (1978) *The Patents Act 1977: Queen Mary College Patent Conference Papers*, London, Sweet and Maxwell.

Vossius, V. (1990) Patent protection for animals; Onco-Mouse/Harvard, *European Intellectual Property Review*, 12, 7.

Walker, P.J. (2004) Disease emergence and food security: global impact of pathogens on sustainable aquaculture production, in Brown, A.G. (ed) Fish, aquaculture and food security: sustaining fish as a food supply, Record of a conference conducted by the ATSE Crawford Fund Parliament House, Canberra.

Warren-Jones, A. (1998) A mouse in sheep's clothing: the challenge to the patent morality criterion posed by "Dolly", *European Intellectual Property Review*, 445.

Warren-Jones, A. (2001) *Patenting rDNA: human and animal biotechnology in the United Kingdom and Europe*, Oxford, Lawtext Publishing.

Warren-Jones, A. (2004) Patenting DNA: a lot of controversy over a little intangibility, *Medical Law Review*, 12, 1, 97.

Watal, J. (1999) Implementing the TRIPs Agreement on patents: optimal legislative strategies for developing countries, in Lippert, O. (ed) *Competitive strategies for the protection of intellectual property*, Canada, Fraser Institute.

Waters-Bayer, A., and Bayer, W. (2004) Research to alleviate poverty in the face of industrialisation of livestock production, in Owen, E., Smith, T., Steele, M.A., Anderson, S., Duncan, A.J., Herrero, M., Leaver, J.D., Reynolds, C.K., Richards, J.I., Ku-Vera, J.C. (eds) *Responding to the livestock revolution*, Nottingham University Press.

Wheeler, M.B. (2007) Agricultural applications for transgenic livestock, *Trends in biotechnology*, 25, 5, 204.

White, J.B., Higher life forms are not patentable in Canada – for now, http://www.osler.com/uploadedFiles/Resources/up-423.pdf, (Accessed: 4 January 2010).

World Bank, Minding the stock: bringing public policy to bear on livestock sector development, http://siteresources.worldbank.org/INTARD/Resources/FinalMindingtheStock.pdf (Accessed: 26 November 2010).

World Food Programme, Food out of reach: pathway to the financial crisis, http://www.wfp.org/photos/gallery/food-crisis-timeline (Accessed: 22 November 2010).

World Health Organization (WHO), Global strategy on diet, physical activity and health, http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf (Accessed: 29 November 2010).

World Health Organization, 2008-2013: action plan for the global strategy for the prevention and control of non-communicable diseases, http://www.who.int/nmh/Actionplan-PC-NCD-2008.pdf (Accessed: 29 November 2010).

World Health Organization, What can I do to avoid a heart attack or a stroke?, http://www.who.int/features/qa/27/en/ (Accessed: 30 November 2010).

World Health Organization, 'Diet, nutrition and the prevention of chronic diseases: report of a Joint WHO/FAO Expert Consultation (2003)', http://www.who.int/dietphysicalactivity/publications/trs916/en/ (Accessed: 17 March 2011).

World Intellectual Property Organization (WIPO), (1979) *WIPO Model Law for Developing Countries on Inventions, Volume 1: Patents*, Geneva.

World Intellectual Property Organization, (1983) Review of regional project activities in 1981/1982, *Industrial Property in Asia and the Pacific*, 2-3.

World Intellectual Property Organization, 'Exclusions from Patent Protection: Memorandum of the International Bureau of WIPO', Document HL/CE/IV/INF/1 (30 May 1988).

World Intellectual Property Organization, 'Industrial Property Protection of Biotechnological Inventions: Report adopted by the Committee of Experts', Document BiOT/CE/IV/4 (28 October 1988).

World Intellectual Property Organization, What is WIPO?, http://www.wipo.int/about-wipo/en/what_is_wipo.html (Accessed: 9 February 2010).

World Intellectual Property Organization, World Intellectual Property Indicators 2010: Foreign-oriented patent families by field of technology, http://www.wipo.int/ipstats/en/ (Accessed: 9 April 2011).

World Intellectual Property Organization, WIPO IP facts and figures 2011, http://www.wipo.int/export/sites/www/ipstats/en/statistics/patents/pdf/wipo_pub_943_2011.pdf (Accessed: 26 October 2011).

World Trade Organization (WTO), 'Council for Trade-related Aspects of IPRS Minutes of Meeting', Document IP/C/M/29 (6 March 2001).

World Trade Organization, 'Council for Trade-related Aspects of IPRS Minutes of Meeting', Document IP/C/M/30 (1 June 2001).

World Trade Organization, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from the European Communities and their Member States', Document IP/C/W/383 (17 October 2002).

World Trade Organization, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from Switzerland', Document IP/C/W/400/Rev.1 (18 June 2003).

World Trade Organization, 'Taking forward the review of Article 27.3(b) of the TRIPs Agreement: Joint communication from the African Group', Document IP/C/W/404 (26 June 2003).

World Trade Organization, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from Peru', Document IP/C/W/447 (8 June 2005).

World Trade Organization, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication by the United States', Document IP/C/W/449 (10 June 2005).

World Trade Organization, 'The relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the protection of traditional knowledge: Technical observations on the United States submission IP/C/W/449 by Bolivia, Brazil, Colombia, Cuba, India and Pakistan', Document IP/C/W/459 (18 November 2005).

World Trade Organization, 'Review of the provisions of Article 27.3(b): Summary of issues raised and points made', Document IP/C/W/369/Rev.1 (9 March 2006).

World Trade Organization, 'Article 27.3(b) - Relationship between the TRIPs Agreement and the CBD and Protection of Traditional Knowledge and Folklore: Communication from the United States', Document IP/C/W/469 (13 March 2006).

World Trade Organization, Understanding the WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf (Accessed: 8 February 2010).

World Trade Organization, Dispute settlement: the disputes, http://www.wto.org/english/tratop_e/dispu_e/dispu_subjects_index_e.htm#selected_subject (Accessed: 10 July 2010).

World Trade Organization, Understanding the WTO – settling disputes, http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm (Accessed: 15 June 2012).

Wu, G., Sun, Y., and Zhu, Z. (2003) Growth hormone gene transfer in common carp, *Aquatic Living Resources*, 16, 416.

Yang, X., Tian, X.C., Kubota, C., Page, R., Xu, J., Cibelili J., and Suidal Jr, G. (2007) Risk assessment of meat and milk from cloned animals, *Nature Biotechnology*, 25, 1, 77.

Yu, P.K. (2009) The objectives and principles of the TRIPs Agreement, *Houston Law Review*, 46, 4, 979.

Yusoff, K., Biotech R&D scenario in Malaysia, http://www.eumbio.org/papers/BFS/R&D%20Scenario.pdf (Accessed: 17 December 2010).

Zarate, A.V. (2010) Current and projected future flows of AnGR between countries and regions, in Biber-Klemm, S., and Temmerman, M., Rights to animal genetic resources for food and agriculture: notes from an interdisciplinary workshop, Working Paper No 2010/05, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1652166 (Accessed: 31 March 2011).

Zjalić, M., Dimitriadou, A., and Rosati, A. (2006) Beef production in the European Union and the CAP reform: an overview of situation and trends, *Stočarstvo (Professional paper)*, 3, 181.