

Diagnostic Gene Patents: Balancing the rights to access to health care and to property

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List of Abbreviations

ACP	African Caribbean Pacific
AIPLA	American Intellectual Property Law Association
AJA	Acting Judge
AMP	Association for Molecular Pathology
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)
APES	Academic and Professional Editing Services
APOE	Apolipoprotein E gene
APP	Amyloid Precursor Protein
ARV	Antiretroviral
ASEAN	Association of Southeast Asian Nations
BEE	Black Economic Empowerment
BI	Boehringer Ingelheim
BIT	Bilateral Investment Treaties
BRCA	Breast Cancer Gene
BRICS	Brazil, Russia, India, China, South Africa
CANSA	Cancer Association of South Africa
CEPA	Comprehensive Economic Partners Hip Agreement
CF	Cystic Fibrosis
CFTR	Cystic Fibrosis Transmembrane Conductance Regulator
CML	Chronic Myeloid Leukaemia
DNA	Deoxynucleic Acid
DTI	Department of Trade and Industry
ECHR	European Convention on Human Rights
ECJ	European Court of Justice
EMA	European Medicine Evaluation Agency
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FET	Fair and Equitable Treatment

FNB	First National Bank
FTA	Free Trade Agreements
FTAA	Free Trade Area of the Americas
FTPL	Fix the Patent Law Organisation
GATT	General Agreement on Tariffs and Trade
GIST	Gastrointestinal stromal tumours
GPO	German Patent Office
GSK	GlaxoSmithKline
GSP	Generalised System of Preferences
HCHR	High Commissioner for Human Rights
HFE	Human Hemochromatosis Gene
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
ICCPR	International Covenant on Civil and Political Rights
ICE	Information, Communication and Entertainment
ICESCR	International Covenant on Economic, Social and Cultural Rights
IMSA	Innovative Medicines South Africa
INPI	The Instituto Nacional da Propriedade (National Institute of Industrial Property)
IPAB	Intellectual Property Appellate Board
IPO	Indian Patent Office
IPR	Intellectual Property Rights
MFN	Most-Favoured-Nation
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organization
NIH	National Institutes of Health
OUP	Oxford University Publication
PCT	Patent Co-operation Treaty
PHRMA	Pharmaceutical Research and Manufacturers of America
PIASA	Pharmaceutical Industry Association of South Africa
PLWC	People Living with Cancer

PTO	Patent and Trademark Office
RNA	Ribonucleic Acid
SABDA	Schizophrenia and Bipolar Disorder Alliance
SACGHS	Secretary's Advisory Committee on Genetics, Health and Society
SADAG	South African Depression and Anxiety Group
SAFMH	South Africa Federation for Mental Health
SANCD	South African Non-Communicable Diseases
SARS	Severe Acute Respiratory Syndrome
SBCL	SmithKline Beecham Clinical Laboratories
SNP	Single Nucleotide Polymorphisms
SUS	Sistema Único de Saúde (National Health System)
TAC	Treatment Action Campaign
TRIPS	Trade Related Aspects of Intellectual Property
UDHR	Universal Declaration of Human Rights
UN	United Nations
UPC	Unified Patent Court
US	United States
USC	United States Code
USPTO	United States Patents and Trademark Office
USTR	US Trade Representative
WHO	World Health Organisation
WorldLII	World Legal Information Institute
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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Declaration

I, *Sameera Ebrahim-Cassim*, declare that this thesis is my original work. I have not submitted this thesis to any other university or institution. Where works of other individuals are used, references are provided.

Abstract

Technological advances in the medical domain are critical in finding effective diagnostic and therapeutic instruments for curing genetic conditions. These advances include developing diagnostic tools used to diagnose such conditions. Diagnostic gene tests are an example of such a tool. These tests are developed using a gene that corresponds with identified disease-causing genes. The creation and development of diagnostic tests results in the patenting of genetic material becoming a general occurrence which raises the question on whether genetic material, being part of the human body and naturally occurring, could in fact qualify as patentable subject-matter. Several global intellectual property systems do accept and include genes, more specifically, diagnostic genes, as patentable subject matter. This results in overpriced diagnostic gene tests being put on the market remaining economically unavailable to most of the public. The discussion observes the benefits and limitations of patents in the field of biotechnology and explores alternative options including but not limited to patent exemptions and licences. The study then seeks to address the issue by analysing the right to property and health care, in order to find a universal application that allows for both the protection of, and accessibility to, innovation. Despite the public having the right to access health care, including access to diagnostic tests, inventors also have a right to property and seek to protect their invention. The discussion suggests that intellectual property laws, specifically those relating to diagnostic gene tests, should be observed and interpreted with the aim to balance the rights to access to health care and property, in order for the public to fully benefit from scientific development. The study also examines this aspect in selecting foreign jurisdictions and providing a comparative analysis that may provide global guidance around intellectual property and health in this regard.

Chapter 1

1.1 Background and Introduction

“Biotechnology” holds various meanings. Many relate biotechnology to genetic engineering and pharmaceutical applications. However, biotechnology involves more than just these applications and can be grouped into the following categories:

- Classical breeding, where microbes, plants and animals are developed by cross-breeding, selection and traditional mutation techniques;
- Modern production biotechnology, where microbial, plant, or animal cell suspensions and enzymes are modified by molecular biology methods and used for production of various molecules;
- Modification of plants and animals; and
- Genetic manipulation of humans.¹

Biotechnology is technology based on biology, which includes deoxynucleic acid (DNA), used to develop technologies and products.² In 1953, after years of research, scientists came to understand human DNA bringing knowledge and greater understanding of the workings of the human body.³ DNA is a vast chemical information database, including the complete set of instructions needed for creating proteins found in all living substances. In addition to dictating attributes, such as hair and eye colour, it also dictates an individual’s predispositions to genetic diseases, such as cancer, sickle cell disease and Alzheimer’s, allowing diagnoses as early as the prenatal stage.⁴ These genetic advancements allow for development in the area of health.⁵

Collectively DNA is referred to as genes and genes are the medium through which living organisms transmit genetic information from one generation to the next.⁶ Genetic diagnostic testing is the subject of this thesis and is used to identify disease susceptibility, establish diagnostic status and design therapeutic regimens in medical care.⁷ In the year 2000, two teams completed preliminary sequence maps of the human genome.⁸ One team was organised by the public sector and one was privately financed. Once the

¹ Leisola M “*Bioscience, Bio innovations and Bioethics*” (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

² For more details on what constitutes biotechnology, see <https://www.bio.org/what-biotechnology> (accessed 29 November 2018).

³ <http://www.nature.com/scitable/topicpage/discovery-of-dna-structure-and-function-watson-397> (accessed 27 February 2015).

⁴ Torrance AW *Gene Concepts, Gene Talk and Gene Patents* Minnesota Journal of Law, Science & Technology 2010 Vol 11(1) 158.

⁵ *Ibid.*

⁶ For more information on how genes operate, see section 2.2.1. See also Dandalides G *What is DNA* Tulane Journal of Technology and Intellectual Property 2011 Vol 14 283. See also *supra* note 3.

⁷ Kane EM *Patent-Mediated Standards in Genetic Testing* Utah Law Review 2008 835. See also Murry J *Owning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 231-232. See also *supra* note 4.

⁸ For more information see Scherer FM *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77 (12) 2 1348–1367 available at

http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015). See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 295.

full genome,⁹ comprising approximately 35000 genes and three billion chemical base pairs was available, scientific manipulation of genes started to take place. This led to biological inventions being created and in turn, patented in order to obtain exclusive rights to such creations.¹⁰ The number of gene related patents massively increased, in turn benefiting countries with large biotechnology industries.¹¹

Patents granted on diagnostic tests and therapeutics however, also have the effect of raising the cost of the treatments and diagnostic tests beyond the financial ability of a substantial segment of the public.¹² This is particularly true in developing countries, lacking a proper biotechnology industry, where the burden of disease is staggering whilst the patented treatment and tests are unaffordable to most of the public.¹³

With the massive increase in patented genetic material, the first issue that rises is whether genetic material, being part of the human body and naturally occurring, could in fact represent patentable subject-matter. Until recently, the United States (US) granted patents on genes developed through genetic engineering, and substances isolated from naturally occurring material, including isolated DNA sequences.¹⁴ In fact, many legal systems of developed and certain developing nations, including Japan, Australia, India, China, the EU and South Africa follow suit.¹⁵ Recent case law has brought this matter back into consideration.¹⁶

Despite patents providing a protective and incentive function with regard to diagnostic genes, they also portray negative effects. These include, as mentioned above, a rise in the cost of the diagnostic test. Another negative effect is the hindrance on further research. With the role of genes within the ambit of diagnostics and therapeutics being relatively unexplored, restrictions generated by patent rights¹⁷ open discussions on whether patents are the most appropriate tool within the biotechnology industry.¹⁸ Viable alternative forms of protection for inventors are explored in order to limit hindrance on further research. Within the ambit of DNA however, viable options are limited due to the nature of genes. For example, most genetic disorders are heterogeneous. A heterogeneous disorder demonstrates a disorder that can be triggered by various mutations on a particular gene sequence, including mutations on certain other gene sequences.¹⁹ The various mutations on the different gene sequences may lead to similar clinical

⁹ The first draft of the human genome sequence was finalised in 2003. For more discussion, see <https://www.genome.gov/12011238/an-overview-of-the-human-genome-project/> (accessed 31 November 2017).

¹⁰ Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 298.

¹¹ Biotechnology companies in the US more than doubled their profits between 1993 and 1999 and tripled their profits by 2001. For more discussion see Williams - Jones B *History of the Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 126. See also Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 735. See also Murry J *Owning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 231-232. See also Torrance AW *Gene Concepts, Gene Talk and Gene Patents* Minnesota Journal of Law, Science & Technology 2010 Vol 11(1) 159 -161.

¹² Murry J *Owning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 232.

¹³ For more discussion, see Salzberg SL *The Perils of Gene Patents* Clinical Pharmacology & Therapeutics 2012 Vol 91(6) 969.

¹⁴ This is discussed in detail in section 6.2.

¹⁵ For further discussion on specific jurisdictions (EU, Brazil, India and South Africa) see chapters 5 and 6 of this thesis.

¹⁶ *Association for Molecular Pathology v Myriad Genetics Inc* 133 S Ct 2107 (2013). The case is discussed in detail in chapter 6.

¹⁷ Restrictions on the use and further research on the gene sequence without the permission of the patent holder.

¹⁸ See chapter 3 for a full discussion on the advantages and disadvantages of patents within the field of biotechnology.

¹⁹ Heterogeneous disorders include α -globin gene disorders, cystic fibrosis and several others.

syndromes so the normal options are not viable on these genes. If for example, there is a patent and an exclusive licence over gene A and gene B for mutations 1, 2 and 3, then testing is driven to the provider holding the licence, even though mutations 5 and 6 on gene F will cause the same disorder. The exclusive licence on gene A and B will discourage work on gene F as the provider holding the licence; can incorporate this work into his testing without providing recognition to the originator.²⁰

In order to find a balance that protects the inventor, increase accessibility and further research, alternatives to the patent in the realm of diagnostic gene patents need to be analysed. Should it be found that patents are the best tool to be used, then the relationship between the right to health care and the right to property needs to be analysed in order to access the status of these rights and the limitation of one right over the other.

1.2 Problem Statement

Whilst diagnostic gene sequences are accepted globally as intrinsically patentable subject-matter, the patenting of diagnostic gene sequences is a challenge as the use of these genes pertain to an individual's health which is valued as a fundamental right.²¹ In addition, the patent results in an extreme cost factor hindering access to technology used within the realm of health care.²² It is apparent that potential users in countries with wealthier economies will not experience the cost implications as severe as users in countries with less wealthy economies. Sub-Saharan Africa presents about 32 from the 48 low-income countries in the world. Between 55 to 60 per cent of the rural population in Sub-Saharan Africa are poor; they survive on less than US\$1 per day.²³ Most urban residents in these countries spend more than 80 per cent of their earnings on food, leaving little for other necessities including health care.²⁴

The complication is that inventors invest time and money into their research and it would not be fair to them to go unrewarded for their innovation and contribution to the advancement of health-related technology.²⁵ In addition, without a reward like that of a patent, there would not be any incentive to embark on new research in this area. In weighing up patent rights against the right to health care, it should be understood that patent rights are not observed negatively as it offers protection for technological progress. Patents are instruments for protecting economic investments resulting in technological progress, whilst also serving as an incentive to develop existing technologies and identify innovative technologies. Removing the ability to obtain patent protection in the biotechnology industry could cause a substantive

²⁰ An exclusive license would allow a licensee the use of the patented gene sequence in order to undertake research. For more discussion see Cook-Deegan R, Chandrasekharan S & Angrist M "The Dangers of Diagnostic Monopolies" (editor) Rai AK *Intellectual property and Biotechnology* 2011 547.

²¹ See chapter 5.5 for a full discussion of the universal protection of the right to health.

²² Salzberg SL *The Perils of Gene Patents* Clinical Pharmacology & Therapeutics 2012 Vol 91(6) 969.

²³ Ndiritu CG *Kenya: Biotechnology in Africa: Why the Controversy?* available at <https://cgspace.cgiar.org/bitstream/handle/10947/5594/Ndiritu.pdf;sequence=1> (accessed 27 February 2016).

²⁴ *Ibid.*

²⁵ Cook-Deegan R, Chandrasekharan S & Angrist M "The Dangers of Diagnostic Monopolies" Rai AK (editor) *Intellectual Property and Biotechnology* 2011 547.

decrease in the number of inventions in this field, and in turn have a detrimental impact on medical advancement. This leads to the query whether individual property rights are under such circumstances more important than an individual's right to health.²⁶

The sentence above begs the simple answer “no”. However, this question needs to be analysed within the legal context as one right may not simply be given preference over another. Both the right to health and property are given global status. However, should fundamental rights allow individuals to gain a property right over a subject-matter that is crucial to the health of the public, if such property right has the effect of making diagnostic tests less economically accessible for many?

In order to answer this main question, various sub-questions need to be explored. Firstly, do diagnostic gene sequences meet patentability criteria in order to qualify as patentable subject matter? If so, then they can be patented and protected under intellectual property rights, however, are patents the most appropriate tool for protection of these gene sequences? Thirdly, keeping in mind that the right to health is a fundamental right, the status of intellectual property rights needs to be established. Are intellectual property rights, assuming they fall under the umbrella of property rights, fundamental? If so, the fundamental right to health and the fundamental right to property need to be valued within the context of diagnostic gene patents and weighed against each other in order to ascertain whether one right may justifiably limit the other.

Even though the discussion questions the patentability of diagnostic genes, the discussion is the first to focus on finding a universal interpretative perspective on intellectual property laws as they pertain to diagnostic genes rather than debate the patentability of these genes.

1.3 Intellectual Property Rights versus Fundamental Rights

Two opposing views regarding the relationship between intellectual property law and fundamental rights law exist.²⁷ The first view indicates that intellectual property law conflicts with fundamental rights law as it protects individually held rights, incompatible with communally based fundamental rights. The latter should be a legal instrument to limit executing and enforcing the former.²⁸ The second view indicates that intellectual property law and fundamental rights law are compatible as they share a goal. Intellectual property rights are personified in the fundamental rights system and create a balance between protection and access.²⁹ The discussion below analyses the relationship between these two regimes and their status,

²⁶ An example of this situation is found in the case of the breast cancer gene, BRCA 1 and BRCA 2. These genes are used in the diagnosis of breast cancer which is the second largest cause of death in women. Patents on these genes have resulted in controversy in several countries including Australia, the United States, Europe and Canada. This is discussed in detail in chapter 6. See Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 124.

²⁷ Grosheide W *Intellectual Property and Human Rights, A Paradox* 2010 5.

²⁸ *Ibid.*

²⁹ Grosheide W *Intellectual Property and Human Rights, A Paradox* 2010 5.

role and effect on the development of genetic diagnostics. In order to do this, international instruments, which provide guidance, are analysed in detail.³⁰

For example, the International Covenant on Economic, Social and Cultural Rights (ICESCR) in Article 15.1 establishes that each individual has the right to partake in “cultural life, to enjoy the benefits of scientific progress and its applications and to enjoy the protection of the moral and material interests resulting from any scientific, literary, or artistic production of which such individual is the author”.³¹ The above statement forms part of the concept of human rights and emphasises the importance of individuals being able to benefit from scientific progress.³² In addition, general comment 14, which serves as guidance in the interpretation of the Covenant, states that health as a fundamental human right is not dispensable for the application of other human rights and promotes research, access to affordable treatments and national measures being for promoting the right to health.³³

However, the Universal Declaration of Human Rights (UDHR) in Article 17 states that every individual has the right to own property and that no individual will be arbitrarily dispossessed of such property.³⁴ As in the ICESCR Article 27(2), it allows all individuals to have a right to the moral and material interests protected when such interests result from any “scientific, literary or artistic production of which they are the author”.³⁵ From the discussion of the ICESCR above, it is clear that international guidance dictate that an individual should benefit from scientific progress and affordability should therefore be promoted. However, also puts to us that no individual should be deprived of property.³⁶ The international status and relationship of both these rights are analysed to assess their value within the context of diagnostic gene tests.

1.4 Relevance of Research

The mapping of the human genome sequence is important in medicine and commerce as it assists in directing the way towards useful innovation including the synthesis of therapeutic molecules, the repair of molecules and searches to identify and correct genetically-based diseases.³⁷ The chain of discovery may also be reversed to identify a genetically-based disease and pin-point the genome sequences shared by individuals with the disease, targeting the search for corrective therapies more attentively.³⁸ Detecting

³⁰ This is discussed in detail in chapter 4.

³¹ Article 15 of the ICESCR which can be found at: <http://www.ohchr.org/EN/ProfessionalInterest/Pages/cescr.aspx> (accessed on 15 August 2015).

³² For more discussion see *supra* note 29 at 15.

³³ General comment 14: *The Right to the Highest Attainable Standard of Health: The Economic and Social Council*.08/11/2000. E/C.12/2000/4.

³⁴ The UDHR can be found at <http://www.un.org/en/documents/udhr/> (accessed on 15 August 2015).

³⁵ Article 27(2) of the ICESCR.

³⁶ Article 17 of the UDHR. *Supra* note 34.

³⁷ Scherer FM *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348–1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

³⁸ Scherer FM *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348–1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

genetic disorders is complex and can be regarded as an essential part in providing health care services.³⁹ Diagnostic genes are specifically chosen for the study as these genes are the first step in combating genetic disorders. Without diagnosis, progress to treatment is impossible. The right to access to health care is included in the Constitution, and imposes the state to take measures to meet the basic needs of each individual in South Africa.⁴⁰ If within the context of diagnostic gene patents, intellectual property laws are to be interpreted from a fundamental law perspective, accessibility and affordability within this ambit would significantly increase.

1.5 Research Methodology

This study is descriptive, prescriptive and comparative. The study comprises a literature review where the South African Patent Act is examined with further relevant legislation and case law. Global agreements relating to both patents and access to biotechnology/pharmaceuticals, are also explored.⁴¹ The descriptive approach is used to provide an overview of the existing position, whilst the prescriptive approach is used in conclusion in the form of recommendations, aimed at encouraging South Africa to view legislation from a certain perspective. The research project includes a comparative study with Europe (with emphasis on Germany), the US, Brazil and India. The reasons for choosing these countries are subsequently provided.

1.5.1 The United States of America

The US has a large biotechnology industry, inventor accommodating patent laws and a large body of gene related cases emanates from US courts.⁴² During 1996-2000, the US filed the largest number of patents at the European Patent Office (EPO) in the biotechnology sector.⁴³ The US Constitution entrenches patent law with the purpose of promoting scientific and technological progress,⁴⁴ while it does not mention the right to health. This jurisdiction exemplifies a pro-patent regime.

³⁹ Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

⁴⁰ Section 27 of the South African Constitution of 1996.

⁴¹ Biotechnology is the production of medicine based on biology, while pharmaceutical medicines have a chemical basis. For more discussion see <https://www.alacrita.com/blog/whats-difference-biotech-pharma/> (accessed 06 February 2018).

⁴² For more discussion on biotechnology related cases see section 6.1.

⁴³ Report from the Commission to the European Parliament and the Council *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* 2002 545.

⁴⁴ Clause 8 Article 1 of the US Constitution.

1.5.2 Europe

Despite a large biotechnology industry,⁴⁵ Europe indicates compassion for human rights in all areas of its law. The study explores Europe in the context of the EU⁴⁶ but the research concentrates on Germany. Germany's *Bundestag*⁴⁷ introduced a provision into the German Patent Statute, limiting the scope of patent protection available for human gene sequences or parts thereof.⁴⁸ The German Patent Statute does not provide for absolute substance protection. The provision requires disclosure of at least one application for a gene sequence to qualify for patent protection. Patent protection for human gene sequences is limited to such application, allowing the independent patenting of further inventive applications.⁴⁹ The statute and other relevant legislation are analysed in detail.

1.5.3 Brazil

As a country experiencing rapid and revolutionary economic growth, Brazil is rapidly joining the ranks of other leading countries concerning intellectual property laws. Brazil's economic position is alike to South Africa's though its patent laws⁵⁰ have been restrictive concerning biotechnological patents.⁵¹ The Brazilian government has established the Agência Nacional de Vigilância Sanitária (ANVISA), an institution equivalent to the Food and Drug Administration (FDA) in the US and to the European Medicine Evaluation Agency (EMA) in Europe, stipulating that pharmaceutical and biotechnological patent applications require an approval from ANVISA as well as the Instituto Nacional da Propriedade Industrial (INPI).⁵²

1.5.4 India

As a result of India's economic situation and vast generic pharmaceutical industry, India has some of the highest patentability standards in the world regarding pharmaceutical and biotechnological inventions. Indian patent practice concerning the patenting of biological materials is relatively new. Section 3 of the Indian Patent Act (IPO) ensures an extremely high standard of patentability.⁵³ Apart from narrow standards of patentability, biotechnology products also face certain additional hurdles, such as mandatory disclosure of biological material, prior approval from the Biodiversity Board and access and benefit issues under the

⁴⁵ European countries account for around 38.8% of the world's patents. See the report from the Commission to the European Parliament and the Council *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* 2002 545.

⁴⁶ At present EU member states are: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Sweden, Slovakia, Slovenia, Spain and until 29 March 2019, the United Kingdom.

⁴⁷ This translates to National Parliament.

⁴⁸ Paragraph 1 Section 4 of the German Patent Statute.

⁴⁹ Christoph A *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It* http://www.germanlawjournal.com/pdfs/Vol07No03/PDF_Vol_07_No_03_279-292_Articles_Ann.pdf (accessed 03 March 2015).

⁵⁰ Law No 9,279 of 1996.

⁵¹ Brazil utilises a dual approval system. See Article 10 and 18 of Law No 9,279 of 1996.

⁵² For more discussion on the INPI see Yumy V & Kunisawa M *"The Brazilian Patent System: Challenges for the Future"* (editor) Shimanami R *The Future of the Patent System* 2012 287. See chapter 7 for full discussion.

⁵³ The Indian Patent Act of 1970.

Indian patent regime.⁵⁴ Indian patent laws are analysed and weighed up against the Indian Constitution, which, like the South African Constitution, enshrines the right to health.⁵⁵

1.6 Structure Overview

Chapter One

The chapter provides a brief understanding of the problems faced in the field of biotechnology in regard to diagnostic gene patents. The problem statement is set out and sub questions are put forward in order to establish the status and relationship between the rights in issue. A brief discussion is provided for each of the jurisdictions chosen for the comparative study.

Chapter Two

The objective of this chapter is to answer the first sub-question put forward in this study, which is to ascertain whether gene sequences qualify as patentable subject matter. The chapter provides a general overview of patent law including patent requirements (both intrinsic and extrinsic) and patent function. The discussion then goes on to patent applicability to genes and the function of gene patents.

Chapter Three

This chapter focusses on the advantages of the patent system and analyses the system's limitations specifically within the context of biotechnology. Considering these limitations, alternative options are analysed in order to ascertain whether more appropriate forms of protection for inventors exist within the area of biotechnology.

Chapter Four

This chapter includes a discussion of relevant global intellectual property instruments including the Paris Convention and TRIPS. This chapter aims to provide an understanding of the international provision and status of intellectual property rights to assist with the classification of these rights. The development and application of these global instruments relating to patents are examined to understand global intellectual property development, regulation and status. The chapter also provides the differences in the implementation of these instruments in developed and developing countries. The purpose, substance and effects of post-TRIPS agreements is also discussed.

Chapter Five

This chapter holds a discussion on global fundamental rights law and its development in relation to the right to health care and the right to property. This chapter aims to provide an understanding of the international status and value of both these rights in order to analyse their relationship. The ICESCR and UDHR are examined concerning their relationship with the laws of property and health in order to

⁵⁴ For discussion see Sharma R *Biotechnology Patenting in India and Related Issues* 4-5.

⁵⁵ Gupta M *Are Gene Patents a Hindrance to Innovation* June 21 2013 available at: <http://www.lexology.com/library/detail.aspx?g=4a3197df-8ee7-4de9-a369-fcabb0cdb3ee> (accessed 22 February 2015).

understand the global context and objectives of these rights. The discussion then observes both of these rights individually followed by an analysis of their relationship.

Chapter Six

This chapter is the first part of a comparative study and focuses on the issue of diagnostic gene patenting in the US and the EU, with specific focus on Germany. The chapter analyses the history and development of intellectual property laws, patent laws in general and patent laws as they relate to genes, within each jurisdiction in order to understand the intellectual property objectives of each jurisdiction. The progression of acceptance of genes as patentable subject matter and its effects are explored. Lastly, the chapter holds a discussion on the use of bilateral trade agreements entered into by both of these jurisdictions in order to obtain favourable intellectual property conditions furthering jurisdictional aims.

Chapter Seven

This chapter is the second part of a comparative study and focusses on intellectual property laws in developing nations Brazil, India and South Africa. The chapter analyses the history and development of intellectual property laws, current patent requirements and steps taken by each jurisdiction in order to increase access to pharmaceuticals. The chapter aims to compare the objectives and legislative developments in relation to pharmaceutical/biotechnological patents, including diagnostic gene patents, with that of developed countries.

Chapter Eight

The last chapter provides conclusions gained from the study and applies these in order to answer each of the questions laid out in the problem statement. Recommendations are made on how the patents relating to diagnostic genes.

Concluding Remarks

Patent law is an instrument for promoting private and occasionally, public interest. Black's law dictionary defines public interest as "the welfare of the public as compared to the welfare of a private individual or company. All of society has a stake in this interest and the government recognises the promotion of and protection of the general public".⁵⁶

Recent times indicate promoting private interests to have precedence over public interest, particularly in biotechnology. Certain of the aspects under public interest embarked above (at least in the case of the patenting of diagnostic genes), have become marginalised. It is essential that a proper balance be established between private interest and public interest, fundamental rights law and intellectual property

⁵⁶ Black's law dictionary can be found at <https://thelawdictionary.org/> (accessed 03 December 2018). See also Grosheide W *Intellectual Property and Human Rights, A Paradox* 2010 242.

law, individual rights and community-based rights, and, an inventor's right to property and a patient's right to health care. Previous studies have addressed the issue of balance between fundamental rights and intellectual property in a general context however this is the first study that aims to promote such balance by proposing an interpretative perspective to intellectual property laws pertaining to biotechnology and specifically diagnostic gene tests.

Chapter 2

2.1 Patent Law

As discussed above, in order to answer the question on whether fundamental rights allow individuals to gain a property right over a subject-matter that is crucial to the health of the public, sub questions need to be answered.¹ The first of these sub questions is whether or not diagnostic gene sequences qualify as patentable subject matter? In order to ascertain whether gene sequences, including diagnostic gene sequences, meet patentability criteria in order to qualify as patentable subject matter, patent requirements and function need to be analysed. The first part of this chapter discusses the intrinsic and extrinsic requirements of a patent. Some of these requirements are straightforward but others have raised questions, which US courts were the first to face. The chapter then discusses the two most well-known theories for the function of a patent in order to ascertain whether these functions are being served in the biotechnology industry. The second part of the chapter discusses diagnostic genes and the function of gene patents in relation to health, and uses cases to illustrate the public benefit aspect of gene patents. Intrinsic and extrinsic requirements are discussed specifically with reference to biotechnology type inventions using US precedence. Even though the discussion below questions the patentability of diagnostic genes by analysing intrinsic and extrinsic requirements, the focus of this chapter is to establish whether patents are an appropriate tool within this context in terms of nature and function.²

2.1.1 A brief overview of patent law

Intellectual property law is a central mean through which governments manage the ownership, use of ideas and technologies, and the distribution of the profits that inventions generate.³ Governments generally further the balance of private rights by including safeguards and exceptions in their intellectual property laws enabling them under certain circumstances, to promote public policy goals, such as building local industries or boosting the availability and affordability of new inventions.⁴ Intellectual property law gives rise to the branch of patent law. In the case of technological progress, governments achieve the above-mentioned goals by granting a patent (upon application), to an inventor who produces an invention that meets the requirements for obtaining such protection. As a result of patents being territorial; the requirements may differ from country to country.⁵

¹ See section 1.2.

² Note that this study is not focused on the patentability of diagnostic genes, but rather on finding a universal interpretation and application of intellectual property laws as they pertain to diagnostic genes.

³ Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 5. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* *Community Genetics* 2005 Vol 8(4) 203-208.

⁴ *Ibid.*

⁵ Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* *Community Genetics* 2005 Vol 8(4) 203-208.

Black's law dictionary defines a patent as: "[a] grant of right to exclude others from making, using or selling one's invention and includes [the] right to license others to make, use or sell it".⁶ This will apply for the term of the patent, which, in most countries is 20 years starting from the date of filing the application.⁷ After this term, the invention disclosed in the application enters the public domain.⁸

2.1.2 Intrinsic requirements and exclusions in qualifying for patent protection

Inventions intrinsically deal with technological progress. The laws of nature, physical phenomena and abstract ideas (not being technology), are not considered patentable subject-matter.⁹ A patent cannot be obtained for a mere idea or suggestion, as it is not an invention yet. Discoveries; scientific theories; mathematical methods; literary, dramatic, musical, or artistic work; computer program; schemes or methods for performing a mental act; and the presentation of information are also excluded from being inventions. These exclusions are found in the patent laws of several jurisdictions, including those chosen for our comparative study namely, the US, the EU, Brazil, India and South Africa.¹⁰

Patent application claims include products and processes reflecting technological progress. A product claim includes a substance or composition, for example a chemical compound would be included with any physical entity, such as an object or machine.¹¹ A product patent would include the product so even if the product is produced using a different method or process, it would still fall under the patent. A process patent on the other hand, only protects the method or process used to create the product. If the same product is created using a different method or process it would not be an infringement of the patent.¹² Process type technology applies to all activities using the material product.¹³ A process patent therefore provides less protection than a product patent.¹⁴ Process patents encourage competition as market prices are lowered and competing companies are incentivised to invest in research to develop more efficient production methods. A patent monopoly will only be maintained by a research-based pharmaceutical

⁶ Black's law dictionary can be found at <https://thelawdictionary.org/> (accessed 03 December 2018). Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 310.

⁷ South Africa offers a protection term of 20 years. See the South African Patents Act 57 of 1978 as amended by Patents Amendment Act 58 of 2002.

⁸ *Ibid.*

⁹ Bently L, Sherman B, Barbosa DB et al *Standing Committee on the Law of Patents Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights* WIPO 2009 13-22 available at http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf (accessed 05 September 2018).

¹⁰ Patent exclusions in South Africa can be found in section 25(2) of the South African Patents Act No.57 of 1978 as amended by Patents Amendment Act No. 58 of 2002. For more details on exclusions in the other named jurisdictions see chapters 6 and 7.

¹¹ Sharma N & Batish S *Product Patent Versus Process Patent in the Pharmaceutical Industry* Journal of Pharmacy Research 2011 4(1) 133-135 available at <http://jpr solutions.info/newfiles/journal-file-56c936769e4213.80225459.pdf> (accessed 05 September 2018).

¹² *Ibid.*

¹³ Process patents cover the product that is directly acquired from the patented process and only applies to the method of making the invention. See Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁴ Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law Winter 2015 688.

company on a process patent until a more proficient way of production is developed, shortening the period of patent monopoly.¹⁵

2.1.3 Extrinsic requirements in qualifying for patent protection

The extrinsic requirements for obtaining patent protection in South Africa are similar to those in various other jurisdictions including those chosen for the comparative study. They involve novelty, inventiveness and industrial applicability.¹⁶

An invention is believed to be new or novel, if it does not form part of the state of the art immediately before its priority date.¹⁷ In instances where all the features of the invention can be found in a single disclosure of prior art, the examiner, during an application examination process, will reject the patent application for its subject-matter, as lacking novelty.¹⁸ In certain jurisdictions however, a patent application can, under certain circumstances, be lodged validly after public disclosure.¹⁹

An invention qualifies as inventive if it provides a previously non-realised technological benefit because of human intervention into nature. Even if an invention is new, it should still be inventive or non-obvious, considering the prior art. This determination is prepared by deciding whether the invention sought to be patented would be obvious to one of ordinary skill in the art.²⁰

¹⁵ *Ibid.*

¹⁶ For specific national legislation for each of the chosen jurisdictions, see chapters 6 and 7. Klopper HB & van der Spuy P *The Law of Intellectual Property* 2012 221. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* *Community Genetics* 2005 October Vol 8(4) 203-208.

¹⁷ This requirement is not fulfilled if the subject matter would have been obvious at the time of application. Courts are directed to consider the differences between the "new" and already existing technology and secondary factors such as commercial success, the need for the invention, and the failure of others to develop the technology previously. For more detail see Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* *Albany Law Journal of Science & Technology* 1997 Vol 7 314. See also Paradise P, Andrews L & Holbrook T *Patents on Human Genes: An Analysis of Scope and Claims* *Science* 2005 Vol 307 1556 available at https://www.researchgate.net/publication/7973593_Intellectual_Property_Patents_on_Human_Genes_An_Analysis_of_Scope_and_Claims (accessed 03 February 2016).

¹⁸ For more on the requirement of novelty see <http://www.bitlaw.com/patent/requirements.html> (accessed 16 April 2015). See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* *Journal of Health Care Law and Policy* 2003 Vol 6(2) 7 284. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* *Community Genetics* 2005 Vol 8(4) 203-208. See also Paradise P, Andrews L & Holbrook T *Patents on Human Genes: An Analysis of Scope and Claims* *Science* 2005 Vol 307 1556 available at https://www.researchgate.net/publication/7973593_Intellectual_Property_Patents_on_Human_Genes_An_Analysis_of_Scope_and_Claims (03 February 2016).

¹⁹ For example, under US patent law, a one-year grace period is in certain instances granted from the date of first public disclosure or offer for sale of an invention. For more detail on this see Paradise P, Andrews L & Holbrook T *Patents on Human Genes: An Analysis of Scope and Claims* *Science* 2005 Vol 307 1556 available at https://www.researchgate.net/publication/7973593_Intellectual_Property_Patents_on_Human_Genes_An_Analysis_of_Scope_and_Claims (accessed 3 February 2016).

²⁰ For more on the requirement of obviousness see <http://www.bitlaw.com/patent/requirements.html> (accessed 16 April 2015). See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* *Journal of Health Care Law and Policy* 2003 Vol 6(2) 7 284. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* *Community Genetics* 2005 Vol 8(4) 203-208. See also Paradise P, Andrews L & Holbrook T *Patents on Human Genes: An Analysis of Scope and Claims* *Science* 2005 Vol 307 1556 available at https://www.researchgate.net/publication/7973593_Intellectual_Property_Patents_on_Human_Genes_An_Analysis_of_Scope_and_Claims (accessed 03 February 2016).

Concerning industrial applicability, the invention should be useful and be have the ability to be applied in the industry, trade or agriculture.²¹

2.1.4 The function of the patent

Why are patents granted? If patentable technology is universally available without a way for the inventor to get a return on investment, the interest in research and development will drop substantively.²² Creations meeting the novel, unique and usefulness criteria are an addition to society's store of knowledge with at least some of them being extremely beneficial to society.²³ The primary function of patents is to protect an invention for a specific period. The protection function also corresponds to an economic incentive to invest money in innovative activities and research and development. The basic idea is that the patent system enables one to invest in research and development projects that would not be otherwise profitable.²⁴

There are two well-known views on the function of patents. The first indicates that since the patent is granted to right holders; it is known to have a rewarding function as it is granted in response to individuals making contributions towards economic and technological development by inventing and then disclosing their inventions.²⁵ The right holder is enabled to capture a return on his or her investment. This is called the reward theory.²⁶ The existence of the reward tends to make the amount of a private investment in invention closer to the value of its social effect. The exclusive ownership rights are incentives for inventors to disclose their inventions rather than withhold them as trade secrets. The patent right may allow the recoupment of costs of research and development and to earn a reasonable remuneration from the invention. It is a *quid pro quo* exchange.²⁷

The US Supreme Court affirms the theory in the case of *Universal Oil Products v. Globe Oil & Refining* (1944)²⁸:

“As a reward for inventions and to encourage their disclosure, the United States offers a 17-year monopoly to an inventor who refrains from keeping his invention a trade secret. But the *quid pro quo* is disclosure of a process or device in sufficient detail to enable one

²¹ For more on the requirement see *ibid*. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 312-313. These extrinsic requirements are generally also found under US patent law though also requiring the aspect of usefulness whilst not specifically dealing with industrial applicability.

²² For more discussion see Martin J *Patents: Issues and Legal Developments* 2002 22.

²³ Pitcher AS *Contrary to First Impression, Genes Are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2002 Vol 6(2) 7 284. See Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 311.

²⁴ Corbel P & Le Bas F *The Evolution of Patent Functions: New trends, Main Challenges and Implications for Firm Strategy* 2011 which is available at <http://www.gate.cnrs.fr> (accessed 24 April 2015).

²⁵ *Ibid*.

²⁶ For more discussion on this theory see Kitch EW *The Nature and Function of the Patent System* available at <http://www.jstor.org/stable/725193> (accessed 23 April 2015). See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

²⁷ Cohen SA *To Innovate or Not to Innovate, that is the Question: The Functions, Failures and Foibles of the Reward Function Theory of Patent law in Relation to Computer Software Platform* available at <http://heinonline.org> (accessed 23 April 2015). See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

²⁸ *Universal Oil Products Co. v Globe Oil & Refining Co.* 322 US 471 (1944).

skilled in the art to practice the invention once the period of the monopoly has expired; and the same precision of disclosure is likewise essential to warn the industry concerned of the precise scope of the monopoly asserted".²⁹

The second view is that patents operate as titles of legal security permitting the right holder to prospect the market for commercial opportunities. This is known as the prospect theory.³⁰ This theory is a predominate function of the American patent system.³¹ The theory holds three major features. The first feature is the scope accorded to patent claims. This includes that which reaches well beyond what the reward function would require.³² The second feature is that there are rules, such as the priority, time-bar and patentability rules, forcing an early patent application, despite not knowing if the invention is an entity of value.³³ The last feature is that several technologically important patents were issued long before commercial exploitation became possible.³⁴

This second theory, disregarded for a certain time,³⁵ dictates that the inventor may not claim more than he invented and the claim, as defining the inventive concept, marks the outer bounds of the inventor's rights. Individuals tend to think of an invention as the object an inventor created or accomplished. The rule seems to imply that the inventor is confined to the claim. This is misleading, as the invention described in the patent claim and the physical embodiment of the invention, indicates two distinct aspects.³⁶ For example, an inventor could claim a process of separating fats into glycerine and stearic, margaric and oleic acids through using heat, pressure and water at any temperature and in any apparatus, and this would be acceptable. This applies even though the inventor used only a few of the possible combinations that would achieve the separation of fats.³⁷

Both these views have shortcomings when applied to biotechnological innovation. They both fail to recognise that other innovation market dynamics create disincentives for pioneer inventive activity in markets that already hold a protected invention. These disincentives stem from the interaction of commercial competitive advantages with intellectual property rights. Optimal innovation is diminished when the initial inventor receives more competitive advantages than the subsequent inventor.³⁸ More importantly, these disincentives could be injurious to developing primary and secondary products.³⁹ This could occur in the following ways:

²⁹ *Ibid.* For more detail on the reward theory, see Denicolò V & Franzoni LA *The Contract Theory of Patents* International Review of Law and Economics 2004 23 365-380.

³⁰ This is also known as the Edmund Kitch theory.

³¹ Kitch EW *The Nature and Function of the Patent System* available at <http://www.jstor.org/stable/725193> (accessed 23 April 2015).

³² *Ibid.*

³³ *Supra* note 30.

³⁴ For more discussion see *supra* note 30.

³⁵ This might be because of the misleading "hornbook" rule. The rule is discussed in Corbel P & Le Bas F *The Evolution of Patent Functions: New trends, Main Challenges and Implications for Firm Strategy* 2011 available at <http://www.gate.cnrs.fr> (accessed 24 April 2015).

³⁶ *Supra* note 30. See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

³⁷ Cohen SA *To Innovate or Not to Innovate, that is the Question: The Functions, Failures and Foibles of the Reward Function Theory of Patent law in Relation to Computer Software Platform* available at <http://heinonline.org> (accessed 23 April 2015).

³⁸ *Ibid.*

³⁹ *Supra* note 35.

- Sub-optimal products are created because of a market with little to no competition. Because of the 'first-to-file' advantages, competitors may attempt to patent and introduce their product to the market prior to it being at an optimal level. This may result in an inventor gaining enough competitive advantage to deter the innovation of superior substitute products.⁴⁰
- Monopolies formed as primary product markets dependent on intellectual property rights hold few large competitors tending to have significant market power in their product market. Inventors are deterred from developing rival primary products and choose to develop secondary products, compatible with the primary products. The increase in size of the compatible secondary product market, reinforces the primary product's dominance in the market.⁴¹
- The welfare of consumers is harmed by the limited choice in the primary product market, and by sub-optimal products monopolising the market.⁴²

Society requires a continued flow of inventions, enabling continuous development in specific fields. Patents are known to promote the flow of inventions necessary in the ever-progressing world. However, further discussion is needed on whether patents are the most appropriate tool within the area of biotechnology.⁴³

2.2 Patent Law and Genes

2.2.1 What is DNA and what is a gene?

Before analysing DNA as patentable subject-matter, the terms "DNA" and "gene" need to be understood. A number of federal court opinions discuss the definition of genes but only the cases of *Amgen Incorporated v. Chugai Pharmaceutical Company*⁴⁴ and *Carnegie Mellon University v. Hoffman-La Roche Incorporated*⁴⁵ provide a definition of a gene. The former defines it generally stating that: "A gene is a chemical compound, albeit a complex one" and the latter defines it as "...a region of DNA that contains information that a cell uses to [create] a particular protein".⁴⁶ Both of these definitions are vague.

⁴⁰ Kitch EW *The Nature and Function of the Patent System* available at <http://www.jstor.org/stable/725193> (accessed 23 April 2015). See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* *Journal of Health Care Law and Policy* 2003 Vol 6(2) 7 284.

⁴¹ *Ibid.*

⁴² The Patent Act only demands novelty, utility and non-obviousness and the US Constitution only grants power to Congress to promote the "useful Arts," not the most useful.

⁴³ For a detailed discussion on the advantages and limitations of patents in the area of biotechnology/pharmaceuticals see chapter 3.

⁴⁴ *Amgen Incorporated v Chugai Pharmaceutical Company* (1991) 927.

⁴⁵ *Carnegie Mellon University v Hoffman-La Roche Incorporated* (2007) US Dst LEXIS 20386.

⁴⁶ *Supra* note 43 at F2d at 1206 and *Ibid* at 8.

In the case of genes, a distinction should be made between the human genome,⁴⁷ where the end product would be a functioning human being which is not patentable subject-matter, and genes, which may be patentable subject-matter.⁴⁸ Gene technology can be categorised into four sub-categories: firstly, genes including isolated nucleotide sequences in whole or in part; secondly, proteins encoded by genes and the function of these proteins in organisms; thirdly, vectors used to transfer genes; and lastly, genetically modified cells, methods used for creating genetically modified products and the use of gene sequences for genetic tests.⁴⁹ Our area of interest is the first category, genes including isolated nucleotide sequences in whole or in part.

Similar to computer software, the information encoded by a gene is observed as operating, much like an algorithm, as it instructs the chemical machinery of every cell to create structures and perform functions in a particular order with a specific effect.⁵⁰ The genome contains the complete DNA sequence of an organism. Every cell of the human body, with the exception of red blood cells, carry over 50,000 genes.⁵¹ The human organism holds 23 pairs of chromosomes, one set from each parent.⁵² DNA is located on each of the chromosomes in each cell of an organism.⁵³ The DNA itself comprises of two strands of connected DNA, indicating a ladder.⁵⁴ This structure is known as the "double helix" structure.⁵⁵ Each rung of the ladder comprises a sugar and a phosphate group containing a nucleic acid base. There are four different nucleic acid bases (nucleotides) that appear in specific complimentary pairs.⁵⁶ The base pair purine adenine (A) only pairs with pyrimidine thymine (T) and purine guanine (G) only pairs with pyrimidine cytosine (C).⁵⁷ In double-helical DNA, the number of A residues should be equal to the number of T residues and the number of G and C residues should also be equal.⁵⁸ The nucleotides of each side of the

⁴⁷ The human genome refers to all DNA present in each human cell, whilst genes are particular sections of DNA. See Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law 2015 688.

⁴⁸ See section 2.2.3 for a full discussion on genes as patentable subject matter.

⁴⁹ Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law 2015 688.

⁵⁰ *Ibid.* See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

⁵¹ Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Tyler LC *Genes and USC s101: Are DNA Sequences Corresponding to Genes Patentable Subject Matter?* Intellectual Property & Technology Law Journal 2007 Vol 19(6) 15.

⁵² Chromosomes are the structures that hold genes. For more information on chromosomes see the National Human Genome Research Institute website available at <https://www.genome.gov/11508982> (accessed 01 July 2015).

⁵³ For discussion see Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 708. See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 300-302.

⁵⁴ For more information on genes see the National Human Genome Research Institute Website available at <https://www.genome.gov/11508982> (accessed 01 July 2015). Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

⁵⁵ *Ibid.* See also Stern R *Association for Molecular Pathology v Myriad Genetics: Sieving the Gene Pool* European Intellectual Property Review 2013 35(11) 685-69.

⁵⁶ *Supra* note 52.

⁵⁷ Torrance AW *Gene Concepts, Gene Talk and Gene Patents* Minnesota Journal of Law, Science & Technology 2010 Vol 11(1) 165. See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609. See also Tyler LC *Genes and U.S.C s101: Are DNA Sequences Corresponding to Genes Patentable Subject Matter?* Intellectual Property & Technology Law Journal 2007 Vol 19(6) 15. See also Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 552.

⁵⁸ *Ibid.* See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 708-717. See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

DNA are matched with the corresponding complimentary bases on the opposite side.⁵⁹ The combinations of the nucleic acid bases on the DNA strands is what makes an organism's genetic code unique.⁶⁰ Figure 1 and 2 portray the double helix structure of DNA and the matched complimentary base pairs.⁶¹

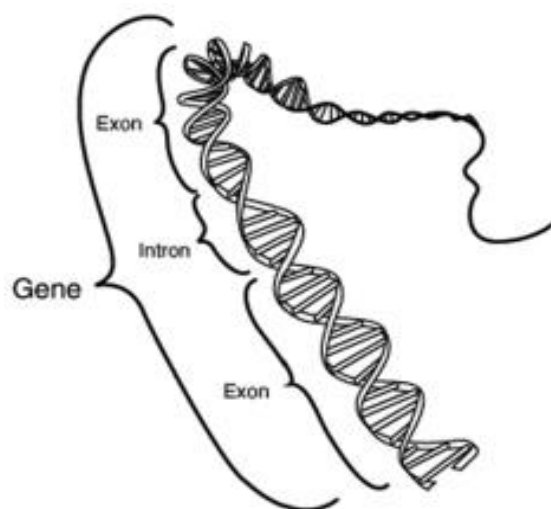


Figure 1

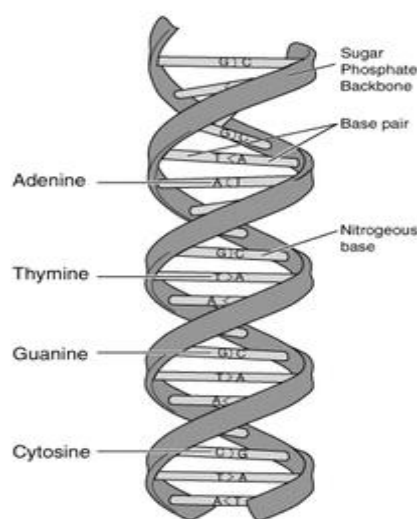


Figure 2

Figure 1 and Figure 2: The double helix structure of DNA

An individual's genetic code is the link between DNA and proteins. The term "gene" suggests a segment of DNA containing a protein code.⁶² A gene is usually expressed in the form of proteins controlling most of the activities in cells, such as function, structure and other activities.⁶³ Only parts of the nucleotide sequence are used to make amino acids, these portions of the gene are called "exons" and the portions not known to have useful coding are called "introns".⁶⁴ When a gene is activated, the nucleotide sequence is read and copied. This process is known as transcription.⁶⁵

During transcription, the cell produces a copy of the activated gene. This copy represents ribonucleic acid (RNA) and not DNA. The removal of introns then alters the structure of the RNA, creating messenger RNA (mRNA)^{66, 67} During translation, the mRNA is read three base segments at a time. This results in a specific

⁵⁹ *Supra* note 52.

⁶⁰ Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 728. See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731. For more information on genes see National Human Genome Research Institute available at <https://www.genome.gov/11508982> (accessed 01 July 2015).

⁶¹ See also https://www.researchgate.net/figure/26623785_fig1_Fig-1-Double-helical-Structure-of-DNA-showing-the-nucleotide-bases (accessed 16 November 2016).

⁶² Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

⁶³ *Ibid.*

⁶⁴ *Supra* note 61. See also Stern R *Association for Molecular Pathology v Myriad Genetics: Sieving the Gene Pool* European Intellectual Property Review 2013 35(11) 685-69.

⁶⁵ For more see http://www.phschool.com/science/biology_place/biocoach/transcription/tcproc.html (accessed 16 November 2016). Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Holman CM *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation* UMKC Law Review 2007 Vol 76(2) 295.

⁶⁶ Messenger RNA. For more discussion on what mRNA is see <https://sciencing.com/mrna-rna-trna-5033460.html> (accessed 06 February 2018).

⁶⁷ For discussion see Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 709. See also Schertenleib D *The*

amino acid being integrated into the chain of amino acids being built to for a particular protein.⁶⁸ The said protein is then used in one of the several processes in the human body.⁶⁹ Figures 3 and 4 portray the processes of transcription and translation respectively.⁷⁰

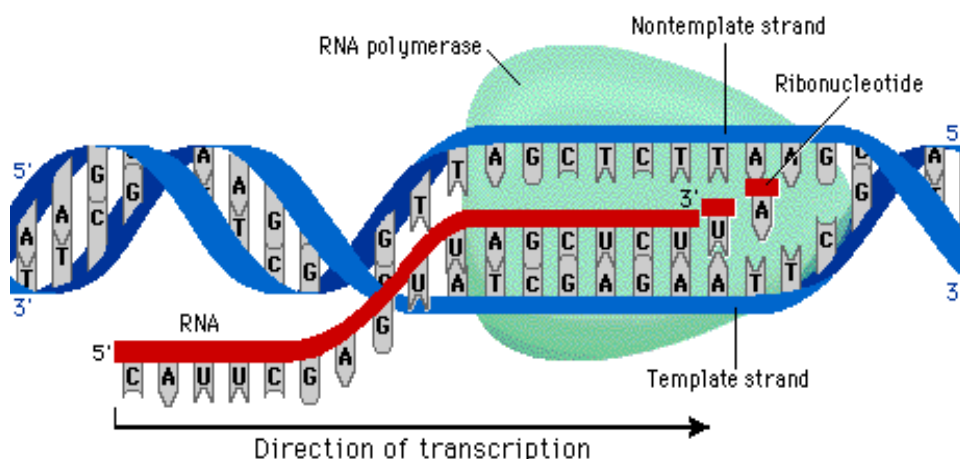


Figure 3

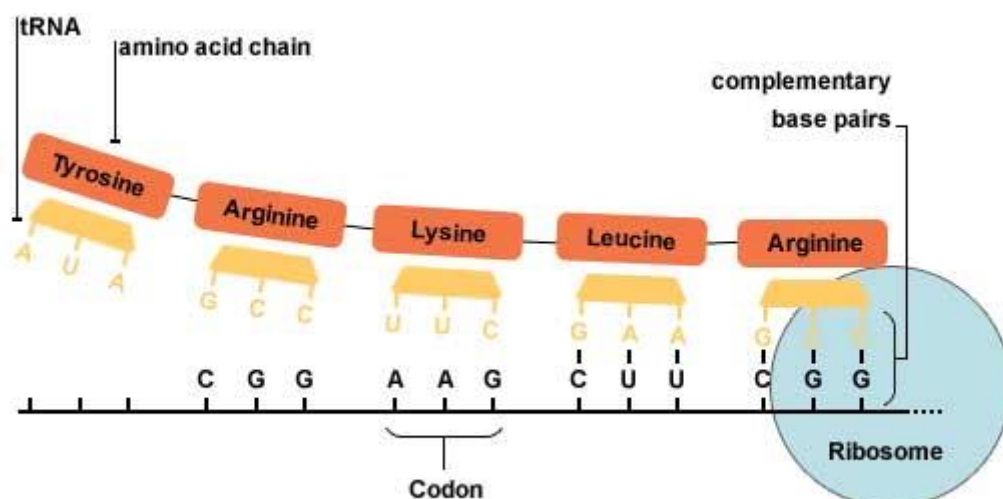


Figure 4

Figure 3 and Figure 4: The processes of transcription and translation

In a patient with a genetic disease, a mutation will be present in the DNA protein code.⁷¹ This will result in either the wrong protein being formed; no protein being formed at all, leading to a deficiency of a particular protein in the patient; or a dysfunctional protein being formed, leading to a genetic disease.⁷² For example,

Patentability and Protection of DNA Based Inventions in the EPO and the European Union European Intellectual Property Review 2003 25(3) 125-138.

⁶⁸ For discussion see Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

⁶⁹ Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 709.

⁷⁰ http://www.phschool.com/science/biology_place/biocoach/transcription/tcproc.html (accessed 16 November 2016).

⁷¹ For further explanation see <https://ghr.nlm.nih.gov/primer/mutationsanddisorders/mutationscausedisease> (accessed 03 August 2018).

⁷² *Ibid.*

instead of a three-subunit sequence coding for the amino acid Valine, a single mutation of just one codon will result in the code for Alanine. This will result in the wrong amino acid being in the amino acid chain and if the substitution occurs in a vital region, the entire function of the protein may be lost.⁷³ In the case of sickle cell anaemia for example, this substitution alters the physical shape of the protein, haemoglobin causing it inefficient to carry oxygen in the blood.⁷⁴ Usually the haemoglobin gene codes as CCTGAGG.⁷⁵ Switching of the chemical letter A to T in the haemoglobin gene results in the codon Valine being substituted for Alanine during translation, resulting in a disease that can cause heart failure, kidney failure, brain damage and early death.⁷⁶ Several types of mutations can occur causing an incorrect protein code. In the example of Huntington's disease, the nucleotide order CAG is repeated several times causing the production of abnormally long versions of the Huntington protein, whilst in other diseases the cause may be the deletion or the addition of a particular amino acid in the sequence.⁷⁷

2.2.2 The function of gene patents regarding public benefit

The early 1990s brought huge sums of public and private funding in developing genetic research and biotechnology.⁷⁸ The potential health advantages resulting from biotechnology is a motivating factor for public investments, with an equal (if not stronger) motivating factor of developing an impressive biotechnology industry essential for encouraging financial growth and creating a knowledge-based economy.⁷⁹ More than 9360 gene patents were granted, covering about 127 000 human genes and partial gene sequences.⁸⁰

The patent system in general, is an intervention into the commercial free-market, designed to prevent market failure, foster innovation and provide a period of monopoly for inventors.⁸¹ As mentioned earlier in this chapter, this intervention is observed as a critical factor for driving innovation for several years. Without patents and their protective function, the public benefit arising from such developments, would be much less. For purposes of this paper, public benefit extends to the public as a whole being able to access

⁷³ Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 709.

⁷⁴ For further detail see <http://atlasgeneticsoncology.org/Educ/GenHemoglobID30014ES.html> (accessed 05 December 2018).

⁷⁵ Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 709. See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

⁷⁶ For further detail see <http://atlasgeneticsoncology.org/Educ/GenHemoglobID30014ES.html> (accessed 05 December 2018). See also http://www.phschool.com/science/biology_place/biocoach/transcription/tcproc.html (accessed 16 November 2016).

⁷⁷ Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 552. For further explanation see also <https://ghr.nlm.nih.gov/condition/huntington-disease#genes> (accessed 02 August 2018).

⁷⁸ For example, the US biotechnology industry invested US\$11 billion in R&D in 1999 and US\$15.6 billion in 2001. Canada's federal biotechnology funding reached C\$314 million in 1998. For more see Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal Vol 10 2002 124.

⁷⁹ Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 124.

⁸⁰ Walpole IR, HJS Dawkins, Sinden PD et al *Human Gene Patents: The Possible Impacts on Genetic Services* Health care available at <https://www.mja.com.au/journal/2003/179/4/human-gene-patents-possible-impacts-genetic-services-health-care> (accessed 30 March 2015).

⁸¹ *Ibid.*

technological developments in order to diagnose or treat specific and general conditions. Public health can only benefit from scientific developments through access irrespective of economic conditions.⁸²

The aspect of public benefit should be assessed against any detriment. As an example, the case of *Myriad*⁸³ brings into question the patent over the BRCA1 and BRCA2 genes. The BRCA1 gene is located on chromosome 17 and has 22 exons, comprising 5,592 base pairs.⁸⁴ BRCA1 codes for a protein that constitutes 1,863 amino acids. The protein is essential for DNA repair and regulating transcription. If a mutation exists in the gene and it is activated, an altered protein is formed and this would lead to abnormal cellular gene expression.⁸⁵ The BRCA2 gene conversely, is even larger than BRCA1 and is located on chromosome 13. This gene has 27 exons, 10,254 base pairs and codes for a protein that comprises of 3,418 amino acids. The function of the BRCA2 protein appears to be parallel to that of BRCA1, although tumours resulting from BRCA2 mutations indicate various cellular expression.⁸⁶

The patent on these genes are granted to Myriad,⁸⁷ an enterprise “specialising in using proteomic and genomic technologies to create break-throughs in medical, diagnostic and therapeutic products”.⁸⁸ Myriad’s BRCA test is based on several high-throughput automated DNA sequencers. The test assesses each of the base pairs within the coding region of both the BRCA1 and BRCA2 genes. The test identifies deleterious mutations, missense mutations, frame shifts or nonsense mutations resulting in protein truncation.⁸⁹ The patent blocks complete gene testing for breast cancer, a disease that can arise from several genes, protecting the inventor by preventing gene testing laboratories from offering an integrated laboratory and counselling clinical service.⁹⁰

⁸² Holman CM *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation* Kansas City Law Review 2007 76(2) 295.

⁸³ *The Association for Molecular Pathology v USPTO* 702 F Supp 2d 181 (SDNY 2010).

⁸⁴ The genes are discussed in detail in Murry J *Ownning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 234. See also Williams-Jones B *History of the Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 126. Caulfield T *Human Gene Patents: Proof of Problems* Chicago-Kent Law Review 2009 Vol 84(1) 7 141-143.

⁸⁵ Deleterious mutations in both these genes are caused by either single or multiple insertions, deletions of nucleotides, by large deletions or rearrangements of the nucleotides. These mutations change the reading frame of triplet codons during protein synthesis. These changes in the frame may result in a premature stop instruction during protein synthesis. This in turn results in a truncated and non-functional protein. Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 127. For further explanation see

<http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/about/risks/breast-cancer-genes> (accessed 11 June 2015) and <http://www.breastcancercampaign.org/about-breast-cancer/breast-cancer-risk-factors/family-history-and-genetics/brca-gene-mutations-and-breast-cancer?gclid=C1bt3vrch8YCFWnltAod0yQAVw> (accessed 11 June 2015).

⁸⁶ <http://www.cancerresearchuk.org/about-cancer/type/breast-cancer/about/risks/breast-cancer-genes> (accessed 11 June 2015). See also <http://www.breastcancercampaign.org/about-breast-cancer/breast-cancer-risk-factors/family-history-and-genetics/brca-gene-mutations-and-breast-cancer?gclid=C1bt3vrch8YCFWnltAod0yQAVw> (accessed 11 June 2015). For more discussion see Murry J *Ownning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 233.

⁸⁷ Myriad is a spin-off company from the Centre for Cancer Genetics Epidemiology at the University of Utah.

⁸⁸ <https://myriad.com/> (accessed 14 January 2018).

⁸⁹ For an explanation of the various types of mutations see

<https://ghr.nlm.nih.gov/primer/mutationsanddisorders/possiblemutations> (accessed 06 December 2018). See also Caulfield T *Human Gene Patents: Proof of Problems* Chicago-Kent Law Review 2009 Vol 84(1) 7 141-143.

⁹⁰ Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 129. See also Brandão LC & Paludo J *Biodiversity and Gene Patents UFRGS Model* United Nations Journal 2013 244-263.

The patent on BRCA1 and BRCA2 was granted to the patentee Myriad in more than one country.⁹¹ This indicates a monopoly over the diagnostic test for breast cancer.⁹² In addition to this, innovation in breast cancer is stifled because the patent also restricts future research.⁹³

Another example where the 'public benefit' can be explored is that of Human Genome Sciences (HGS), a pharmaceutical company holding a patent over the CCR5 receptor gene in the US.⁹⁴ The gene is described as an antiviral in 1995. In 1996, the National Institutes of Health (NIH) discovered that the same gene partakes in the transmission of the Human Immunodeficiency Virus (HIV).⁹⁵ HGS held the patent which would not allow other companies to use the CCR5 gene for AIDS research without their permission despite the patent claim not specifically mentioning the gene having any utility in fighting AIDS.⁹⁶ Once again, the gene patent prevented further research in a crucial area. Luckily in this case, HGS, knowing what the consequences would be if they failed to, allowed scholars to conduct further research on the CCR5 gene despite the patent.⁹⁷

In the case of the HFE gene, two mutations over the patented HFE gene are linked to hemochromatosis.⁹⁸ Since hemochromatosis can be treated by periodic therapeutic phlebotomy,⁹⁹ it is a candidate for population screening, potentially opening up a large market for clinical genetic testing services.¹⁰⁰ A US patent is granted over the gene in 1998 to Mercator Genetics.¹⁰¹ The patent granted the right to exclude others from testing for two mutations, C282Y and H63D on the HFE gene. Mercator then merged with Progenitor and the latter was assigned Mercator's pending and issued patents.¹⁰² Progenitor then granted an exclusive licence to Smith Kline Beecham Clinical Laboratories (SBCL) for an advance payment and

⁹¹ The patent was granted in the US, Europe, Canada Australia and New Zealand.

⁹² This is problematic as breast cancer is the second leading cause of death in women. See Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 127. See also Caulfield T *Human Gene Patents: Proof of Problems* Chicago-Kent Law Review 2009 Vol 84(1) 7 141-143.

⁹³ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study 2014 No.08 <http://ssrn.com/abstract=2503314> (accessed 26 June 2015).

⁹⁴ For more information on the CCR5 gene see <https://ghr.nlm.nih.gov/gene/CCR5> (accessed 30 October 2018).

⁹⁵ Lopalco L *CCR5: From Natural Resistance to a New Anti-HIV Strategy* Viruses 2010 Vol 2 574-600.

⁹⁶ Strier F *Stemming the Gold Rush: Public Policy Alternatives to Gene Patenting* available at <http://onlinelibrary.wiley.com/doi/10.1111/j.0045-3609.2005.00003.x/full> (accessed 15 April 2015). See also Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

⁹⁷ Gupta M *Are Gene Patents a Hindrance to Innovation* 2013 available at <http://www.lexology.com/library/detail.aspx?g=4a3197df-8ee7-4de9-a369-fcabb0cdb3ee> (accessed 22 February 2015). See also Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

⁹⁸ Hemochromatosis is the most common form of iron overload disease. As much as 80–85% of haemochromatosis is caused by the two most common mutant alleles of the HFE gene, C282Y and H63D. See Merz JF, Kriss AG, Leonard DGB et al *Diagnostic Testing Fails the Test* Nature available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220021/> (accessed 18 June 2015).

⁹⁹ An example of this would be regular blood donation.

¹⁰⁰ Merz JF, Kriss AG, Leonard DGB et al *Diagnostic Testing Fails the Test* Nature available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220021/> (accessed 18 June 2015).

¹⁰¹ Patent numbers 5,712,098; 5,753,438; and 5,705,343. Mercator Genetics is an American Genomics company based in San Francisco Bay. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* Community Genetics 2005 Vol 8(4) 203-208.

¹⁰² Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 708-717. See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

ongoing fees worth around \$3 million.¹⁰³ SBCL then sub-licensed for upfront fees and royalties.¹⁰⁴ Due to these patent related cost increases, 30 per cent of the laboratories offering diagnostic testing for hemochromatosis prior to grant of the patent, stopped offering the testing.¹⁰⁵

In the case of Alzheimer disease, familial early-onset Alzheimer's is typically triggered by an autosomal dominant mutation in one of the three genes: PSEN1,¹⁰⁶ PSEN2 or APP.¹⁰⁷ Late-onset Alzheimer's holds only one clearly established genetic risk factor known as the Apolipoprotein E gene (APOE).¹⁰⁸ Patents relevant to the genetic testing for all the genes named above were granted in the US. The APOE gene and the APP sequence are not patented but rather the "methods" of testing are patented.¹⁰⁹ PSEN1 and PSEN2 gene sequences are both patented; these patents are held by Duke University and are exclusively licensed to Athena Diagnostics.¹¹⁰ The licensing agreement prevents pre-symptomatic screening testing and can only be used for pre-diagnosed dementia patients.¹¹¹

In addition to the concerns indicated above resulting from patents been granted on genes, it should also be considered that as discussed in chapter 1, most genetic disorders are heterogeneous. This indicates that various genes and mutations on these genes lead to clinically similar syndromes. An exclusive licence over one or a few common genes can drive testing to one provider, regardless of whether this patent covers all varieties of the disease.¹¹²

2.2.3 DNA and genes as patentable subject-matter

The intrinsic and extrinsic requirements as listed in sections 2.1.2 and 2.1.3 above, are required for every patent application, including DNA. These requirements are discussed below with particular reference to DNA sequences.

¹⁰³ For more discussion see Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 708-717. See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

¹⁰⁴ SBCL required an advance fee of \$25,000 from academic laboratories and 5 to 10 times more than this from commercial laboratories, plus royalties of as much as \$20 per test. Merz JF, Kriss AG, Leonard DGB et al *Diagnostic Testing Fails the Test* Nature available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220021/> (accessed 18 June 2015).

¹⁰⁵ Gold ER & Knoppers BM *Biotechnology IP & Ethics* 2009 219. See also Cho MK & Merz JF *What Are Gene Patents and Why Are Individuals Worried about Them?* Community Genetics October Vol 8(4) 203-208.

¹⁰⁶ Found on chromosome 14. See Campion D, Flaman JM, Brice A et al *Mutations of the Present in Gene in Families with Early-onset Alzheimer's Disease* Human Molecular Genetics 1995 4(12) 2373-2377. See also EL Koedam, V Lauffer, AE van der Vlies et al *Early-Versus Late-Onset Alzheimer's Disease: More Than Age Alone* Journal of Alzheimer's Disease 2009 19(4) 401-440.

¹⁰⁷ *Ibid.*

¹⁰⁸ This gene is found on chromosome 12. See Skeehan K, Heaney C & Cook-Deegan R *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer disease* Genetics in Medicine 2010 Vol 12(4) 71.

¹⁰⁹ Patents related to APOE are as follows: US 5508167, US 5716828 and US 6027896. See K Skeehan, C Heaney & Cook-Deegan R *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer Disease* Genetics in Medicine 2010 Vol 12(4) 71.

¹¹⁰ Skeehan K, Heaney C & Cook-Deegan R *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer Disease* Genetics in Medicine 2010 Vol 12 (4) 71.

¹¹¹ *Ibid.*

¹¹² Cook-Deegan R, Chandrasekharan S & Angrist M *"The Dangers of Diagnostic Monopolies"* (editor) Rai AK *Intellectual property and Biotechnology* 2011 547. See also Scherer FM *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(1) 2 1348-1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

2.2.3.1 The intrinsic requirements distinguishing inventions from discoveries

In applying intrinsic requirements to biotechnological inventions involving DNA sequences, a first area of concern is whether such inventions intrinsically constitute patentable subject-matter. Approaches to determine subject-matter eligibility are fundamentally categorical as they tend to proceed by classifying the invention.¹¹³ For example the invention will be classified as an isolated but otherwise naturally occurring genetic sequence or a genetically engineered bacterium.¹¹⁴ The decisive question is whether the invention overlaps with an exception.¹¹⁵

Most patent law systems recognise a distinction between an invention and a discovery and prohibit the patenting of discoveries.¹¹⁶ Inventions are human interventions into the realms of nature. A distinguishing factor between an invention and a discovery or product of nature is authorship.¹¹⁷ This distinction should be made prior to assessing the other patentability requirements. To “invent” indicates to devise, originate, produce, or construct by original thought.¹¹⁸ Jervis provides the example of a chemist starting with old and naturally occurring atoms and employing well-known chemical reactions to chemically rearrange the atoms to form a unique compound, creating a composition that is patent-eligible.¹¹⁹ In contrast, a discovery indicates to establish, obtain sight or knowledge for the first time. For example, where a pre-existing composition was identified *de novo*, an unknown pre-existing composition is discovered.¹²⁰ Manipulation of an organism can result in a naturally occurring organism becoming the subject of a patent if it meets the other statutory criteria for patentability.¹²¹

The issue of invention progressed as cases were heard by the courts.¹²² The issue first came to a US Supreme Court in 1948 in the case of *Funk Brothers Seed Co v. Kalo Inoculant Co.*¹²³ In *casu* the natural product doctrine intersects with the categorical exclusion of natural phenomena. The applicant presented a mixture of bacterial species exhibiting the surprising property of mutual non-inhibition.¹²⁴ The applicant claimed that the invention combined these species to form a useful combination in a manner not thought possible.¹²⁵

¹¹³ Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 732. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

¹¹⁴ Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1060. See also *ibid* at 732.

¹¹⁵ *Ibid.*

¹¹⁶ *Supra* note 112.

¹¹⁷ Murry J *Owning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 242-243. See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 732.

¹¹⁸ <https://www.merriam-webster.com/dictionary/invent> (accessed 06 December 2018).

¹¹⁹ Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics Inc* Florida Coastal Law Review 2014 3 92.

¹²⁰ *Ibid.*

¹²¹ *Supra* note 112 at 733.

¹²² Note that majority of initial cases regarding gene patentability were heard by US courts.

¹²³ *Funk Brothers Seed Co. v Kalo Inoculant co* 333 U.S. 127 (1948). Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739-741.

¹²⁴ *Ibid.*

¹²⁵ *Supra* note 122.

The court held that combining several species of existing bacteria is not patentable as all the elements of the invention are known, and exist in nature.¹²⁶ It stated that the inventor simply made a discovery of certain of the handiwork of nature.¹²⁷ The mere fact the applicant combined products of nature did not render the combination a "patentable" invention as the individual components of the invention are naturally occurring.¹²⁸ In 1958, the court decided in *Merck and Co v. Olin Mathieson Chemical Corp*¹²⁹ whether a purified vitamin may be patented. Vitamin B is produced through fermenting certain fungal species.¹³⁰ The defendant claimed that the product is an unpatentable product of nature.¹³¹ The opinion relied heavily on the utility doctrine. The court stated that in its natural state vitamin B has no utility, neither therapeutically or commercially.¹³² The court found that despite the chemical identity with the natural product, the purified vitamin B can be patented as it exhibits a function.¹³³

In 1980 the issue is addressed again in *Diamond v. Chakrabarty*.¹³⁴ The case deals with a modified bacterium declared patentable.¹³⁵ The bacterium is claimed to be new as the patent applicant modified its composition, resulting in the incorporation of four plasmids capable of degrading oil to perform a function that it could not accomplish in its natural state.¹³⁶ The invention is in the bacterium and not in the methods used to modify and isolate bacterium.¹³⁷ The court noted that a new bacterium with distinctive features compared to alternative bacteria is found naturally with potential use. According to the court, in this case a bacterium is therefore a statutory patentable subject-matter when, cumulatively:

¹²⁶ *Funk Brothers Seed Co. v Kalo Inoculant co* 333 U.S. 127 (1948). Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739-741. The case is also discussed in Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2)7 294. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739-741.

¹²⁷ *Ibid.* For more discussion on the case see Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹²⁸ *Funk Brothers Seed Co. v Kalo Inoculant co* 333 U.S. 127 (1948). Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739-741. The case is also discussed in Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2)7 294. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739-741.

¹²⁹ *Merk & Co. v Olin Mathieson Chemical Corp* 104 253 F.2d 156 (1958).

¹³⁰ The case is discussed in Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

¹³¹ *Ibid.*

¹³² *Supra* note 128. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739. The case is also discussed in Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 732.

¹³³ *Ibid.*

¹³⁴ *Diamond v Chakrabarty* 447 US 303 313 (1980).

¹³⁵ For case discussion see Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 319. See also Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski* Case Western Reserve Journal of Law, Technology & the Internet 2012 43.

¹³⁶ Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 739. The case is also discussed in Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 732.

¹³⁷ *Diamond v Chakrabarty* 447 US 303 313 (1980). For more discussion on this case see Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (Accessed 19 June 2015). See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 319. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study 2014 08 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

- It has "markedly different characteristics from any found in nature";
- It is useful (effectively or potentially); and
- The inventive activity can be directly attributed to the inventor and not to nature.¹³⁸

The court's opinion in *Diamond v. Chakrabarty* relied on the distinction between nature-made and man-made inventions. The Supreme Court stated that Congress realised that the relevant distinction was between naturally occurring products and human-made inventions as opposed to being between living and non-living objects.¹³⁹ In *casu*, the respondent's microorganism is the result of human creativity. The court held that "the patentee has produced a new bacterium with *markedly different characteristics* from any found in nature and one *having the potential for significant utility*".¹⁴⁰ In affirming that section 101 of the US Patent Act covers modified bacteria, in spite of bacteria being living things, the court quoted the House and Senate Committee Reports accompanying the 1952 Patent Act, stating that "Congress intended statutory subject-matter to 'include anything under the sun that is made by man' ".¹⁴¹ The court clarifies the limits of patentable subject-matter, by stating that this is not to suggest that section 101 of the US Patent Act has no limits or that the Act embraces a discovery.¹⁴²

For genes to be patentable, human authorship is attributed to genes isolated from their natural environment.¹⁴³ Patentability is not attributed to the methods of isolating or purifying genes, but to the gene itself.¹⁴⁴ Conversely, there is *indirect* human intervention as the ingenuity is in the processes and methods

¹³⁸*Diamond v Chakrabarty* 447 US 303 313 (1980). For more discussion on this case see Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing the "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 319. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study 2014 08 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹³⁹ Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 737-743. See also Tyler LC *Genes and U.S.C s101: Are DNA Sequences Corresponding to Genes Patentable Subject Matter?* Intellectual Property & Technology Law Journal 2007 Vol 19(6) 15. See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 735.

¹⁴⁰ *Supra* note 137.

¹⁴¹ The case is also discussed in De Carvalho NP *The Problem of Gene Patents* available at <http://heinonline.org> (accessed 13 March 2015). See also Doll JJ *The Patenting of DNA* Science 1998 Vol 280(5364) 689-690. See also Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 736.

¹⁴² Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 736. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: the Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study No.08 2014 <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Scola A *Uncommon Genes, Unpatentable Subject Matter* 2011 Seattle University Law Review Vol 34 916. See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹⁴³ The term "isolated" is defined in the patent as "substantially separated from other cellular components which naturally accompany a native human sequence or protein, e.g., ribosomes, polymerases, several other human genome sequences and proteins". See Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology Vol 15(4) 2014 553.

¹⁴⁴ Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The "Useful Arts"* Albany Law Journal of Science & Technology 1997 Vol 7 319. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: the Role of Patents in Facilitating Innovation* Centre for Law

of isolation, not in the isolated or purified genes, as the genetic composition remains the same as in their natural environment.¹⁴⁵ Should the composition be different from that which is naturally occurring, it would qualify as novel and non-obvious. Novelty and obviousness are not useful for intrinsically distinguishing between patentable and non-patentable discoveries. This distinction should be made before assessing the other requirements of patentability. The decision in the above-mentioned cases and especially that of *Diamond v Chakrabarty*¹⁴⁶ has an important influence on patent thinking and policy globally. Having established precedence, the decision has led to an astonishing number of cases where courts have accepted genetic material as patentable subject-matter.¹⁴⁷

2.2.3.2 The extrinsic requirements with particular emphasis on inventiveness

In 1991 US courts again got the chance to address the requirements of patentability, this time the extrinsic requirement of obviousness. In the case of *Amgen Inc v. Chugai Pharmaceutical*,¹⁴⁸ the US Court of Appeals for the Federal Circuit made progress by allowing a patent to be issued for the genetic sequence of erythropoietin, a blood protein.¹⁴⁹ The court failed to consider the obviousness of the protein.¹⁵⁰ The patent covers both a non-recombinant method for purifying erythropoietin and compositions of highly purified erythropoietin.¹⁵¹ The court followed the precedent set by *Diamond v. Chakrabarty*¹⁵² in holding that a DNA sequence could not be conceived as an invention until the gene containing the sequence is isolated.¹⁵³ The court briefly recognised the methodological focus of the obviousness analysis.¹⁵⁴

In the case of *In re Kubin*¹⁵⁵ the obviousness requirement is addressed again.¹⁵⁶ The court held that the gene patent in question is obvious as “the prior art [taught the] protein of interest, a motivation to isolate

and Genetics 2014 Occasional study No.08 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹⁴⁵ Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 15 available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 319. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: the Role of Patents in Facilitating Innovation* Centre For Law and Genetics 2014 Occasional study No.08 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹⁴⁶ *Diamond v Chakrabarty* (1980) 447 US 303 313.

¹⁴⁷ An example is the case of *American Cyanamid v Berk Pharmaceuticals* (1976) RPC. 231.

¹⁴⁸ *Amgen Inc. v Chugai Pharmaceutical* 927 F2d 1200 (1991).

¹⁴⁹ A protein which acts by stimulating the growth of red blood cells. Erythropoietin is used primarily for the clinical treatment of anaemia, particularly anaemia caused by renal disease. For more discussion see Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 319.

¹⁵⁰ The case is discussed in Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 295.

¹⁵¹ For more detail see http://www.leagle.com/decision/1989800706FSupp94_1773 (accessed 24 July 2015).

¹⁵² *Diamond v Chakrabarty* 447 US 303 313 (1980).

¹⁵³ *Amgen Inc. v Chugai Pharmaceutical* 927 F2d 1200 (1991). The case is discussed in Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1993 Vol 79 735.

¹⁵⁴ In a footnote, the court states: “note [s] that both the district court and the parties have focussed on the obviousness of a process for making the EPO gene, despite the fact that it is products (genes and host cells) claimed in the patent, not processes.” *Amgen Inc. v Chugai Pharmaceutical* 927 F2d 1200 (1991). For more discussion on the case see Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1993 Vol 79 735.

¹⁵⁵ *In re Kubin* 561 F3d 1351 (Fed. Cir. 2009).

¹⁵⁶ For case discussion see <http://www.cafc.uscourts.gov/images/stories/opinions-orders/08-1184.pdf> (accessed 24 July 2015).

the gene coding for that protein and illustrative instructions... for cloning this gene”.¹⁵⁷ The court appears to limit the acceptability of gene patents where “the improvement is more than the predictable use of prior art elements according to their established functions”.¹⁵⁸ Prima facie non-obviousness for a DNA molecule depends on a lack of similarity between the claimed molecule and DNA molecules previously disclosed.¹⁵⁹ If this is not present, the inventor would need to indicate that the claimed DNA has unexpected properties.¹⁶⁰

Conventional analysis of the obviousness requirement does not observe the process of invention, but rather, the obviousness of the invention product. This is explained further by Cannon who claims that there should be a reasonable expectancy of success prior to the invention being found legally obvious.¹⁶¹ This expectation can be measured by the “availability of techniques reasonably likely to accomplish the suggestion”.¹⁶² A biotechnology invention should therefore be unattainable through use of reasonably accessible scientific methods.¹⁶³ Cannon suggests that by explicitly acknowledging that obviousness analysis properly evaluates the *methods* of scientific research, a clear and workable standard can be established.¹⁶⁴

2.3 Conclusions

There is a school of thought that believes that genes and their functions are scientific in nature rather than technological in nature, thus in essence being discoveries as opposed to inventions.¹⁶⁵ This is mainly because information confined in isolated DNA, is not “markedly different” from information confined in the genomic DNA. The information in a nucleotide sequence dictates the formation of a specific protein.¹⁶⁶ The isolated DNA sequence should code for a different protein from that which it would have coded for if found in nature in order for the information content to qualify as markedly different. The piece of DNA that is ‘isolated’ exists in nature, comprising the same sequence, introns and promoters.¹⁶⁷ This metaphor by Brazil depicts the question of patentability of diagnostic gene material:

“If you walked into the woods and discovered a new type of mineral, picked it up and brought it back to society, would you be entitled to a patent for that mineral? What if that mineral weighed

¹⁵⁷ *In re Kubin* 561 F3d 1351 (Fed. Cir. 2009). The case is also discussed in Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 742.

¹⁵⁸ *In re Kubin* 561 F3d 1351 (Fed. Cir. 2009). The case is also discussed in Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 742. See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 713-720.

¹⁵⁹ Murry J *Owning Genes: Disputes Involving DNA Sequence Patents* Chicago-Kent Law Review 1999 Vol 75(1) 12 244.

¹⁶⁰ *Ibid.*

¹⁶¹ Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1993 Vol 79 736.

¹⁶² *Ibid.*

¹⁶³ *Supra* note 161.

¹⁶⁴ *Supra* note 161.

¹⁶⁵ De Carvalho NP *The Problem of Gene Patents* available at <http://heinonline.org> (accessed 13 March 2015). See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 733.

¹⁶⁶ Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) available at <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

¹⁶⁷ *Ibid.*

two tonnes or was buried deep underground and it required substantial financial resources and arduous work to retrieve it? The answer to both questions is unequivocally no. Now what if you went out into the woods, discovered a new type of bacterium in the soil, retrieved it from the soil and brought it back to society, would you be entitled to a patent then? The answer is, surprisingly, yes. What characteristic does an isolated naturally occurring organism have that a naturally occurring mineral lacks that makes the isolated organism eligible for a patent?"¹⁶⁸

Despite valid reservations about genes even qualifying as patentable subject matter, they have been globally accepted as such as evidenced by the cases discussed in section 2.2.3. As this study does not pertain to the actual patentability of diagnostic genes, but rather focuses on a way to protect innovation stemming from these genes, as well as increasing accessibility to such innovation, the next question to address is whether patents on diagnostic genes actually serve the function of a traditional patent?

Patents are traditional instruments used in several industries, serving to provide protection and economic reward to inventors thereby supplying both a rewarding and a security function.¹⁶⁹ The system provides an incentive for innovation as public goods will be scarce without the compensation that intellectual property rights provide.¹⁷⁰ The first function i.e. protection, is served in the area of biotechnology however, the second function relating to incentive is only partly served due to the nature of genes.

The negative effects that patents have on public health by limiting access is great. Optimal innovation may also be diminished by the presence of monopolies, thereby affecting technological progress. However, without patent protection, the incentive for developing technology by further research is insufficient.¹⁷¹ This begs the question that even though diagnostic genes strictly qualify as patentable subject matter, are patents the most appropriate tool in this area?

¹⁶⁸ Brazil C *You Didn't Build That: The Case Against Patentability of Isolated Organisms* University of Kansas Law Review 2015 761.

¹⁶⁹ Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 43.

¹⁷⁰ Kitch EW *The Nature and Function of the Patent System* 289 available at <http://www.jstor.org/stable/725193> (accessed 23 April 2015). See also Scherer FM *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348–1367. See also Doll JJ *The Patenting of DNA* Science 1998 Vol 280(5364) 689-690.

¹⁷¹ Helfer LR & Austin GW *Mapping the Global Interface* 2011 20.

Chapter 3

3.1 The Patent System in Biotechnology

Two centuries ago, Thomas Jefferson stated that: “if nature had made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself, but the moment it is divulged, it forces itself into the possession of everyone and the receiver cannot dispossess of it himself. Its peculiar character, too, is that no one possesses the less, because each possesses the whole of it. He who receives an idea from me, receives instructions himself without lessening mine; as he who lights his taper at mine, receives light without darkening mine. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man and improvement of his condition, seems to have been peculiarly and benevolently designed by nature”.¹

Considering the above, Jefferson, the first US patent examiner, would be doubtful about awarding patents on such basic scientific discoveries on the detailed structure of the human genome. Recent years indicate biological sciences to be observed as a highly-organised enterprise pursued at considerable expense by both profit-oriented and non-profit institutions.² Research in biological sciences, including research on diagnostic genes, experienced a global process of commercialisation during the last 20 to 30 years, mainly driven by variations in intellectual property laws since the 1980s and caused a rapid increase in filing of biotechnology patents.³ Global patent activity is at an all-time high in this field.⁴ Patent-holders in the field, as in other fields, are provided exclusive rights to prevent others from exploiting the patented inventions. Patent-holders are required to disclose information relating to the invention in return for the exclusive rights. This disclosure is an essential element of the patent system. It is the basis of the balance between the inventor’s interests and those of the society.⁵

¹ FM Scherer *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348-1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

² *Ibid.*

³ In 1978 the USPTO granted less than 20 patents in the field of genetic engineering and by 1989 the total number of biotechnology patents being granted each year had risen to 2,160. By 2002 the number had risen to 7,763 and by 2014 to 42,584. Octaviani A *Biotechnology in Brazil: Promoting Open Innovation* (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* 2008 151. See also Piekut M *Polarization of the European Union: Patent Activity and R&D Expenditure* Journal of Intellectual Property Rights 2013 Vol 18(4) 330-337.

⁴ Murphy E *Report: Patent Activity at a High but Decline in Scientific Research could indicate Innovation Slowing Intellectual Property Watch* available at <http://www.ip-watch.org/2015/06/04/report-patent-activity-at-a-high-but-decline-in-scientific-research/> (accessed 25 September 2016). See also Octaviani A *Biotechnology in Brazil: Promoting Open Innovation* (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* 2008 151. For updated statistics see https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2017-chapter2.pdf (accessed 11 December 2018).

⁵ Prepared by the Secretariat - *Report on The International Patent System* Standing Committee on the Law of Patents Twelfth Session Geneva June 2008 10.

The previous chapter establishes that gene sequences, once isolated, do qualify as patentable subject matter, however gene patents, specifically diagnostic gene patents, carry negative effects and do not necessarily serve the full function of a patent indicating that patents may not be the best protective/incentive tool within the area of biotechnology.⁶

One of the patent system's primary regulatory purpose is to prevent the market from failing to produce technical knowledge at adequate levels. The overriding rationale of the patent system is that without patent protection there may be insufficient incentives to invent and to innovate.⁷ The patent excludes others from appropriating the benefits without sharing the costs. In this respect, the patent system creates competition that will eventually benefit consumers and scientific development.⁸ Patents also serve other objectives, such as attracting foreign investment, facilitating technology transfer and dissemination, and providing incentive. However, are patent privileges the most effective incentive for biotechnology research or whether other incentive arrangements also drive research and innovation, without limiting third party access to the invention?⁹ Does the patent system offers too much protection, stifling research and development in certain sectors, including biotechnology?¹⁰

Research and development in biological sciences is subject to particular scrutiny as this type of research invokes fundamental human needs, including health care. The products of this type of research are typically subject to intensive and lengthy regulatory processes, which firstly, create the need to establish appropriate mechanisms and incentives to generate necessary data on the impact of new technologies and secondly, opens concerns about access to the end product.¹¹ The proper functioning of the patent system depends on open and effective competition in the market to promote innovation; an absence of interference with competition as a decentralised discovery procedure for innovation opportunities; and as a price-setting mechanism for innovation rewards.¹² The system needed to reward innovation in this sensitive industry must hold a delicate interplay of privileges and responsibilities. It should accommodate innovation protection, knowledge development, health care, technological and scientific progress and education. Both insufficient and excessive protection prejudice operating the market; under-protection undermines the incentives to exploit innovation opportunities, whilst overprotection compromises other market participants' freedom to operate and compete on merits.¹³

This chapter explores both the strengths and limitations of the patents system within the area of biotechnology. Alternatives to the patent are explored later in the chapter in order to answer the second

⁶ See section 2.2.2 above.

⁷ Octaviani A *Biotechnology in Brazil: Promoting Open Innovation* (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* 2008 157.

⁸ Prepared by the Secretariat - *Report on The International Patent System* Standing Committee on the Law of Patents Twelfth Session Geneva 2008.

⁹ *Supra* note 7.

¹⁰ *Supra* note 7.

¹¹ *Supra* note 7 at 82.

¹² *Supra* note 7 at 82.

¹³ *Supra* note 7.

sub question as to whether patents are in fact the most appropriate form of protection/incentive for diagnostic gene patents.

3.2 Strengths and Foundations of the Patent System

The patent system provides incentives for investing in innovation by granting a limited monopoly, allowing the patentee the opportunity to profitably exploit the invention.¹⁴ The patent system encourages dissemination by requiring the disclosure and publication of the invention particulars. This leads to a wider use of the invention.¹⁵

The importance of the patent system (in the case of biological inventions), is attributed to four factors: the excessive costs of research and development; the low costs of imitation; precise definition of claims for new chemical molecules,¹⁶ making it easier to prove infringement; and the long life-span of pharmaceutical inventions. The presumption against patenting basic information on natural phenomena might be overcome if the prospect of securing exclusive property rights in scientific discoveries for a limited period serves as a necessary or important incentive. This should ensure investments in scientific research, serve to elicit discoveries that would otherwise not be made, or to accelerate the pace at which scientific knowledge advances.¹⁷ Three of the main advantages of the patent system within the biotechnology industry, with specific focus on genes, are subsequently discussed.

3.2.1 The reward theory

As discussed in chapter two,¹⁸ patents are said to provide a “prospect” function, under which broad patents provide owners “an incentive to make investments to maximise the value of an invention without fear that the fruits of the investment will produce unpatentable information appropriable by competitors”.¹⁹ By offering a period of exclusivity, patents provide an economic incentive for inventors “to engage in desirable behaviour”.²⁰ From an economic perspective, the patent system addresses market failure and restores the

¹⁴ Haracoglou I *Competition Law and Patents – a Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 22. See also Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 41–75.

¹⁵ *Ibid.*

¹⁶ Broad patents may facilitate follow-on inventions by controlling the licensing terms and avoiding duplicative efforts. They may also hinder it if the transaction costs are high or if there is an overarching threat of infringement. One of the central goals of the patent system is ensuring that the granting of an overly restrictive legal monopoly does not impede follow-on research building on previous inventions. The function of the patented invention as an output has to be balanced against its function as an input for further development. See Haracoglou I *Competition Law and Patents – a Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 22.

¹⁷ FM Scherer *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348-1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

¹⁸ See section 2.1.4

¹⁹ Prepared by the Secretariat – *Report on The International Patent System* Standing Committee on the Law of Patents Twelfth Session Geneva 2008 8. The theory is discussed in detail in section 2.1.4.

²⁰ Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

incentives to invest in knowledge production, as without it the public would be able to use the invention freely despite the inventor being the only bearer of the development costs.²¹

3.2.2 Research and development

Another advantage of the patent system is the promotion of future research and development due to the ability to recoup research and development costs.²² Pharmaceutical and biotechnological development requires early capital to propagate human clinical trials and obtaining appropriate approval when necessary. This development phase carries an excessive cost requiring stronger guarantees for market exclusivity to recoup future costs. Concerning DNA patenting, the cost of bringing a genetic test to market can be divided further into two distinct costs being research and development costs and marketing approval costs.²³ A patent also has the potential to reduce duplication of research and development. Patented technology provides innovators with an indication of the research activities and developments in the field. This limits researchers from partaking in duplicate research and bearing unnecessary costs.²⁴

3.2.3 Technology transfer

The transfer of technology nationally and globally is important. Patents serve this function by creating globally acceptable property rights.²⁵ Without the patent system, researchers will be reluctant to share technology as there is a high-risk of imitation by their competitors. Patent rights encourage technology transfer in providing owners with legal certainty.²⁶ In recent years, the generation and dissemination of knowledge, led by developing communication and information networks, such as the internet, became particularly important amongst other industrialised economies. The patent system involves a vital part in the dissemination of knowledge, essential in the fields of pharmaceuticals and biotechnology as it relates to medical development.²⁷

3.3 Limitations of the Patent System

The patent system, despite its advantages discussed above, attracts scepticism as to its validity and public benefit in the field of gene patents, including diagnostic gene patents. This is partly because of a fundamental paradox. The patent system seeks to promote the production of public goods, yet it creates

²¹ Prepared by the Secretariat - *Report on The International Patent System* Standing Committee on the Law of Patents Twelfth Session Geneva 2008 8.

²² Cook-Deegan R “*Gene Patents*” (editor) MG Crowley *From Birth to Death and Bench to Clinic: The Hastings Centre Bioethics Briefing Book for Journalists, Policymakers and Campaigns* 2008 69-72.

²³ Pharmaceutical companies can spend up to 15 per cent of their revenues on research and development, in addition to expenditures on administration, advertising and promotion costs. See *ibid*.

²⁴ Prepared by the Secretariat - *Report on The International Patent System* Standing Committee on the Law of Patents Twelfth Session Geneva 2008 8.

²⁵ *Ibid*.

²⁶ *Supra* note 24 at 10.

²⁷ *Supra* note 24.

exclusions to public access.²⁸ It is in the field of public health, which the incentive effect and public welfare is most critically scrutinised. This is also of particular importance in the case of genetic testing for a predisposition to diseases.²⁹ Early diagnosis and restrictions to availability are factors of concern.³⁰ Patents by nature limit what others can do, offering a period of exclusive rights over the invention to the patent-holder in return for public disclosure of information on the invention. In the case of human gene sequences, the “invention” is information.³¹ Gene patents especially, limit what can be achieved in the realm of scientific research and medical care. There would be no alternatives to a patented gene in diagnosis, treatment and research.³² The basis for research and knowledge in genetics is attained through collaborative work between public and private sectors. Developing research requires this collaboration to continue.³³ Various limitations of the patent system as it pertains to biotechnology and genes in particular, are discussed below.

3.3.1 Stifling of research and innovation

The patent system is designed for a different research and development environment from that of the modern biotechnology industry. There is growing concern regarding the patent system in its current form, restricting rather than facilitating innovation in the field.³⁴ The patent system protects and rewards the inventor, but is also a means to create an incentive for others to attempt and “invent around” the patent in order to promote development. The latter is not possible when a gene sequence is the subject of patent protection.³⁵ Patents on so-called base products prevent further research on the gene, removing any incentive for further research on that particular gene.³⁶ The Myriad case involving the BRCA1 and 2 genes, provides a good example of research frustrated by patents.³⁷

Researchers in the private sector for example, will not be researching BRCA1 and 2, as it is possible that whatever derives from their research with commercial value will ultimately be owned by the owner of the original patent.³⁸ Specific limitations on research include blocking patents, anti-commons/patent thickets and delays in scientific progress. These are discussed below in more detail.

²⁸ *Supra* note 24 at 78.

²⁹ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008.

³⁰ *Ibid.*

³¹ Paradise J, Andrews L & Holbrook T *Patents on Human Genes: An Analysis of Scope and Claims* Policy Forum Intellectual Property Science 2005 Vol 307 available at https://www.researchgate.net/publication/7973593_Intellectual_Property_Patents_on_Human_Genes_An_Analysis_of_Scope_and_Claims (accessed 3 February 2016).

³² *Ibid.*

³³ B Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 16 10–50.

³⁴ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: the Role of Patents in Facilitating Innovation* Centre for law and Genetics – University of Tasmania Occasional study 2014 08 3.

³⁵ This is discussed further in Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 10 783 – 784.

³⁶ Jacobs P & Van Overwalle G *Gene Patents: A Different Approach* European Intellectual Property Review 2001 Vol 23(11) 505-506.

³⁷ This case is discussed in detail in section 5.2.4. For case discussion see also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

³⁸ For more discussion on concerns regarding the impact that the patents will have on research in the public and private sectors see Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

3.3.1.1 Blocking patents

The term “blocking patent” is defined in a broad sense, indicating any patent as a blocking patent, as patents essentially hinder others from constructing, using, offering for sale, selling or importing the patented invention. In summary, a blocking patent is defined as a patent covering vital features of the invention and cannot be invented around.³⁹ Regarding genetic diagnostics, patents encompassing a claim on a gene sequence or part of a gene sequence, such as a mutation or method to determine the association between a specific mutation and an inherited disease, is a blocking patent.⁴⁰ The challenge relating to blocking patents can be overcome by using licensing policies, however, challenges could still arise with restrictive licensing. Gene patents are either not licenced or restrictively licenced.⁴¹ A patent covering a gene sequence, vital for diagnosing a genetic disease, is licenced either exclusively to only one or two laboratories globally, or not licenced at all.⁴² Studies have looked into alternative restrictive licensing practices such as only licensing to certain laboratories for a specific purpose i.e. clinical use.⁴³

3.3.1.2 Anti-commons/thickets

Intellectual property commentators have a growing concern for what is known as the “tragedy of the anti-commons”.⁴⁴ An intellectual property patent thicket creates anti-commons. The latter allows each patent owner exclusive rights. This indicates that no individual patent owner would have an effective privilege of use.⁴⁵ This raises a concern that anti-commons will hinder innovation because of the cost of bringing downstream technologies to market.⁴⁶ The challenge indicates that individual patent owners would own most of these mutations. To screen the entire genome, a licence would be needed from each patent-holder.⁴⁷ This would not only delay progress but also increase costs. Several researchers reported difficulties accessing patented inventions and anti-commons having a detrimental impact on subsequent research.⁴⁸

³⁹ For more on blocking patents see <https://www.patentlawyer.io/what-is-a-blocking-patent/> (accessed 09 December 2018).

⁴⁰ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4(2).

⁴¹ *Ibid.*

⁴² The *Myriad* case represents a key example of the restrictive license policy. The case is discussed in detail in section 6.2.4.

⁴³ For more information on this see Cho MK, Illangasekare S, Weaver MA et al *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services* The Journal of Molecular Diagnostics 2001 Vol 5(1) 3. See also Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4(2).

⁴⁴ Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Cook-Deegan R “*Gene Patents*” (editor) MG Crowley *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers and Campaigns* 2008 69-72.

⁴⁵ *Ibid.*

⁴⁶ For example, it would be better to screen that person’s entire genome for all known mutations as opposed to only checking whether a specific mutation exists on a particular gene within an individual. See Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

⁴⁷ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property 2013 Vol 4(2).

⁴⁸ For example, in the case of the thermostable enzyme *Thermus aquaticus* (commonly known as Taq and used as a basic biotechnology tool) DNA polymerase, Hoffman-La-Roche accused a few US universities and research institutes and more than 200 scientists of infringing its patents by purchasing Taq for use in the PCR process from a company. According to Roche, the

When a scientist encounters a patent-protected gene, three options become available to them. They may either, stop or avoid researching the particular gene;⁴⁹ licence the rights to research the gene from the patent-holder; or continue research disregarding legal liability.⁵⁰ All these options could potentially result in a reduction of fundamental research and development in genetics.⁵¹ The first two options can be illustrated in research conducted on the gene associated with hemochromatosis, a hereditary liver disease caused by progressive iron overload.⁵² Approximately 80 to 85 per cent of hemochromatosis cases are caused by two specific mutations in the HFE gene, causing it to be a prime candidate for genetic screening tests.⁵³ SBCL holds the patents for the gene and its two mutations.⁵⁴ About 119 American laboratories commenced genetic testing for hemochromatosis prior to the granted patents. 30 per cent of these laboratories surveyed ceased research as soon as the patent rights were enforced. For those that continued developing a genetic test, SBCL asked for an upfront fee of \$25,000 from academic laboratories and as much as \$250,000 from commercial laboratories, plus a fee of \$20 per test.⁵⁵ The patent interfered with clinical adoption of the test. The quality of testing was potentially compromised by limiting developing higher quality or lowering cost alternative testing methods.⁵⁶

The third option, choosing to ignore, not inquire, or remain unaware of the intellectual property status of several of the genes being studied. This is credited to several factors: for example, patent-holders deciding not to enforce gene patents or the assumption that fundamental research is exempt under US patent law, ultimately leads to litigation.⁵⁷

universities were not licensed to sell Taq for such use. Similar problems faced research development in Alzheimer's disease, cystic fibrosis, hemochromatosis, Canavan disease and spinocerebellar ataxia. See Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 568. See also Haracoglou I *Competition Law and Patents – a Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 9-11. See also Cook-Deegan R "Gene Patents" (editor) MG Crowley *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers and Campaigns* 2008 69-72. See also Müller-Langer F *Creating R&D Incentives for Medicines for Neglected Diseases: An Economic Analysis of Parallel Imports, Patents and Alternative Mechanisms to Stimulate Pharmaceutical Research* doctoral thesis - Hamburg University 2008 54.

⁴⁹ An inventor finding a second application for the same patented gene sequence would have the chance to obtain a patent on the invention but would be frustrated by the dependence of his patent on the former patent. This dependence of the second patent on the first one, would inhibit medical development. See Schrell A, Bauser H & Brunner H "Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany" (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

⁵⁰ Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access - BIO* Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 391.

⁵¹ According to a study that surveyed genetics lab directors, it was established that at least 25% of labs had abandoned one or more genetic tests that they themselves had developed, due to notification from the patent holder or licensee. In addition, 53% of genetics labs had stopped developing new clinical genetic tests due to concerns about gene patents and licensing patent rights. See Jacobs P & Van Overwalle G *Gene Patents: A Different Approach* European Intellectual Property Review 2001 Vol 23 11 505-506.

⁵² *Supra* note 50.

⁵³ This gene causing hemochromatosis and is discussed in section 2.2.3. See Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access - BIO* Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 391.

⁵⁴ *Supra* note 50.

⁵⁵ *Supra* note 50.

⁵⁶ *Supra* note 50.

⁵⁷ *Supra* note 50. See also Cook-Deegan R "Gene Patents" (editor) MG Crowley *From Birth to Death and Bench to Clinic: The Hastings Centre Bioethics Briefing Book for Journalists, Policymakers and Campaigns* 2008 69-72.

3.3.1.3 Delays in scientific progress

Another way that patents hinder research in the field of biotechnology is by causing a delay in the research phase. Studies indicate that the publication of new biotechnology discoveries can be delayed as a result of patenting activities, as illustrated by the HFE gene where submission took more than a year after the first patent was filed.⁵⁸ These publishing delays can have an unfavourable effect on patients as they delay access to diagnostic testing.⁵⁹ Research is further delayed by stacking intellectual property obligations as successive instruments used in the course of an extended research project. This has the potential to impede or even preclude developing new and better diagnostic and therapeutic products.⁶⁰ As mentioned in the previous section, patents create obstacles to subsequent research and development and add to a thicket of rights that firms should negotiate, prior to prevailing their products on the market.⁶¹ Researchers should attempt to negotiate to use the patented gene. Patent owners may withhold a licence or only licence exclusively to one or a restricted number of licensees.⁶² Patent thickets create “tollbooths” during product development.⁶³ As mentioned above, this challenge is likely to be exacerbated if the protection afforded by individual patents are so broad they have the potential to block whole areas of research and product development.⁶⁴ In addition, the incentive to undertake research in this area is lost. Instead, by not initially exploiting asserting their patent rights, they may inadvertently allow others to develop genetic tests, vaccines, or medical therapies.⁶⁵ As soon as a commercially viable application is developed, the patent owner may act against the innovator. Such action may include: collecting royalties for the past infringement; blocking the invention from being put on the market during the patent term; or claiming the invention as their own. These factors may discourage researchers from further research in areas where a patent is already held, thereby fostering a lack of treatment development.⁶⁶

3.3.2 Excessive pricing and monopolies

Another major concern in diagnostic gene patenting is the cost implications of patents on research conducted on the patented gene sequences.⁶⁷ Multiple patents on various parts of the same gene may

⁵⁸ Merz JF, Kriss AG, Leonard DGB et al *Diagnostic Testing Fails the Test* available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220021/> (accessed 18 June 2015).

⁵⁹ Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

⁶⁰ Supra note 58.

⁶¹ Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15(1) available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Cook-Deegan R “Gene Patents” (editor) MG Crowley *From Birth to Death and Bench to Clinic: The Hastings Centre Bioethics Briefing Book for Journalists, Policymakers and Campaigns* 2008 69-72.

⁶² Haracoglou I *Competition Law and Patents – a Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 9-11.

⁶³ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: the Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 30.

⁶⁴ *Ibid.*

⁶⁵ Supra note 62.

⁶⁶ Andrews LB *The “Progress Clause”: An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 580.

⁶⁷ Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

have a negative impact on access of the gene for research, as the patent thicket will require royalties charged for diagnostic tests. Additional non-exclusive licences can become excessive.⁶⁸

Effects of inflated costs are also observed in cases where the exclusive right may allow firms to establish a monopoly position.⁶⁹ A monopoly results in higher prices and the possibility of under-provision of the product. In the case of pharmaceutical and biotechnological patents, including diagnostic gene patents, a monopolistic market situation indicates limited social benefits.⁷⁰ Monopolies may also cause discouragement for other researchers in gene technology, limiting further research.⁷¹

The pharmaceutical industry is increasingly being condemned for its excessive prices. Ideally, pharmaceuticals on the market should be priced, including the cost with a reasonable profit. The following factors may contribute to the soaring prices:

- The lack of competition;
- Restrictions on access of raw materials and ingredients;
- High taxes;
- Branded pharmaceuticals quoted at a much higher price than generic products;
- Pharmaceutical with an elevated level of promotional campaigns cost more.⁷²

The price of pharmaceuticals does not always correlate with the costs of research and development and production. Marketing costs, profit margins, subsidies, tariffs and taxes are also being added. Pharmaceutical firms spend more on advertising and promotion than on research development, and this cannot be justified by the need for patent exclusivity.⁷³ A lack of justification for allowing patent-based pricing to generate income for advertisements exists, particularly when dealing with essential pharmaceuticals, independent from advertising.⁷⁴ The Curie Institute claims that the monopoly on exploitation will lead to a loss of expertise and information amongst physicians and research scientists in

⁶⁸ For example, royalties' charges of SBCL's and Bio-Rad are up to \$20 per test and \$12.50 per test for Canavan's disease with no up-front fees. These prices do not seem excessive, though once combined with other royalties, "stacking royalties", these costs add up. This is termed "stacking of royalties". A study conducted comparing the cost of the Myriad BRCA test, of which Myriad is the sole provider, with the costs of Myriad gene tests for the colon cancer genes FAP and HNPCC, in which fields Myriad has four and six competitors respectively, indicate little monopolistic effect on pricing. If the test is broken down to price per amplicon, Myriad charges \$38.05 per amplicon for their BRCA test, \$40.80 per amplicon for their FAP test (non-profit competitors charge between \$28.57 and \$39.88 per amplicon) and \$49.17 per amplicon for their HNPCC test (non-profit competitors charge between \$30.00 and \$77.44 per amplicon). See Merz JF, Kriss AG, Leonard DGB et al *Diagnostic Testing Fails the Test* available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220021/> (accessed 18 June 2015). See also Müller-Langer F *Creating R&D Incentives for Medicines for Neglected Diseases: An Economic Analysis of Parallel Imports, Patents and Alternative Mechanisms to Stimulate Pharmaceutical Research* doctoral thesis - Hamburg University 2008.

⁶⁹ Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 580.

⁷⁰ FM Scherer *The Economics of Human Gene Patents* Academic Medicine 2002 Vol 77(12) 2 1348–1367 available at http://journals.lww.com/academicmedicine/fulltext/2002/12001/the_economics_of_human_gene_patents.6.aspx (accessed 17 June 2015).

⁷¹ *Ibid.*

⁷² Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability: A Case Study of the Pharmaceutical Industry in Thailand* 2006.

⁷³ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 31.

⁷⁴ *Ibid.*

Europe; they will no longer be allowed to improve diagnostic technologies and methods and will therefore not be in a position to advance their research in acceptable circumstances.⁷⁵ As an example, the “compulsory” requirement to send DNA samples obtained from high-risk individuals to Myriad, will assist the US Corporation to increase its copyright-protected genetic data bank. This will grant it unchallenged control over the main research materials concerning genes coding for breast and ovarian cancer predisposition, hindering further innovation in this area.⁷⁶

3.4 Limitations on Access to Health care

As patents, by definition, involve a degree of exclusivity, their grant is bound to affect access to the patented technology. When grants are unjustified or over broad, lack of access is bound to be unwarranted.⁷⁷ As discussed above,⁷⁸ gene patent monopolies combined with exclusive licensing, result in little or no competition, hindering access to patented medications. In particular, patents limit the number of laboratories possibly offering genetic diagnostic tests. These may be forced to stop offering these tests due to the limitations of the patent.⁷⁹ As discussed above, this is due to the soaring prices beyond what patients can afford, as well as the stifling of further research which develop genetic tests and therapies.⁸⁰ The US faces the most serious impact of soaring prices due to the absence of a government pharmaceutical price control mechanism.⁸¹

Single test providers eliminate a patient’s option to get a second opinion to confirm an ambiguous result. This is important as serious medical decisions, such as whether to agree to a mastectomy, need to be made based on these test results.⁸² Product quality is also affected as the lack of competition defeats the purpose of developing and improving technologies.⁸³

⁷⁵ Müller-Langer F *Creating R&D Incentives for Medicines for Neglected Diseases: An Economic Analysis of Parallel Imports, Patents and Alternative Mechanisms to Stimulate Pharmaceutical Research* doctoral thesis - Hamburg University 2008.

⁷⁶ *Ibid.*

⁷⁷ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 31.

⁷⁸ See section 3.3.2 above.

⁷⁹ Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

⁸⁰ *Ibid.*

⁸¹ In Europe universal coverage shields many from high pharmaceutical prices but in the US patients have to pay an average of 20% of pharmaceutical prices. As discussed in chapter five, in the case of Myriad’s BRCA 1 and 2 tests, some of the plaintiffs were patients who claimed that they were unable to obtain the test because of the cost which was over \$3000 USD per test. A case study comparing the effects of the tightly controlled BRCA patents to patents on colon cancer-associated genes, which were subject to non-exclusive licenses, concluded that the key effect of patents is likely to be on the amount produced rather than price. See Agitha TG *Impact of IP on Public Health: The Developed Country Scenario* Journal of Intellectual Property Review 2013 18(4) 382-383.

⁸² Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

⁸³ *Ibid.* The BRCA patents provide a paradigm example of how exclusive control of genetic testing can affect product quality. In a study published in 2006, the test Myriad employed to detect breast cancer risk missed mutations that caused the disease. Researchers sampled DNA from 300 members of high-risk families in which four or more members had been diagnosed with either breast or ovarian cancer, all of which had received negative test results from Myriad. Six methods were used to search DNA for breast cancer gene mutations and found that 12% of the patients that were studied carried rearrangements of BRCA1 or BRCA2 not included in Myriad’s array. The Myriad test would not have picked up these mutations, perhaps leading to false negatives. The Myriad opinion cited a study finding that 12% of those from high-risk families and who tested negative with the test from Myriad had cancer-predisposing variants of those genes so more comprehensive testing would have been beneficial. A study concluded by the US Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) in 2010 and it was found

3.5 Alternatives to Patents

"The fundamental moral objections raised to patenting DNA were that it would reduce human beings to the status of "biological machines". Furthermore, there were concerns that allowing such patents would confer "ownership" over a part of the human body. These objections are not soundly based for the following reasons. A gene is a molecule, albeit a large and complex molecule. It is not life in itself and could not produce life except as part of a living system. Moreover, a patent on a gene does not grant ownership of the information contained in it; it merely confers rights to the patentee to prevent others from commercially exploiting that information in defined ways, for a limited period."⁸⁴

In 1955 Jonas Salk developed a vaccine for polio and was endeared to the public by refusing to patent the vaccine.⁸⁵ Francis Collins and colleagues first cloned the Cystic fibrosis-linked, CFTR gene and ensured broad licensing. Twenty years later, dozens of laboratories (both private and public), competed in CFTR testing based on service, innovation and quality.⁸⁶ Current trends opposite to these threaten to impede the advancement of genetic diagnostic testing and insufficient protection fails to adequately incentivise innovation in novel genetic testing methods.⁸⁷

that there was evidence of denial of access to tests not covered by insurance, difficulties in obtaining second opinions and one instance where a patent dispute restricted access to tests for an 18-month period and that even though patents or exclusive licences could stimulate development of a genetic test, there were no cases requiring exclusive rights. Key findings in the SACGHS report included:

- Gene patents do not assist basic genetic research, development of genetic tests or stimulate disclosure of research discoveries.
- Patient impact of human gene patents has included limitations on available testing due to market clearing, limitations on access to testing due to health insurance issues and constraints on obtaining second opinions and sample sharing for quality assurance.
- Gene patents constrain developing complex testing and parallel sequencing.
- The prospect of patent protection stimulates certain private investment in basic and advanced genetic research. Patents can incentivize companies to invest resources in genetic research.
- Evidence suggests that patents do not encourage public research as knowledge would be shared openly if not patented. Ultimately this report had a strong anti-patent flavor, so much so that three members of the committee issued a dissenting statement disagreeing with several the committee's findings on the hazards of gene patenting for human health.

This is based on case studies conducted by the Center for Genome Ethics, Law & Policy, at Duke University's Institute for Genome Sciences and Policy, for 10 clinical conditions focusing on the development, access and quality of tests. See Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 29 -30. See also Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 568. See also Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access* – BIO Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 385 -389.

⁸⁴ In the context of this paper, this author agrees with this statement. For more discussion see Lupton ML *Patenting Genetic Material: Is it Permissible in South Africa?* South African Mercantile Law Journal 1997 Vol 9. See also Report Q 150 by the South African Group *Patentability Requirements and Scope of Protection of Expressed Sequence Tags (EST's), Single Nucleotide Polymorphisms (SNP's) and Entire Genomes* available at https://www.aippi.org/download/committees/150GR150south_africa.pdf (accessed 15 May 2015).

⁸⁵ Baicus A *History of Polio Vaccination* World Journal of Virology 2012 Vol 1(4) 108 -114.

⁸⁶ Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access* - BIO Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 385 -389.

⁸⁷ *Ibid.*

Several potential policies can be adopted to overcome this challenge. The first suggestion is that genes could be excluded as a patentable subject-matter.⁸⁸ Patents should not be granted on DNA sequences but only be granted for new biotechnological and pharmaceutical products, such as new vaccines and genetic tests based on DNA.⁸⁹ Conversely, only patents on the end products would be granted, whilst patents on the base product used to manufacture these products would be refused. This indicates that there would be no more patents on DNA sequences as a product claim, but there would be patents on using DNA to diagnose, prevent or treat a specific disease and on the resulting end product.⁹⁰ A blanket exclusion is unlikely to be an appropriate response as no one-size-fits-all formula exists, provided the multitude of possible claims that may be made in this area. A statutory exception may have the effect of excluding protection that should properly be regarded as legitimate.⁹¹ Patent practice would also invariably find creative ways to work around an exception. Consequently, protection claims that should properly fall within the exception, will not necessarily be excluded.⁹² Empirical research completed in Europe indicates that method patents could have a more substantial impact on access to genetic testing than gene patents.⁹³ Their research concluded that “proposals aimed at banning patents on human genes do not provide a plausible solution, unless the ban would be on patents for broad genetic diagnostic methods as such”.⁹⁴ The alternate to the patent would need to alleviate the alleged hampering effect of patent thickets, all whilst still providing an incentive for researchers.⁹⁵

To find a balance between rewarding innovation and scientific benefit, alternatives to the patent and their limitations need to be explored. Investors need to find regimes, enabling them to recoup investment costs without impeding follow-on innovation, opening new opportunities for stimulating investment in sub-patentable innovation, without impoverishing the public domain.⁹⁶

3.5.1 Prize scheme

A simple and non-patent involving scheme signifies a monetary prize awarded to the inventor that first develops a genetic test or pharmaceutical that meets the requirements concerning a medical profile as determined by an independent committee of experts.⁹⁷ This would serve as an incentive allowing a

⁸⁸ Andrews LB *Patents: The Need for Bioethics Scrutiny and Legal Change* Yale Journal of Health Policy, Law and Ethics 2005 Vol 5 403.

⁸⁹ *Ibid.*

⁹⁰ For more discussion see Van Overwalle G “*Reshaping Bio-Patents: Measures to Restore Trust in the Patent System*” (editor) Somsen H *The Regulatory Challenge of Biotechnology Human Genetics Food and Patents* Biotechnology Regulation Series 2007.

⁹¹ *Ibid.*

⁹² Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania 2014 Occasional study 08 172.

⁹³ Research completed by Huys et al. See Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: A Comparison Under Current European and US patent law* European Journal of Human Genetics 2011 19 1104–1107.

⁹⁴ *Ibid.*

⁹⁵ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4(2).

⁹⁶ Van Overwalle G “*Reshaping Bio-Patents: Measures to Restore Trust in the Patent System*” (editor) Somsen H *The Regulatory Challenge of Biotechnology Human Genetics Food and Patents* Biotechnology Regulation Series 2007.

⁹⁷ *Ibid.*

researcher to recoup the costs of research and development.⁹⁸ In exchange of the monetary prize, the innovator foregoes the intellectual property rights to the innovation and the invention is placed in the public domain where it will be open to generic manufacturing. The latter would allow for the price of the innovation to decrease close to cost of production, which will minimise the access challenge and the economic inefficiency, stemming from dead weight losses.⁹⁹ This option would assist with the stifling of further research if the mechanism only awards a prize to the company reaching a specific pharmaceutical goal first.¹⁰⁰ This will add significant risk and uncertainty to companies entertaining engaging in a research and development of the specified product.¹⁰¹ In addition, this is a risk for a researcher unable to recoup their research and development costs if they do not end up being the first to develop the product.

An economically rational decision for a researcher to enter into a “winner-takes-all” race presupposes a close to perfect comparative knowledge in the sense that an enterprise should possess not only a good estimate of its own chances of reaching the pharmaceutical goal but also a good estimate of competing enterprises’ research efforts and degree of success in clinical trials involving their contender for the prize.¹⁰² Other challenges with the mechanism include the lack of any incentives to produce second generation pharmaceuticals for a medical condition once the first entry pharmaceutical has been awarded a prize with the source of the initial monetary award.¹⁰³

3.5.2 Patient-care exemption

Patient care exemption is a narrow exemption that would apply to circumstances pertaining to patient-care.¹⁰⁴ The US Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) report recommends limited exemptions for providing second opinions and patient-care exemption as beneficial. The first type of exemption addresses the concern regarding second opinions without removing a patent-holder’s investment benefits.¹⁰⁵ The SACGHS argues that would be non-effective “because there would be little incentive and several disincentives, for a laboratory to develop and maintain a test simply to provide second opinions or verification requests”.¹⁰⁶

In the case of an exemption for the purpose of patient-care, the exemption is “an exemption from liability for anyone who infringes a patent on a gene whilst making, using, ordering, offering for sale, or selling a

⁹⁷ Ruse-Khan HG *The International Legal Framework for the Protection of Utility Models: Unmatched Flexibility for Domestic Experimentation?* Max Planck Institute for Intellectual Property and Competition Law (Munich); Associate Fellow, Centre for International Sustainable Development Law (Montreal) 175.

⁹⁸ Sonderholm J *Intellectual property rights and the TRIPS agreement: An Overview of Ethical Problems and Some Proposed Solutions Development Dialogue on Values and Ethics* - The World Bank 2010 10.

⁹⁹ *Ibid* at 10-11.

¹⁰⁰ *Supra* note 98.

¹⁰¹ *Supra* note 98.

¹⁰² *Supra* note 98.

¹⁰³ *Supra* note 98.

¹⁰⁴ For more information see Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

¹⁰⁵ *Ibid*.

¹⁰⁶ *Supra* note 104.

genetic test for patient-care purposes”.¹⁰⁷ The exemption operates on the basis that gene “patents do not appear to be necessary to stimulate research and genetic test development, in part because development costs are minimal for genetic diagnostic tests”.¹⁰⁸ These costs may change as the FDA recently took action to increase regulating diagnostic tests, taking a data-driven approach requiring test-kit manufacturers to provide data supporting any analytical and clinical claims related to the use and effectiveness of a product. The SACGHS asserts that despite the FDA’s more extensive regulatory framework, exclusive rights will not be necessary for genetic diagnostic test development, citing the cystic fibrosis case study where multiple parties developed test kits with non-exclusive licences. The SACGHS confirms that since appropriate approval is required for diagnostic kits, exclusive rights are unnecessary.¹⁰⁹

3.5.3 The research exemption

Researchers could easily infringe a gene patent when undertaking research without knowing beforehand whether the comparison will infringe. A research exemption is a defence to infringement in such cases allowing researchers to only use the patented invention for research purposes.¹¹⁰ The exemption would be helpful in the context of genetic testing as it allows “[r]esearch and development to make testing more comprehensive, more accurate or less expensive”, improving testing quality.¹¹¹

Multiple genes acting together are portrayed outwardly in the form of human characteristics, genetic predispositions and diseases. Genetic diseases with multiple gene influence are called polygenic. In certain cases, as many as 100 various genes could be involved, thereby potentially involving 100 different patent right holders. It is for this reason that the research exemption would be valuable.¹¹²

The research exemption is similar to the experimental use doctrine which originates in the US as a narrow judge-made exemption to patent infringement for anyone who makes, uses or sells a patented invention purely to satisfy scientific curiosity, or for philosophical reasons.¹¹³ Regarding this doctrine it was judicially stated that “it could never be the intention of the legislature to punish a man who constructed a patented machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects”.¹¹⁴ The doctrine is further elaborates, regarding the exceptions

¹⁰⁷ *Supra* note 104.

¹⁰⁸ *Supra* note 104.

¹⁰⁹ *Supra* note 104.

¹¹⁰ *Supra* note 104.

¹¹¹ *Supra* note 104.

¹¹² For example, hearing loss is connected with at least sixty-five different genes, two of which are patented. Both of these are exclusively licensed to Athena Diagnostics. If Athena asserts its patent rights, they can block further research on the genes hampering developing diagnostic tests or they could ask for high royalty fees to undertake research using their genes. Each gene contributing to the disease could also be worked on independently which would result in sixty-five different genetic tests which would need to be taken to diagnose the disorder.

¹¹³ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 44-70.

¹¹⁴ The experimental doctrine exemption was initially explained by Judge Story in a dictum in the case of *Whittemore v Cutter* 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813). For more this discussion on this see also Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 44-70.

to infringement, adding that to constitute an infringement, it should involve “the making with intent to use for profit, not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification”.¹¹⁵ The 2002 US decision of *Madey v. Duke* further affirms the existence of the doctrine, and defines its applicability in a narrow sense. The scope of the exemption remains unclear concerning applicability and policy.¹¹⁶ The court also held that the exception for the experimental use excludes private research universities, despite the notion that university researchers with no commercial interests might be left liable for infringement.¹¹⁷

In Europe, the research exemption states that rights conferred by a patent will not extend to “acts done for experimental purposes relating to the subject-matter of the patented invention”.¹¹⁸ It is governed by national law.¹¹⁹ Due to various domestic legislation and court decisions, the scope of the exemption varies between countries. Belgium for instance, widened the research exemption. The Belgian patent law stipulates that a patent-holder’s rights exclude “acts carried out for scientific purposes ‘on’ or ‘with’ the subject-matter of the invention”.¹²⁰ The new wording is aimed at exempting research “on” and “with” the subject-matter.¹²¹ The word “on” in this instance refers to research confirming whether the patented invention works as described in the patent or confirmation of the novelty and inventiveness of the invention. For example, if there is a patent on gene sequence A which is used to identify disease 1, then research “on” gene sequence A would be involving the sequence as connected to disease 1. Experiments “with”, on the other hand, refers to experiments using the patented invention to investigate other entities. The patented invention is used as an instrument.¹²² Referring to the example above, this would be research using gene sequence A as connected to disease 2.

The research exemption has its challenges. Many observe that the research exemption allows research *using* the patented invention.¹²³ The exemption only allows research *on* the patented invention itself.¹²⁴ Depending on the way the claims are written; the research exemption can allow for examination of the

¹¹⁵ *Swain v Guild* 21 F. Cas.554AT 555 (No.12, 391).

¹¹⁶ *Madey v Duke University* 307 F.3d 1351 (Fed. Cir. 2002).

¹¹⁷ The reasoning behind the decision is that non-commercial research still advances a university’s educational aim to increase the status of the institution and acquire lucrative research grants, students and faculty. Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 489. See also Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15(1) available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

¹¹⁸ Article 54(1) of the European Patent Convention (EPC).

¹¹⁹ Article 64(3) of the EPC provides that an infringement of a European patent is addressed under national legislation.

¹²⁰ Belgian Patent Law 1984.

¹²¹ For discussion see Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 489.

¹²² For discussion see Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 436.

¹²³ Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 759.

¹²⁴ For example, the research exemption could cover research on gene A itself (if gene A was patented) or, depending on the wording of the claim, it could cover research involving the use of gene A. See also *Ibid*.

invention or more. The scope and interpretation of the research exemption is undefined and is therefore an unsuitable solution to the challenges relating to gene patents.¹²⁵

3.5.4 Restriction of the scope or period of the patent

As observed from the examples provided in this paper, there is a proliferation unduly broad DNA patents causing a situation where new patents are dependent on earlier patented inventions.¹²⁶ This may ultimately cause a reluctance to enter into research in certain fields where genes have already been patented and where royalty stacking and higher transaction costs are present. This in addition limits the access of patients needing these patented products. The question is whether DNA patents follow the norm of wide and absolute protection, or would a more restricted purpose-bound protection be more suitable? Should a patent for a DNA sequence include all probable future applications, or be restricted to the specific use described in the patent application?¹²⁷

The *Nuffield Council of Bioethics*' report raises concerns regarding granting broad patents where the disclosed use in the claim is specific to the subject-matter. For example, protection is sought primarily for DNA sequences as such and extended with their application in method or use-claims.¹²⁸ Broad patents effectively provide an exclusive right to control all research and development of tests, therapy and diagnostics. The wording of the claims hold an important bearing on the effect of patent on health care and innovation.¹²⁹

A traditional product claim of DNA offers broader protection than a specific use claim on DNA, specifically when patentees invest time and money in discovering genes for which they found minimal function. A narrow scope patent would only be obtainable on a particular developed application, with no rights on the possible use and the possible application.¹³⁰ The scope of the patent should be limited in the application enabling others to use and patent the same DNA sequence for other applications (purpose-bound protection).¹³¹

A broader scope of protection, conversely, would provide strong incentives for breakthrough inventions and weaken incentives for the follow-on inventors. The work of Scotchmer and Green indicate that a broad

¹²⁵ The SACGHS report recommends an exemption for protected genes in the pursuit of research, but does not define research. The report fails to clearly establish the limits of the exemption. *Supra* note 122.

¹²⁶ An example of this is the patents on the BRAC1 and 2 genes.

¹²⁷ Van Overwalle G *"Reshaping Bio-Patents: Measures to Restore Trust in the Patent System"* (editor) Somsen H *The Regulatory Challenge of Biotechnology Human Genetics Food and Patents* Biotechnology Regulation Series 2007.

¹²⁸ Verbeure B, Matthijs G & Van Overwalle G *Analysing DNA Patents in Relation with Diagnostic Genetic Testing* European Journal of Human Genetics 2006 Vol 14 26–33.

¹²⁹ *Ibid.*

¹³⁰ Jacobs P & Van Overwalle G *Gene Patents: A Different Approach* European Intellectual Property Review 2001 Vol 23(11) 505-506. See also Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 478.

¹³¹ Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 478.

scope patent puts patentees at a disadvantage in negotiating the terms of licences, which may result in additional costs in attempting to “invent around” the blocking first generation patent.¹³² Innovation is often cumulative enabling the patent to interfere with further discovery; inhibition of progress as opposed to discouraging inventions. Weak and narrow patents encourage firms to cross-licence and disseminate; this may discourage fundamental inventions.¹³³

With regard to a limitation of the term of a patent, the current patent system is primarily a one-size-fits-all framework as patents covering cutting-edge pharmaceuticals, novel microchip technology and simple innovation, generally receive the same twenty-year term and impart the same legal rights.¹³⁴ Shortening the term of the patent could decrease duplicative costs involved in the race to innovate. It would also make innovations available for widespread use by the public sooner, allowing those innovations to increase the economy’s productive capacity. Increasing the technological commons would then beneficially increase the rate at which innovations could build on earlier innovations, potentially increasing the rate of innovation.¹³⁵ The current patent term is twenty years from the date of *filing*. After a patent is filed, the patent office examines it. On average a patent will take about three years before it is issued.¹³⁶ The average life of an issued patent is about 17 years. If patents would be weakened by half, it would be divided by two; three years would be added for pendency.¹³⁷ The result is that a half-strength patent would last about eleven and a half years from the date of filing.¹³⁸ Shortening the patent term would decrease the expected profits from patents. According to the incentive to invent and incentive to commercialise theories of patents, the decrease in expected profits would shift expenditures away from research and development or to different research and development, decreasing the number of innovations.¹³⁹ Fewer innovations would also decrease the productive capacity of the economy.

A barrier exists in the form of the 1994 TRIPS Agreement. This agreement requires the patent term to be at least twenty years from the filing date.¹⁴⁰ Whatever the merits of shortening the patent term, it is politically impossible at this time, as this was one of the provisions that the US insisted on during the negotiation period.¹⁴¹ Even if TRIPS did not represent a major obstacle, the political economy of patent law suggests that it would be extremely difficult to push through a change in the patent term. Specifically,

¹³² Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008. See also Green S & Scotchmer S *On the Division of Profit Between Sequential Innovators* Rand Journal of Economics 1995 Vol 26 20-33. See also Scotchmer S *Standing on the Shoulders of Giants: Cumulative Research and Patent Law* Journal of Economic Perspectives 1991 Vol 1 29.

¹³³ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008

¹³⁴ Osborn LS, Pearce J & Haselhuhn A *The Case for Weaker Patents* St Johns Law Review 2015 53-54.

¹³⁵ *Ibid* at 133.

¹³⁶ This is the average in the US and Europe.

¹³⁷ *Supra* note 133.

¹³⁸ *Supra* note 133 and note 134.

¹³⁹ *Ibid*.

¹⁴⁰ Article 33 of TRIPS. For more discussion around this provision see Harris DP *TRIPS’ Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business Vol 25(1) 2004 134.

¹⁴¹ The TRIPS Agreement is discussed in detail in section 4.4.

whilst certain industries such as software might welcome the change, other industries, most notably the biotechnology and pharmaceutical industries, would fiercely oppose it.¹⁴²

3.5.5 Patent pools

A patent pool can be observed as an agreement between patent-holders to “pool” their intellectual property rights, specifically rights essential or complimentary to a particular technology to the “pool”.¹⁴³ First, patent owners licence their technology to one another, often through a multiparty agreement between patent owners to establish the pool. Second, licences are bundled into one package and licenced out by the pool to third party licensees.¹⁴⁴ Pools may also offer standard licensing terms to licensees who are not members of the pool. The typical patent pool allocates a portion of the licensing fees to each member according to a pre-set formula or procedure.¹⁴⁵ Patent pools create general, but conditional openness. In exchange for a fee, patent pools convert exclusive patent rights into shared rights.¹⁴⁶ Patent pools encourage technological development, whilst reducing costs by alleviating patent thickets.¹⁴⁷

The sewing machine industry formed the first licensing pool in 1856.¹⁴⁸ In 1917, an aircraft pool was formed between US aircraft manufacturers and the Information, Communication and Entertainment (ICE) sector formed several global pools.¹⁴⁹ The ICE sector also holds several modern pools including: a DVD pool and a MPEG-2 pool, related to digital video compression.¹⁵⁰ The first pool formed in genetics was the Golden Rice pool.¹⁵¹

In the biotechnology and pharmaceutical industries, patent pools could operate at two levels; the first being during discovery and development; the second being during distribution and post registration.¹⁵² The most publicised example of a contemplated pool is the proposal to pool patents relevant to the potential

¹⁴² Osborn LS, Pearce J & Haselhuhn A *The Case for Weaker Patents* St Johns Law Review 2015 55-56.

¹⁴³ Van Zimmeren E, Vanneste S & Matthijs G, et al *Patent Pools and Clearinghouses in the Life Sciences* Trends in Biotechnology 2011 Vol 29(11) 570.

¹⁴⁴ *Ibid.*

¹⁴⁵ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 11 -13.

¹⁴⁶ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4.

¹⁴⁷ Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 16 10–50.

¹⁴⁸ Lampe R & Moser P *Do Patent Pools Encourage Innovation? Evidence from the Nineteenth-Century Sewing Machine Industry* Journal of Economic History 2010 Vol 70(04) 898-920.

¹⁴⁹ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4.

¹⁵⁰ For more information on these pools see *ibid.*

¹⁵¹ Developing Golden Rice required an astonishingly large array of patent-protected technologies; it called for seventy patent-protected technologies belonging to over thirty public and private sector entities. Fortunately, these patent-holding entities cooperated by offering free licenses to promote distribution of the crop to the developing world. For more discussion see Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15 1 available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015).

¹⁵² Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 225-226. See also Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 51.

development of a Severe Acute Respiratory Syndrome (SARS) vaccine and diagnostic kit.¹⁵³ In this case, the potential licensors had not developed any products at the time of these discussions, resulting in limited opportunity to evaluate scope of claims or essentiality. It transpired that the feared SARS outbreak never materialised and with economic incentive lacking, formation of the pool was never concluded.¹⁵⁴ Around the same time, Médecins Sans Frontiers and Essential Inventions¹⁵⁵ proposed a pool for patents relating to fixed combination AIDS drugs. The intended purpose of this pool was to enable cost-effective manufacturing of antiretrovirals (ARVs), specifically fixed dose combinations and paediatric formulations and second line ARV treatments.¹⁵⁶ The pool is now fully functional and administered by UNITAID.¹⁵⁷ The pool recently signed licence agreements with the NIH, Gilead Sciences and ViiV Health care (a collaboration between Glaxo SmithKline, Pfizer and Shionogi), to allow for sub-licensing for generic manufacture.¹⁵⁸

Patent pools may have significant benefits, as they may remove the need for stacking licences and decrease licensing costs by operating as a “one stop” system for non-member licensees.¹⁵⁹ Pools are a potential solution to patent thickets and they also encourage research funding, benefitting all partners in the pool.¹⁶⁰ The risks associated with research and development are shared amongst pool members, allowing them to be less risk averse. Members of a patent pool may choose to have the pool administered by an independent body. When administration of a pool is centralised, patent-holders are spared the often-significant burden of managing their patents.¹⁶¹ As a result of the commercial focus of diagnostics, it is considered a good area for using patent pools. The number of patent-holders can be managed. Since genetic diagnostic tests are expected to take certain time to develop, recording developments in the market is also possible.¹⁶² Patent pools would be ideal for diseases detected by multiple genetic variations on a single gene and diseases caused by several genes (polygenic diseases).¹⁶³

Patent pools are also criticised as potentially ineffective as the industry comprises diverse, participants and parties, often involved in one-off transactions; the usefulness of pools may be limited.¹⁶⁴ The diversity

¹⁵³ For more discussion see *ibid*.

¹⁵⁴ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 225-226. See also Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 51.

¹⁵⁵ Essential Inventions Inc. was organized in 2004 to promote the creation and distribution of essential inventions and other works that support public health, nutrition, learning, and access to information and cultural life. See <http://essentialinventions.org/> (accessed 07 March 2018).

¹⁵⁶ *Supra* note 154.

¹⁵⁷ A facility created by several developing countries and supported by the WHO.

¹⁵⁸ Another example is the pool for open innovation against Neglected Tropical Diseases established by GSK.

¹⁵⁹ *Supra* note 154.

¹⁶⁰ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4.

¹⁶¹ *Ibid*.

¹⁶² Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁶³ These include Alzheimer's, cystic fibrosis, spinocerebellar ataxia, myotonic dystrophy, hereditary ovarian or breast cancer, and hereditary haemochromatosis. See Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁶⁴ Haracoglou I *Competition Law and Patents – a Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008.

of membership could lead to instability.¹⁶⁵ Pools may also be unattractive to patent-holders where they have the effect of increasing the density of collaborative arrangements with little associated benefits. There may be an associated increase in transaction costs. Even though patent pools should reduce costs, a real possibility exists that non-blocking or substitute patents may be included in a pool, inflating royalties.¹⁶⁶ Another potential challenge is inequality in remuneration for particular pool members. Patent pools are also usually dependent on the voluntary decision to pool the patents, unlikely to arise in the absence of interdependence in cases of access to essential inputs.¹⁶⁷

There seems to be certain scepticism regarding the usefulness of patent pools in the biotechnology industry. In a study by Nicol, respondents were asked about their knowledge of, experience with and attitudes towards patent pooling, clearing house mechanisms and cross licensing. These studies indicate low levels of engagement with each of these.¹⁶⁸ A Swiss survey reports that biotechnology companies are careful about collaborating with other companies and are therefore not keen to adopt this approach.¹⁶⁹ Although patent pooling may provide a solution to patent thickets and intellectual property blockages, the validity of the patents in question should be beyond doubt for patent pools to achieve this benefit.¹⁷⁰ Empirical evidence has indicated that certain patent pools were created in the biotechnology industry, such as the Single Nucleotide Polymorphism (SNP) Consortium and the Genbank pool.¹⁷¹ These are observed as particularly effective pools. Conversely, empirical evidence from Germany indicates that patent pools are not deemed to be effective in increasing access to genetic inventions due to the difficulty in assessing contributions. In certain cases, pools were also found to be inefficient.¹⁷²

3.5.6 Licences

Licensing agreements is a form of protected knowledge sharing that is often beneficial to parties. Conditions including time, scope, area of activity and jurisdiction may limit licences.¹⁷³ Patent owners (the licensors) can grant licences providing recipients (the licensees) permission to exploit the patent, promising not to bring a suit against the licensees for infringing the patent. Individuals using the technology

¹⁶⁵ Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁶⁶ Van Overwalle G *Exclusive Ownership Versus Open Commons: The Case of Gene Patents* The WIPO Journal: Analysis of Intellectual Property Issues 2013 Vol 4.

¹⁶⁷ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008.

¹⁶⁸ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool In Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 11 -13.

¹⁶⁹ For full details see Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁷⁰ *Supra* note 168 at 225.

¹⁷¹ *Supra* note 167.

¹⁷² For example, the patent pool between VISX and Summit Technology, the only two FDA-approved manufacturers of lasers used in photo refractive keratotomy, was condemned as it was perceived to act as an instrument for fixing prices and eliminating horizontal competition between the companies, in view of the ability of both companies to enter the market independently. See Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008.

¹⁷³ For discussion see Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008.

protected by a patent must request a license from the patentee, provided this activity is not covered by a research or other type of exception.¹⁷⁴ Various types of licences and exceptions are discussed below.

3.5.6.1 Exclusive licences

Exclusive licences entail an exclusive right provided to use the invention without any further rights. In addition to exclusive licences being anticompetitive (in cases where basic technology is used and further research is required), limiting it to one research body could be risky and does not combat the issue of hindering further research and innovation.¹⁷⁵

3.5.6.2 Semi-exclusive licences

This type of licence allows both parties to use the invention. Further licences cannot be granted.¹⁷⁶ In the field of genetics this may function as the patent-holder will have the authority over their intellectual property rights, in addition to making the licence exclusively available to a licensee; no other researchers will gain a licence. This is not ideal as it may still stifle research, increase costs and limit patient access.¹⁷⁷

3.5.6.3 Non-exclusive licence

A licensor may confer a right to use an invention to several parties through a non-exclusive licence. This type of licence allows the holder to retain the right to use it and to license it further.¹⁷⁸ In Europe, there is evidence that the licensing system functioned well for several genetic tests. For instance, the patent for the cystic fibrosis transmembrane conductance regulator gene¹⁷⁹ and its mutations, useful for the diagnosis and carrier testing of cystic fibrosis, was licenced at reasonable, non-exclusive conditions to more than 60 manufacturers and laboratories.¹⁸⁰ Competition for quality results in great improvements in the test over the years and prices remained competitive. In addition, free access to the CFTR gene sequence was granted to genetic diagnostic testing services in academic hospitals using laboratory-developed methods.¹⁸¹ A similar licensing approach was used for Tay-Sachs disease.¹⁸²

¹⁷⁴ Van Zimmeren E, Vanneste S & Matthijs G et al *Patent Pools and Clearinghouses in the Life Sciences* Trends in Biotechnology November 2011 Vol 29(11) 570.

¹⁷⁵ Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁷⁶ Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents In Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 11 -13.

¹⁷⁷ *Ibid.*

¹⁷⁸ *Supra* note 175. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics 2009 Vol 42(1) 41-58.

¹⁷⁹ The CFTR gene.

¹⁸⁰ For more detail on this see Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁸¹ *Ibid.*

¹⁸² Huys I, Matthijs G & Van Overwalle G *The Fate and Future of Patents on Human Genes and Genetic Diagnostic Methods* Nature Reviews Genetics 2012 Vol 13 441.

3.5.6.4 Ex-officio licensing

Ex-officio licensing is statutory in nature. In the case of this type of licence, a minister of health, or the like, is provided the authority to grant licences enabling patented inventions to be used in situations involving public health where the involved parties cannot reach consensus. Certain countries designed a specific public health licence apart from the general compulsory licence.¹⁸³ For example, France recently implemented an ex-officio licence for national public health reasons in its law on bioethics.¹⁸⁴ The French government included a *licence d'office* in its *Loi relative à la bioéthique* that would be decided upon by the Minister of Health in cases where using the patent invention would be important for the provision of public health services and where the patent owner and the user could not establish a licensing agreement.¹⁸⁵

3.5.6.5 Compulsory licences

Another possible solution offered to remedy the issue involves issuing compulsory licences for gene patents on diagnostic tests to applicants under judicially set conditions. Compulsory licences would force patent-holders to license gene sequences.¹⁸⁶ General compulsory licensing entails an official authority to grant a licence to a third party in cases where the patent-holder refuses to do so.¹⁸⁷ The competent authority will grant the licence to an applicant compensating the patent-holder by providing reasonable remuneration. Contrary to other balancing mechanisms in the patent system, compulsory licences do not arise automatically but instead only after a decision by the competent body after proper deliberation.¹⁸⁸ A compulsory licence does not deprive a patentee of any rights inclusive of the right to own exploitation. A compulsory licence is therefore a mandated non-exclusive licence of sorts.¹⁸⁹

Article 31 of the TRIPS Agreement allows for compulsory licences.¹⁹⁰ The provision is limited and the party seeking the licence should attempt to reach an agreement with the patent-holder to obtain a voluntary licence on reasonable terms. In certain circumstances, compulsory licences may be issued. These circumstances include: the non-use of a patent for three years from its grant or four years from its

¹⁸³ Van Overwalle G “*Reshaping Bio-Patents: Measures to Restore Trust in the Patent System*” (editor) Somsen H *The Regulatory Challenge of Biotechnology Human Genetics Food and Patents* Biotechnology Regulation Series 2007.

¹⁸⁴ Law 2004-800 of 2004 on Bioethics. For more discussion, see also *supra* note 180.

¹⁸⁵ Law 2004-800 of 2004 on Bioethics.

¹⁸⁶ For more discussion see Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15(1) available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 11 -13.

¹⁸⁷ *Supra* note 180.

¹⁸⁸ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 55.

¹⁸⁹ Ellis GC *Emerging Biotechnologies Demand Defeat of Proposed Legislation that Attempts to Ban Gene Patents* Richmond Journal of Law & Technology 2008 Vol 15(1) available at <http://law.richmond.edu/jolt/v15i1/article1.pdf> (accessed 19 June 2015). See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics – University of Tasmania Occasional study 2014 08 11 -13.

¹⁹⁰ See *Trips: A More Detailed Overview of the Trips Agreement* https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

application; when necessary to use a second otherwise infringing patent constituting a technological advancement and in cases of extreme urgency, crisis, or to remedy anticompetitive behaviour.¹⁹¹

The practical implication is that member countries have the flexibility to design a system of compulsory licensing considering its own national circumstance and incorporate this into their own national laws.¹⁹² Certain jurisdictions are more accommodating towards compulsory licences than others.¹⁹³ For instance, a compulsory licence can only be obtained in Belgium when it has been indicated that the patent owner is not exploiting his monopoly rights for four years and on the condition that the patent is not being infringed.¹⁹⁴

Several factors promote granting of compulsory licences for example, compulsory licences may be considered desirable, where the demand for a product is not met.¹⁹⁵ According to the economic theory, a monopolist will intentionally under-supply goods to maximise profit. In such circumstances, compulsory licences may facilitate entry into the market, leading to enhanced consumer choice and lower prices.¹⁹⁶ Compulsory licences may also be desirable in certain cases as they may facilitate further innovation. This is especially important in the case of technological improvements closely tied to earlier patents. Proponents of this view argue that intellectual property rights can reinforce market power in the areas of network industries.¹⁹⁷ Compulsory licences may, under appropriate circumstances, be desirable in the case of products vital to the public, such as those relating to public health.¹⁹⁸ Some countries, such as the US, have enacted more sector-specific legislation to provide for the particular interests affected by pharmaceutical patenting.¹⁹⁹

¹⁹¹ *Ibid.* For discussion, see also Jain D & Darrow JJ *An Exploration of Compulsory Licensing as an Effective Policy instrument for Antiretroviral Drugs in India* Health Matrix 2013 Vol 23(2). See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies Comparative Politics* 2009 Vol 42(1) 41-58.

¹⁹² Ruse-Khan HG *The International Legal Framework for the Protection of Utility Models: Unmatched Flexibility for Domestic Experimentation?* Paper prepared for WIPO Regional Seminar on the Legislative, Economic and Policy Aspects of the Utility Model System 175.

¹⁹³ For discussion, see Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

¹⁹⁴ Matthijs G *The European Opposition Against the BRCA Gene Patents* Springer Familial Cancer 2006 Vol 5 101. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies Comparative Politics* 2009 Vol 42(1) 41-58.

¹⁹⁵ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 55. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies Comparative Politics* 2009 Vol 42(1) 41-58.

¹⁹⁶ *Ibid.*

¹⁹⁷ *Supra* note 195.

¹⁹⁸ *Supra* note 195.

¹⁹⁹ For example, the Public Health Emergencies Act 110 provides the US Secretary of Health and Human Services broad discretion to issue compulsory licences to address public health emergencies. The latter provides that when determining reasonable remuneration, the following factors should be taken into account:

- the risks and costs associated with the invention; the efficacy and innovative nature and the importance of the invention or of products using the invention to public health;
- the degree to which the invention has benefited from publicly funded research; the need for adequate incentives for the creation and commercialisation of new inventions;
- the public's interest in health care services; the public health benefits of wider access to inventions;
- the benefits of making inventions available to working families and retired persons; and
- the need to correct anti-competitive practices or other public interest considerations.

See Public Health Emergencies Act HR 3235 of 2001. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies Comparative Politics* 2009 Vol 42(1) 41-58.

Conversely, compulsory licences are also severely criticised as it may reduce incentives for the original innovation as a reduction in incentive would dramatically reduce the level of investment.²⁰⁰ Compulsory licences could discourage the intellectual property owner to engage in further research as he would have normally used the profits from the intellectual property rights for this purpose. Empirical evidence is ambiguous in this matter. An analysis of patenting activity from 1954 to 1956 indicate that patent owners subject to compulsory licences significantly reduced their patenting activity.²⁰¹ By contrast, a 1975 study did not find any evidence that compulsory licences adversely affected corporate research and development expenditure. It would seem therefore, that the effect also depends on other factors, such as first-mover advantages and royalty rates.²⁰² Another issue that arises is political acceptance. Non-Governmental Organisations (NGOs) and academics interviewed between 2008 and 2010 believe that the government of India had not utilised the compulsory licence provision in their 2005 Indian Patent Act from fear of being sanctioned by the US, Europe, or Japan.²⁰³ All stakeholders express the view that the US pressures developing countries to limit using compulsory licensing. A drawback of compulsory licensing provisions within TRIPS is that it is not an essential signatory requirement but rather an option that member nations have for implementation into their domestic legislation.²⁰⁴

The usefulness of the compulsory licence provision in the context of research instruments depends on both the substantive and the practical aspect. Substantively most countries contemplate licences where the public's interest so dictates. Other countries refer more specifically to the cases of non-use, dependent patents and emergency or anticompetitive situations.²⁰⁵ More than ninety-six countries have a certain form of compulsory licensing in their legislation. This instrument is rarely invoked.²⁰⁶ There are two reasons for this: firstly, most medicines in developing countries are free of patents with the result that there was little need to override market exclusivity. Secondly, the threat of permitting the production of competing generic medicines in the case of certain countries led pharmaceutical companies to offer pharmaceuticals at cheaper prices.²⁰⁷ Abbott and Cottier note that infrastructural shortfalls, amongst other factors, are responsible for the lack of using compulsory licensing.²⁰⁸ The threat of a compulsory licence can persuade a patent owner to negotiate a voluntary licence on commercially reasonable terms, consequently obviating

²⁰⁰ Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics 2009 Vol 42(1) 41-58.

²⁰¹ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 56. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics 2009 Vol 42(1) 41-58.

²⁰² *Ibid.*

²⁰³ Jain D & Darrow JJ *An Exploration of Compulsory Licensing as an Effective Policy Instrument for Antiretroviral Drugs in India* Health Matrix 2013 Vol 23(2).

²⁰⁴ See *Trips: A More Detailed Overview of the Trips Agreement* https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

²⁰⁵ *Supra* note 201 at 58.

²⁰⁶ Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25 99.

²⁰⁷ An example is when the pharmaceutical company Roche offered a 40 per cent price reduction on its AIDS drug, Viracept, to Brazil after the Brazilian government publicly announced in 2001 that it would issue a compulsory license to a local laboratory. Fink C *“Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective”* (editor) Newfarmer R *Trade, Doha and Development a Window into the Issues* The World Bank 2006.

²⁰⁸ Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25 99.

the need for compulsory licence.²⁰⁹ The anthrax episode in the US is an example of this.²¹⁰ The anthrax incident is not different from a developing country's ability to use TRIPS' compulsory licensing provisions to address issues such as the AIDS pandemic.²¹¹ The anthrax incident emphasises the significance of compulsory licensing in protecting and advancing the public's interest.

Brazil effectively and consistently manages to control the costs of ARV drugs by effectively threatening to issue compulsory licences under the terms of the TRIPS Agreement.²¹² The same applies in the case of India, using compulsory licences under section 84(1) of the Indian Patent Act. An applicant may request a compulsory licence if: after three years from the date the patent was granted, the public need covered by the claim, is not fulfilled; the invention is not economically available to the public; or the patented invention is not "worked in" or manufactured in the country, to the fullest extent possible.²¹³

Various European countries have amended national compulsory licence regimes to remedy the challenges arising from restrictive licensing practices in the field of genetic testing. France amended the existing compulsory licence regime by broadening it to include genetic diagnostics in 2004²¹⁴ while Belgium introduced a new compulsory licence regime for public health through the Patent Act of 2005.²¹⁵ Both these compulsory licences are considered legitimate: if the quantity or quality of medicines is insufficient to meet the needs of the public, if medicines or methods are economically unavailable, if there is exploitation that opposes the interests of public health, or if the patent is used in anticompetitive practices.²¹⁶ The German patent regulations further allow, in cases of well-founded requests, using patented biological material in the public's interest under a compulsory licence.²¹⁷ A compulsory licence may be sought against obstructive patents in diagnostics.²¹⁸

²⁰⁹ For discussion see *ibid.*

²¹⁰ After the September 11 2001 terrorist attacks, the US expressed concern relating to the use of anthrax as an instrument of biological warfare. As a result, the US needed to obtain Cipro which is the antibiotic needed to treat anthrax. The patent to Cipro is held by Bayer, a German company. The US grew concerned that they would not be able to obtain the required amounts of the drug and threatened to override Bayer's patent to instigate the production of a generic drug under compulsory licenses based on "national interest". As a result, Bayer was persuaded to provide the drug to the United States at half their original asking price. Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25 99.

²¹¹ Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25 99.

²¹² As a result of such manoeuvring, the average cost per individual per day of ARV treatment decreased by 65 per cent for one drug and 59 per cent for another - a testament to the effectiveness of the mere availability of compulsory licensing, even if no compulsory license is issued. See Jain D & Darrow JJ *An Exploration of Compulsory Licensing as an Effective Policy Instrument for Antiretroviral Drugs in India* *Health Matrix* 2013 Vol 23(2).

²¹³ In 2012 the Indian Patent Office issued its first compulsory license (after amending its Patent Act), to a domestic generic drug maker which ended Bayer AG's monopoly over an anti-cancer drug and authorises the production of a low-cost version for the Indian market. See Choudhury M *What is India's New National Intellectual Property Rights (IPR) Policy?* available at <https://www.quora.com/What-is-Indias-new-National-intellectual-property-rights-IPR-policy> (accessed 26 October 2016).

²¹⁴ Article 18 of Loi 2004-800 du 2004 relative à la Bioéthique (Law 2004-800 of 2004 on Bioethics) and Article 10 of Loi 2004-1338 du 2004 relative à la Protection des Inventions Biotechnologiques (Law 2004-1338 of 2004 on the Protection of Biotechnological Inventions).

²¹⁵ Article 31 bis section 1 of the Belgian Patent Act of 2005. The Belgian Patent Act is modelled after the French system. Compulsory licenses can be granted for "a) a medicine, a medical device, a medical device or product for diagnosis, a derived or combinable therapeutic product; b) the process or product necessary for the fabrication of one or more products indicated under a); and c) a diagnostic method applied outside the human or animal body".

²¹⁶ Article 31 bis of the Belgian Patent Act of 2005.

²¹⁷ Section 24 German Patent Act.

²¹⁸ Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* *UC Irvine Law Review* 2011 Vol 1(2) 492-493.

3.6 Conclusions

The impediments to research caused by patents might be greater in the field of genetics than in any other area of science. Research in this field includes research into gene function, the role of gene sequences in diseases and specific to this study, downstream research to create or improve diagnostic tests for these diseases.²¹⁹ There is no doubt that gene patents positively participate in incentivising developing gene diagnostics. It also creates a stifling of research and development and an obstruction to patients' access.²²⁰ These negative effects in clinical health care lead to barriers in accessing gene-based diagnostics by patients both due to test availability and due to test price.²²¹

In view of facilitating commercialisation and ensuring access to patented technologies, several alternatives and limitations are considered to find the appropriate balance between the interest of the public and that of the private patent-holder. The current patent system regarding the patenting of genomic material supports the interest of the private patent-holder.²²² At first glance, the benefits of gene patenting such as the necessary funding gained from commercialisation providing funding for ongoing developments and the infringement exception for medical treatments appear outweighed by possible negative impacts ranging from health and high costs to duplicative efforts and stifling research. Yet of all considerations, the central question should be whether an appropriate balance is attained between public and private interest in the current patent system, specifically as it applies to genetic material.²²³ It is submitted that in considering the alternatives above, licensing cannot be the answer. Even when patent owners are willing to license rights to multiple laboratories; the cost, complexity and time delays involved in obtaining the licence still serve as an obstruction to researchers. In a study survey, American scientists of various disciplines reported how patents directly affected their research decisions as follows: 58 per cent delayed research, 50 per cent changed research and 28 per cent abandoned research.²²⁴ The study reports that 58 per cent of scientists did not participate in certain areas of research because of complex licensing negotiations for patent rights.²²⁵ Although compulsory licensing will not overcome all the opposition to genetic patents,²²⁶ it could assist in addressing several of the challenges keeping useful biotechnological

²¹⁹ Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 568.

²²⁰ A survey by Cho et al found that patents and licenses have negatively affected the ability of clinical laboratories to develop and provide genetic tests and to perform research. See also Cho M *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics* Trends in Biotechnology 2010 Vol 28(11) 548. See also Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

²²¹ The BRCA1 gene raised concerns that the patent would hamper innovation and the identification of new tests and diagnostic methods, impairing equitable access to testing and the public health approach. For discussion, see Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access* - BIO Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 391. See also Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 4-5.

²²² Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 300.

²²³ *Ibid.*

²²⁴ For more discussion see Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 300.

²²⁵ *Ibid.*

²²⁶ See section 3.5.6.5 or a full discussion on the disadvantages of compulsory licenses.

and pharmaceutical products from the public, whilst continuing to promote more research and development.²²⁷

The patent balance assumes a particular significance in the biotechnology/pharmaceutical industry as it is an industry affecting public policy as it improves health and the standard of living. In contrast with several other industries, the pharmaceutical/biotechnology industry relies heavily on the patent system to appropriate returns and considerable innovation is based on the patent system.²²⁸ The current patent system is however, non-dimensional. Traditionally, patent law is applied across all fields of technology, despite economic research demonstrating that innovators across various fields are not the same. Patent rules providing the correct balance between patent incentives and competition needs to be established.²²⁹

An option would be to tailor the patent system to meet the diverse needs of industries.²³⁰ The ideology underlying this approach is based on the idea that adjusting patent law to various sectors serves to provide the best economic effect.²³¹ Factors to consider would include economic and social welfare. Other elements, such as fairness of a just reward, legal certainty and transparency may spur a more nuanced decision on the best way to accommodate differing patterns of innovation.²³² Keep in mind that the optimal level of national protection depends on both policy incentives within the country and policies of neighbouring countries. With only one country maintaining a patent system whilst a neighbouring country does not, invested resources and development costs will be the responsibility of the first country.

Alternatively, consumers in the neighbouring country will face lower costs and will free off the investments of their neighbours.²³³ It is for this reason that developed countries seek to unify standards of patentability ensuring they are not bearing the costs of stronger intellectual property rights.²³⁴ Challenges may develop as new techniques develop, for example, there is a gradual shift from gene-based tests to genome-based tests. Patent claims for RNA interference are also evolving and may bring serious patent thickets.²³⁵ It is the author's submission that the field of genetic patents should indeed vary from other fields and intellectual property laws within this field should be observed with the aim to promote a balance of the rights to access to health care and to property, in order to fully benefit society.

²²⁷ *Supra* note 224.

²²⁸ Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 25.

²²⁹ Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski Case* Western Reserve Journal of Law, Technology & the Internet 2012 75.

²³⁰ Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 492-512.

²³¹ *Ibid.*

²³² *Supra* note 230.

²³³ Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law 2015 698.

²³⁴ *Ibid.*

²³⁵ For more discussion see Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

Chapter 4

4.1 Global Instruments Relating to Intellectual Property Law

Should we accept that none of the alternative forms of protection discussed in the previous chapter provide inventors with enough incentive and reward as a patent right, then consideration must be given to observing diagnostic gene patents with the aim to balance the rights to access to health care and to property in order to fully benefit society. It is necessary to first establish the international status of intellectual property law in order to ascertain its relationship with the right to health care. This chapter aims to analyse the global presence of intellectual property through international instruments. The discussion aims to create an understanding of the development and objectives of international intellectual property instruments and the effect of these instruments in the context of aiding or hindering accessibility of biotechnology such as diagnostic gene tests. Even though international instruments are not binding, they provide guidance and attempt to unify international standards. Jurisdictional differences in the interpretation and implementation of these instruments must be noted as it plays a role in identifying the primary intellectual property objectives of developing and developed countries indicating core issues faced when interacting with health care.

Global agreements assist to coordinate the process of obtaining patents and ensuring that all countries abide by a set of minimum standards. Even though national laws govern the grant and enforcement of patents, it is global agreements and conventions that serve as guidelines for such national laws.

This chapter discusses the following global instruments relating to patents:¹

- The Paris Convention;
- TRIPS Agreement.

The Paris Convention serves as the initial international instrument to bring regulation to the area of intellectual property and while the TRIPS Agreement introduced amongst other things, a minimum standard of protection. The development and context of both of these instruments are important as they serve as a guide to the international aims within this area of law and the negotiations surrounding these instruments, particularly the TRIPS Agreement, which depict the disregard for the needs of developing countries in relation accessibility of biotechnology and pharmaceuticals.

4.2 The Paris Convention for the Protection of Industrial Property

The second half of the last century indicates the development of a more globally focussed flow of technology. The increase of global trade made harmonisation of industrial property laws in the patent field

¹ The Patent Cooperation Treaty (1970), the Strasbourg Agreement (1971), the Patent Law Treaty and the Budapest Treaty (1977) will not be addressed in this chapter as they all focus on procedural issues and not substantial ones.

urgent.² Creators in various countries found the transfer of technology difficult due to the lack of uniformity and impracticality.³ In 1873 a global exhibition of inventions was held in Vienna.⁴ The need for global protection became even more apparent when several foreign exhibitors refused to attend the exhibition for fear of their ideas being stolen and commercially exploited.⁵ In order to make inventors feel more secure, a special law was enacted to offer temporary protection to attendees of the Congress in Vienna for Patent Reform which was held later that same year.⁶ The Congress in Vienna for Patent Reform explained principles on which an effective and useful patent system should be based. Governments were urged “to bring about an international understanding upon patent protection shortly afterwards”.⁷ Following this, Paris hosted an international congress on industrial property in 1878, where it was held that a global diplomatic conference should be held and their task would be to determine the basis of uniform legislation in the field of industrial property. The latter was drafted and was adopted at the 1880 Paris conference.⁸ The draft contained several substantive provisions that remain in the convention today.

The final draft was approved in 1883 in Paris at a diplomatic conference.⁹ Eleven states signed the Convention when it came into effect on 7 July 1884.¹⁰ The Convention specifies that contracting states are constituted into a Union for the protection of industrial property.¹¹ Since the Paris Convention underwent the following revisions, each progressively strengthening the rights of intellectual property holders:¹²

- 1886 in Rome;
- 1890 and 1891 in Madrid;
- 1897 and 1900 in Brussels;
- 1911 in Washington;
- 1925 in The Hague;
- 1934 in London;
- 1958 in Lisbon;

² An example of this is that patent applications had to be made roughly at the same time in all countries to avoid a publication in one country destroying the novelty of the invention in the other countries. See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241. See also www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf (accessed 5 April 2015).

³ *Ibid.*

⁴ The Austria-Hungary international exhibition of 1843.

⁵ For more information on this see www.wipo.int/treaties/en/general (accessed 02 June 2015).

⁶ Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 5 July 2015). See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241.

⁷ See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241. See also Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003.

⁸ For more discussion see Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003 18.

⁹ *Ibid.*

¹⁰ These included Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain and Switzerland.

¹¹ Article 1 of the Paris Convention on Industrial Property. For discussion see Bodenhausen GHC *Guide to Applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 9.

¹² The Paris Convention can be found at https://www.wipo.int/treaties/en/text.jsp?file_id=288514 (accessed 11 December 2018). For further details on each revision see Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003 14.

- 1967 and 1979 in Stockholm.¹³

The last amendment in 1979 was concurrent with establishing the World Intellectual Property Organisation (WIPO) which assumed responsibility for further administering the Convention.¹⁴ This obliges all members of WIPO to adopt the Convention.¹⁵ As a result there is a total of 172 signatories to the Convention, including South Africa.

4.2.1 Contentions of the Convention

Following the Stockholm Convention, developing countries, such as Brazil and various African countries voiced their concerns regarding the Convention's balance between the public's interest of the member nations granting the patent and the rights of the patentee to be inequitably weighted towards the patentee.¹⁶ They consequently proposed that the convention be revised in areas concerning national treatment; right of priority; independence of patents; compulsory licensing and revocation; and importation of products manufactured by a process patented in the importing country.¹⁷ Developed countries, such as the US and various European countries, rejected this proposal and declared that any favoured treatment of developing countries could only be transitional.¹⁸ Where developed countries operate their technology transfer through multinational corporations¹⁹ viewing the purpose of global conventions to yield effective protection of industrial property; developing countries adhere to the ideas of reciprocity and equal treatment under global conventions and believe the purpose of these treaties to be transfer of technology.²⁰ Despite developing countries constituting the majority of the total number of countries in the union, developed countries are the significant patentees and, until this challenge, were the controlling force in the Paris Union.²¹

The main substantive differences between the 1884 version of the Paris Convention and subsequent conventions concern local working requirements and compulsory licensing.²² At the fifth revision in Lisbon in 1958 the issue of pharmaceuticals and chemical substances as patentable subject-matter, was revised.

¹³ Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 05 July 2015).

¹⁴ See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241. See also Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003.

¹⁵ Kitch EW *The Nature and Function of the Patent System* 289 available at <http://www.jstor.org/stable/725193> (accessed 23 April 2015). See also Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003.

¹⁶ For more detail see Loughran RA *The United States Position on Revising the Paris Convention: Quid Pro Quo or Denunciation* *Fordham International Law Journal* 1981 Vol 5(2) 420.

¹⁷ *Ibid.*

¹⁸ *Supra* note 16 at 421.

¹⁹ Multinational corporations, transnational corporations and transnational enterprises are used interchangeably in this regard.

²⁰ *Supra* note 16 at 424.

²¹ *Supra* note 16 at 424.

²² The Paris Convention can be found at https://www.wipo.int/treaties/en/text.jsp?file_id=288514 (accessed 11 December 2018). For more details on the differences between each version see Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003 14.

The latter is previously not explicit in the Paris Convention of 1884.²³ The final provisions are discussed below concerning the Convention that came into effect on 7 July 1884.

4.2.2 Principle provisions of the Convention

The Convention addresses trademarks, patents, competition and industrial designs, amongst other factors.²⁴ There are four main categories within the Convention, these are listed and discussed below:

- Rules of substantive law which guarantee the right to national treatment²⁵ in each of the member countries;
- The right of priority;
- Definition of rules establishing rights and obligations of natural individuals and legal entities, or rules requiring or permitting the member countries to enact legislation following those rules; and
- Administrative framework which was set up to implement the Convention and include the final clauses of the Convention.²⁶

4.2.2.1 National treatment

Articles 2 and 3 of the convention relate to national treatment. They require all member states to allow for the same quality and quantity of protection of foreigners that is granted to nationals. This ensures that the efforts of a foreigner will be protected in the foreign nation and the inventor will not be at a disadvantage to national inventors concerning scope and protection quality.²⁷ Article 2(3) is an exception to this principle as it allows member states to impose conditions relating to judicial or administrative procedure and jurisdiction.²⁸

²³ The Paris Convention can be found at https://www.wipo.int/treaties/en/text.jsp?file_id=288514 (accessed 11 December 2018). For more details on the differences between each version see Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO) TRIPS Issues Papers* 2003 14.

²⁴ Article 1 (2) states: "The protection of industrial property has as its object (b) patents (c), utility models (d), industrial designs (e), trademarks (f), service marks (g), trade names (h), indications of source (i) or appellations of origin (j) and the repression of unfair competition (k)". See also Bodenhausen GHC *Guide to applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 1 21.

²⁵ National treatment indicates foreign owners of industrial property or their licensees are entitled to the same treatment accorded nationals of the country where the foreign owners or licensees have applied for, or been granted, a patent right. See Loughran RA *The United States Position on Revising the Paris Convention: Quid Pro Quo or Denunciation* Fordham International Law Journal 1981 Vol 5(2) 418.

²⁶ The Paris Convention for Industrial Property which can be accessed at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 12 December 2018).

²⁷ *Ibid.* For more discussion see Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 5 July 2015). See also Bodenhausen GHC *Guide to Applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 27. See also Oddi S *The International Patent System and Third World Development: Reality Or Myth?* Duke Law Journal Vol 1987 831. See also Kono T *Intellectual Property and Private International Law* 2012 15.

²⁸ Article 2(3) reads "The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved". This exception was recommended by developing countries who advocated for a less rigid application of the principle of national treatment.

4.2.2.2 The right of priority

Article 4 allows for eligible applicants who file a first regular patent application in any of the countries of the Union, to file successive applications in other countries of the Union for a defined period. The successive applications will have the same filing date as the first filed application.²⁹ This is important as all applications filed within the priority right period will have priority over intervening applications for the same or a similar invention.³⁰ With regard to patent applications the right to priority is particularly important as it conserves the novelty of the invention within the countries of the Union.³¹ The novelty is conserved despite any act that would normally destroy the novelty of an invention.³²

4.2.2.3 Rules establishing rights and obligations of natural individuals and legal entities

Article 4bis encompasses the principle that a patent application in one country of the Union is examined and either granted or denied independent of applications for patents for the same or related inventions that is filed in other countries within the Union.³³ The forfeiture, expiration, or nullity of a patent in a particular member nation does not result in forfeiture of the patent in the jurisdiction of another member nation.³⁴

- Article 4bis(5) ensures that patent terms as embarked in Article 4bis are measured in accordance with the applicable national law and is not shortened by a priority claim.³⁵
- Article 4ter affords that the “inventor has the right to be named as such in the patent”.³⁶
- Article 4quarter provides that a patent may not be voided resulting in the product being gained through a patented process and limited on its sale or importation under the domestic law.³⁷
- Article 5A (1) provides that products imported to a member country, having a patent in the country of manufacture will not forfeit patent rights in the country of importation.³⁸

²⁹ See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241.

³⁰ *Ibid.*

³¹ *Supra* note 29. See also Oddi S *The International Patent System and Third World Development: Reality Or Myth?* Duke Law Journal Vol 1987 831.

³² Including publication or exhibition.

³³ The Paris Convention for Industrial Property which can be accessed at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 11 December 2018). For discussion see also Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 5 July 2015). See also Bodenhausen GHC *Guide to applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 1 61.

³⁴ The Paris Convention for Industrial Property which can be accessed at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 11 December 2018). See also Loughran RA *The United States Position on Revising the Paris Convention: Quid Pro Quo or Denunciation* Fordham International Law Journal 1981 Vol 5(2) 428. See also Bodenhausen GHC *Guide to applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 Vol 1 61.

³⁵ Including publication or exhibition.

³⁶ The procedure for the exercise of this right of the inventor will be regulated by member states in national legislation. The Paris Convention for Industrial Property which can be accessed http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 11 December 2018).

³⁷ Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 05 July 2015).

³⁸ The Paris Convention for Industrial Property which can be accessed http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 11 December 2018). Article 5A was added in 1958. See *ibid.* See also Thujo Gathii J *What History Teaches us about International Protection of Intellectual Property Rights: the Case of Least Developed Countries* Georgia Journal of International and Comparative Law 2012-2013 41.

- Article 5A (2) - (4) allows countries to enact legislation leading to the granting of compulsory licences.
- Article 5quater provides for a product imported into a country of the union where a patent protecting the manufacturing process of the product already exists, the patentee will have rights, concerning the imported product, provided by the legislation of the country of importation, based on the process patent.³⁹

4.2.2.4 Administrative framework

Member states are obligated to establish a central industrial property service.⁴⁰ The latter is responsible for communicating with the public on matters of patents and trademarks. The service includes publication of an official periodical journal.⁴¹ Member countries are permitted to conclude separate agreements amongst members for protecting industrial property.⁴² These agreements cannot contain any provisions that contravene those of the Paris Convention.⁴³ Lastly, the Convention provides that disputes that cannot be settled may be taken before the International Court of Justice.⁴⁴

Despite the Convention setting out a binding framework for member nations,⁴⁵ the scope of its provisions may be limited as the Convention allows member states the freedom to nationally legislate on industrial property queries according to their interests or preferences.⁴⁶ Concerning patents, the Convention does not provide for patentability requirements as these are left to individual national legislation.⁴⁷ Member states are also afforded freedom in determining the rights that will be granted in their national legislation. An example of this is the granting of the right of priority to someone other than those entitled to the right by the Convention.⁴⁸

³⁹ The Paris Convention for Industrial Property which can be accessed http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 11 December 2018). See also Thuo Gathii J *What History Teaches us about International Protection of Intellectual Property Rights: the Case of Least Developed Countries* Georgia Journal of International and Comparative Law 2012-2013 41.

⁴⁰ Article 12 of the Paris Convention on Industrial property available at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 13 June 2017).

⁴¹ Chapter 5 of the *WIPO Intellectual Property Handbook International Treaties and Conventions on Intellectual Property* 153.

⁴² Article 19 of the Paris Convention on Industrial property available at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 13 June 2017).

⁴³ Article 19 of the Paris Convention on Industrial property. Member States of the Union may make special agreements for the protection of industrial property either bilaterally or in the form of multilateral treaties. Reiss S M *Commentary on the Paris Convention for the Protection of Industrial Property* www.lex-ip.com/Paris.pdf (accessed 05 July 2015). See also The Paris Convention for Industrial Property which can be accessed at http://www.wipo.int/treaties/en/text.jsp?file_id=287556. See Bodenhausen GHC *Guide to applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property February 1 1968 193.

⁴⁴ Article 28 of the Paris Convention on Industrial property available at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 13 June 2017).

⁴⁵ Loughran RA *The United States Position on Revising the Paris Convention: Quid Pro Quo or Denunciation* Fordham International Law Journal 1981 Vol 5(2) 417.

⁴⁶ Bodenhausen GHC *Guide to Applying the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 Vol 1 15.

⁴⁷ These include requirements such as whether a patent application should or should not be examined before determining whether a patent is granted or not, the term that it should be granted for, whether the patent should be granted to the first inventor or to the first applicant for a patent or whether patents should be granted for products only, for processes only, or for both.

⁴⁸ Article 2 and 3 of the Paris Convention on Industrial property available at http://www.wipo.int/treaties/en/text.jsp?file_id=287556 (accessed 13 June 2017). For more discussion see also Bodenhausen GHC *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised at Stockholm in 1967* World Intellectual Property 1968 Vol 1 16.

4.2.3 Summary

The Paris Convention made domestic patents more tolerable by restricting certain protectionist measures. The Convention unifies the following aspects in the field of industrial property:

- Patents granted in member countries are treated as if they are free of any patents for the same invention obtained in other countries, including non-member countries;⁴⁹
- National treatment is established through administering the same quality and quantity of protection for national individuals and foreigners;⁵⁰
- A patent granted on an application claiming the priority of one or more foreign applications, should be provided the same duration it would have if no priority is claimed.⁵¹ An extended application cannot revoke the priority date of a first application.⁵²

These measures assist in setting up a level playing field for global competition.⁵³ As a result of the 19th century producing several patents, global patents became a controversial issue. Developing countries argue for a new global economic perspective that would be a departure from what is observed by them as a structural decline in the terms of trade. They argued that the Paris Convention hides traditional strengthening of stronger countries at the expense of weaker countries and suggested that there should be differential treatment for countries structurally disadvantaged.⁵⁴ International law once again, needed to provide for the discontentment on harmonisation in this area of law.

4.3 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

4.3.1 History and background

Most global agreements focus on procedural coordination and national treatment, leaving substantive protection to individual states. The lack of provisions defining minimum substantive rights and enforcement of those rights is thought to be the justification of TRIPS.⁵⁵ Prior to the 1986 Uruguay round, WIPO, an agency of the United Nations (UN) dealt with intellectual property at an international level.⁵⁶ The Uruguay

⁴⁹ Article 4bis of the Paris Convention for Industrial Property. For more discussion, see also Gold ER & Knoppers B *Biotechnology IP & Ethics* 2009 74.

⁵⁰ Article 2 & 3 of the Paris Convention for Industrial Property. For more discussion, see also Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* available at www.lex-ip.com/Paris.pdf (accessed 05 July 2015).

⁵¹ See also Reiss SM *Commentary on the Paris Convention for the Protection of Industrial Property* www.lex-ip.com/Paris.pdf (accessed 05 July 2015).

⁵² Article 4bis (5) of the Paris Convention for Industrial Property.

⁵³ Gold ER & Knoppers BM *Biotechnology IP & Ethics* 2009 74.

⁵⁴ *Ibid* at 75.

⁵⁵ Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25 104.

⁵⁶ WIPO was responsible for administering 23 treaties including the WIPO Convention. Treaties include: intellectual property protection treaties; global protection systems; and, classification treaties. For more information see Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips But Not Trips Plus* *International Law and Politics* Vol 42 981-1028. See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25 104.

round negotiated under the auspices of the General Agreement on Tariffs and Trade (GATT),⁵⁷ between 1986 and 1994, aimed to introduce intellectual property rules for the first time into the multilateral trading system. The levels of protection between developing countries and developed countries were still substantially different as countries had various levels of both intellectual property protection and intellectual property enforcement.⁵⁸ Throughout global negotiations during the 1980s and 1990s, developing countries, such as India and Brazil argued that in sectors, including health, nutrition and agriculture, public policy reasons mandated the compulsory licensing of technology in the alternative restrictions of patent rights.⁵⁹ The US threat of unilateral actions such as sanctions met their resistance during negotiations.⁶⁰

Despite lengthy negotiations, several agreements were reached, including the TRIPS Agreement.⁶¹ The Agreement establishes minimum levels of protection, amongst other patent rights, for WTO members.⁶² It is the first multinational intellectual property treaty to contain an enforcement provision stating that countries should not only enact compliance legislation but also implement domestic enforcement mechanisms.⁶³ It is somewhat of a revolution in intellectual property law, and enhances substantive standards of intellectual property conventions negotiated within WIPO and incorporates them into one comprehensive agreement.⁶⁴ The Agreement requires all WTO members⁶⁵ to adhere to both the Berne⁶⁶ and Paris Conventions.⁶⁷ Conversely, countries not signatories to these conventions and at that time already were or may in future become WTO members had or in future will have to abide to the above conventions.

4.3.2 Principle provisions of TRIPS

TRIPS was developed, amongst others to:

- Provide minimum intellectual property rights through domestic laws;

⁵⁷ The General Agreement on Tariffs and Trade. See https://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf (accessed 05 June 2015).

⁵⁸ The reason for this is that each country widely has a different history, culture and political climate. See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 104.

⁵⁹ *Ibid.*

⁶⁰ The U.S. exerted trade pressure on uncooperative developing countries through the section 301 mechanism of the Trade Act of 1974 and the Generalized System of Preferences (GSP).

⁶¹ TRIPS was adopted in Marrakesh, Morocco, on April 15, 1994. See http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (accessed 05 May 2015). See also Ragavan & Srividhya *Patent and Trade Disparities in Developing Countries* 2012 69.

⁶² The WTO regulates international trade amongst member states. Member states make up 80% of the world's nations and the vast majority of the world's trading nations. The WTO allows member states to form agreements central to the expansion of global trade including GATT, GATS (the General Agreement on Trade in Services) and the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement. See Subhan J *Scrutinized: The TRIPS Agreement and Public Health* *McGill Journal of Medicine* 2006 Jul 9(2) 152–159.

⁶³ Helfer LR & Austin GW *Human Rights and Intellectual Property Mapping the Global Interface* 2011 29. See also Thuo Gathii J *What History Teaches Us About International Protection of Intellectual Property Rights: The Case of Least Developed Countries* *Georgia Journal of International and Comparative Law* 2012 41.

⁶⁴ *Ibid.*

⁶⁵ At present WTO has 164 members including South Africa. For more detail, see <https://www.wto.org> (accessed 15 May 2015).

⁶⁶ The Berne Convention is for the Protection of Literary and Artistic works.

⁶⁷ The Paris Convention for the Protection of Industrial Property discussed in section 4.2.

- Provide effective enforcement of those rights; and
- To submit disputes to the WTO dispute settlement system.⁶⁸

In addition, the TRIPS Agreement provides for basic principles of intellectual property, including national and most-favoured-nation treatment. General rules guarantee procedural issues faced during acquisition and maintenance of intellectual property rights do not invalidate the substantive benefits that should stem from the Agreement.⁶⁹ The Agreement has equal applicability to WTO member countries, while developing member states were given a longer period to incorporate them into their national legislation.⁷⁰

TRIPS lists its objectives as follows: to relax the global trading rules whilst still providing protection of private intellectual property rights by decreasing piracy and misappropriation, to eliminate “free-riding”, resulting from certain countries not protecting intellectual property rights and to decrease barriers to global trade, whilst still considering the need for promoting adequate protection of intellectual property rights.⁷¹

TRIPS allows countries to determine their own methods of compliance to the Agreement. It also allows countries to provide more extensive protections than those mandated. In the field of patent law, Article 33 of the Agreement affords a 20 year protection period⁷² from the date of filing, providing that countries grant patents for all fields of technology for new inventions, “involve an inventive step and are capable of industrial application”.⁷³ These requirements are open to interpretation under national legislation⁷⁴ and each country can decide on implementation according to their local conditions.⁷⁵ Article 8 states that members can adapt to protect the health and nutrition of the public and to encourage promoting their interest in both socio-economic and technological development sectors.⁷⁶

⁶⁸ See http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (accessed 05 May 2015).

⁶⁹ *Trips: A More Detailed Overview of The Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

⁷⁰ Article 1 of the Trade-Related Aspects of Intellectual Property Rights Agreement. See *Trips: A More Detailed Overview Of The Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

⁷¹ Article 7 and Preamble of the Trade-Related Aspects of Intellectual Property Rights Agreement http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 105.

⁷² In order to provide incentives for to engage in beneficial research, TRIPS encourages patent terms of a long duration to allow enough

time for costs to be recovered. For more discussion see Harris DP *TRIPS' Rebound: A Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 2 134.

⁷³ Article 27(1) of the Trade-Related Aspects of Intellectual Property Rights Agreement. For the purposes of this paper, the terms “inventive step” and “capable of industrial application” is synonymous with the terms “non-obvious” and “useful” respectively. See also *Trips: A More Detailed Overview of the Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015). For further discussion, see Ragavan S Patent and Trade Disparities in Developing Countries 2012 69. See also Gregory S *Intellectual Property Rights and South Africa's Innovation Future* Trade Policy Report No 23 South African Institute of International Affairs 21-22.

⁷⁴ The Agreement only indicates that patents should be granted for new, inventive and useful inventions - but it does not define these terms. See Report by Access Campaign *TRIPS, TRIPS Plus and Doha* 2011 available at <http://www.msfacecess.org/content/trips-trips-plus-and-doha> (accessed at 14 May 2015).

⁷⁵ Human Rights Commission - report of the High Commissioner *Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights* U.N.Doc.E/CN.4/Sub.2/2001/13 - June 27 201 available at <https://www.ohchr.org/en/issues/globalization/pages/reportshc.aspx> (accessed 19 September 2017).

⁷⁶ Article 8 of the Trade-Related Aspects of Intellectual Property Rights Agreement. See Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 132. See also Fink C “*Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective*” (editor) Newfarmer R *Trade, Doha and Development a Window into the Issues* The World Bank 2006.

Patents are specifically addressed in section 5 of the Agreement and Article 27(1) requires member countries to extend patent availability to any invention, both products and processes, as long as the technical requirements of novelty, inventiveness and industrial applicability are met.⁷⁷ Article 27(2) excludes all inventions against *ordre public* or against the grounds of morality, as unpatentable subject-matter.⁷⁸ This extends to inventions being excluded in order “to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not merely because the exploitation is prohibited by their law”.⁷⁹ Diagnostic, therapeutic and surgical methods used for the treatment of humans or animals may also be excluded from patentability.⁸⁰

TRIPS also contains two types of exceptions and limitations to patents. Article 30 provides for member states to afford limited exclusions to the private rights offered by a patent. These exceptions should not clash with using the patent and unjustly prejudice the interests of the patent-holder.⁸¹ Individuals receiving the right to use a patented innovation without the consent of the patent holder may approach the government to grant a licence.⁸² This right is provided for under Article 31. The individual should take reasonable steps to obtain a voluntary licence and can only approach the government for a compulsory licence if the patent-holder unreasonably refuses to grant a licence.⁸³ The licence, amongst others, allows generic products to be produced and put on the market at a much lower price than the original patented product. This is possible as generic companies only face production costs and do not incur the costs of research and development.⁸⁴ Note that despite unlimited grounds for the granting of compulsory licences, the following still needs to be ensured:⁸⁵

⁷⁷ Article 27 (1) of the Agreement on Trade Related Aspects of Intellectual Property Rights. See also *Trips: A More Detailed Overview of The Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

⁷⁸ Article 27 (2) of the Agreement on Trade Related Aspects of Intellectual Property Rights.

⁷⁹ *Ibid.* See also *Trips: A More Detailed Overview of The Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

⁸⁰ Article 27 (3) of the Agreement on Trade Related Aspects of Intellectual Property Rights. The reason for the exclusions is to do away with the distinction between product and process patents, which is most visible with respect to pharmaceutical and chemical patents and allows manufacturers to patent pharmaceutical products as long as they do not use the same patented process. Article 27 prohibits this. See also Gregory S *Intellectual Property Rights and South Africa's innovation Future* Trade Policy Report No. 23 South African Institute of International Affairs 21-22. See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* North- western Journal of International Law & Business 2004 Vol 25(1) 106.

⁸¹ Article 30 of the Agreement on Trade Related Aspects of Intellectual Property Rights.

⁸² These are known as a compulsory license. See Article 31 of the Agreement on Trade Related Aspects of Intellectual Property Rights available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 107.

⁸³ Countries may justify compulsory exception concerning article 8(1) and article 8(2) but still have to be consistent with Article 31. The Trade-Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion see also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Jul 9(2) 152–159. See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 107 and 136. See also Collins-Chase Ct *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 771. See also Müller-Langer F *Creating R&D Incentives for Medicines for Neglected Diseases: An Economic Analysis of Parallel Imports, Patents and Alternative Mechanisms to Stimulate Pharmaceutical Research* doctoral thesis - Hamburg University 2008.

⁸⁴ Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159. See Harris DP *TRIPS' Rebound: An Historical Analysis of how the TRIPS Agreement can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 107 and 136.

⁸⁵ Article 31 of the Agreement on Trade Related Aspects of Intellectual Property Rights. See Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 106 and 136. See also Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 319.

- (1) The proposed licensee should make an effort to reach an agreement with the patent-holder for a voluntary licence;⁸⁶
- (2) The breath and period of the licence should be restricted to the purpose of the licence;⁸⁷
- (3) The licence is exclusive and cannot be transferred to third parties;⁸⁸
- (4) The licence use should be "predominantly for the supply of the domestic market";⁸⁹
- (5) The license ends when "the circumstances which led to it cease to exist and are unlikely to recur";⁹⁰
- (6) "Adequate remuneration" should be provided to the right holder by the government;⁹¹
- (7) the decision to grant a compulsory licence is subject to independent judicial review.⁹²

Member countries may adopt reasonable measures to prevent or control the licensing of intellectual property rights that are abusive and anticompetitive.⁹³ These measures should be consistent with other provisions of the Agreement.⁹⁴

Finally, in Article 66(2), TRIPS obliges developed countries to promote technologies to lesser-developed countries in promoting and encouraging technology transfer.⁹⁵ This provision exists in order to assist developing countries with such compound issues such as the access to affordable drugs.⁹⁶

⁸⁶ This requirement may be waived in case of "national emergency," "other circumstances of extreme urgency," or "in cases of public non-commercial use." See Article 31 (1)(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1)108.

⁸⁷ See Article 31 (1)(c) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁸⁸ See Article 31 (1)(d) – (e) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁸⁹ See Article 31 (1)(f) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁹⁰ See Article 31 (1)(g) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁹¹ See Article 31 (1)(h) of the Agreement on Trade Related Aspects of Intellectual Property Rights. 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁹² See Article 31 (1)(i)-(k) of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁹³ Article 40 of the TRIPS Agreement.

⁹⁴ Article 34 of the Agreement on Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). For more discussion, see Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 108.

⁹⁵ Article 66 (2) of the Agreement on Trade Related Aspects of Intellectual Property Rights.

⁹⁶ *Ibid.*

4.3.3 Comment and criticisms of TRIPS

The TRIPS Agreement faces several criticisms including claims that the agreement provides for unreasonably strong protection and may lead to the prevention of access to affordable medicines in developing nations.⁹⁷ Criticism also include claims that TRIPS is simply old-fashioned, Western-style imperialism, assisting developed countries and private rights to the detriment of developing countries and public interests.⁹⁸ Noam Chomsky, a well-known academic⁹⁹ states: “There is nothing liberal about the TRIPS Agreement. It is a highly protected system, designed to ensure that private tyrannies, which is what corporations are, monopolise the technology and the knowledge of the future”.¹⁰⁰ In addition, health advocacy groups, such as The Network,¹⁰¹ claim that harmonising trade policies doesn’t make sense when all countries are at various stages of development, and cannot be governed by the same law?¹⁰² Developing countries claim that the TRIPS Agreement ignores the diversity of national needs.¹⁰³

These comments are in blatant contrast to comments by high-profile public officials. For example, WTO Director-General Supachai Panitchpakdi¹⁰⁴ states with reference to the Doha assignment:¹⁰⁵ “It proves once and for all that the WTO can handle humanitarian and trade concerns. This question was especially difficult. The fact that WTO members have managed to find compromise on such a complex issue bears testimony to their goodwill”.¹⁰⁶ Kofi Annan, then UN Secretary-General,¹⁰⁷ states: “intellectual property protection is vital to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world’s poorest people. The United Nations fully supports the TRIPS Agreement including the safeguards incorporated within it”.¹⁰⁸

⁹⁷ Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Jul 9(2) 152–159. Hamilton M *The TRIPS Agreement: Imperialistic, Outdated and Overprotective* Journal of Transnational Law Vanderbilt University 1996 Vol 9 613.

⁹⁸ *Ibid.*

⁹⁹ For more information, see <http://www.chomsky.info/> (accessed 05 June 2015).

¹⁰⁰ Chomsky N *Speech Asian College of Journalism Chennai* available at http://www.greenmac.com/World_Events/aninterac.html (accessed 18 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹⁰¹ The Network is a Pakistani health advocacy group. For more information about the group see <http://www.thenetwork.org.pk/> (accessed 05 June 2015).

¹⁰² Statement made by Dr Zafar Mirza, Executive Coordinator of The Network. Rizvi M *TRIPS Will Push Health Care Beyond Poor Third World Network* available at <http://www.twinside.org.sg/title/beyond-cn.htm> (accessed 18 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Jul 9(2) 152–159. See also Hamilton M *The TRIPS Agreement: Imperialistic, Outdated and Overprotective* Journal of Transnational Law Vanderbilt University 1996 Vol 9 613. See also Harris DP *TRIPS’ Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* *Northwestern Journal of International Law & Business* 2004 Vol 25(1) 131.

¹⁰³ For more information, see Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 2.

¹⁰⁴ Supachai Panitchpakdi was the Secretary-General of the UN Conference on Trade and Development (UNCTAD) from 1 September 2005 to 31 August 2013. Prior to this, Panitchpakdi was the Director-General of the World Trade Organization from September 1 2002 to September 1 2005.

¹⁰⁵ Paragraph 6 of the Doha Declaration.

¹⁰⁶ This statement can be found on the World Trade Organization website <http://www.wto.org> (accessed 15 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹⁰⁷ Kofi Annan served as the seventh Secretary-General of the United Nations from 1997 to 2006.

¹⁰⁸ Annan K *Interview World Health Organization* 2001 available at <http://www.who.int/inf-pr-2001/en/pr2001-19.html> (accessed 18 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

Further criticism of the TRIPS Agreement include both implementing its provisions in sovereign countries, the provisions themselves, and the existence of the Agreement.¹⁰⁹ TRIPS allow member countries to interpret the meaning of “new, inventive and useful” and therefore the flexibility to determine whether for example a new formulation or a new combination of two existing molecules will qualify as a new, inventive and useful invention, deserving of a patent.¹¹⁰

The implementation of the TRIPS Agreement’s intellectual property standards has a considerable impact on access to medicines and public health. By limiting competition and local manufacturing, the danger is that TRIPS extends high pharmaceutical prices and worsens the access to medicine crisis.¹¹¹ With TRIPS, life-saving medicines are considered in the same vein as mere consumer goods and the devastating impact of unreasonable prices is mostly ignored. The balance between the private interests of the patent-holder and the larger interests of society is severely skewed. It is a one-size-fits-all policy aiming at extending the stricter patenting laws previously used in industrialised countries to developing countries, regardless of their radically different social and economic conditions.¹¹²

4.3.4 Conclusion on treaties with the emphasis on TRIPS

The clarification of the extension of patents to pharmaceutical products and processes marked an expansion of global patent rules. TRIPS aims to embark a relatively high standard of minimum protection for all WTO members, including several developing countries where previous commitment to patents, copyright and trademarks were non-existent or equivocal at best.¹¹³ Unlike other global agreements, TRIPS includes consequences for non-compliance including trade sanctions.¹¹⁴ Prior to adopting TRIPS, around 50 countries did not recognise any patent protection for biotechnology/pharmaceuticals while countries such as India recognised a patent only for the product but not the process.¹¹⁵ The TRIPS Agreement is therefore largely successful in providing a forum for nations to unify their patent laws by requiring conformity with TRIPS by all WTO members.

The previous chapter establishes that genes, including diagnostic genes,¹¹⁶ are accepted as patentable subject-matter. Considering the provisions discussed, certain conclusions can be drawn in the light of Article 27(2).¹¹⁷ Based on Article 27(2) alone, a member state may also consider genes as unpatentable

¹⁰⁹ This is discussed further in Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹¹⁰ Report by Access Campaign *TRIPS, TRIPS Plus and Doha* 2011 available at <http://www.msaccess.org/content/trips-trips-plus-and-doha> (accessed at 14 May 2015).

¹¹¹ *Ibid.*

¹¹² *Supra* note 109.

¹¹³ For more discussion, see Helfer LR *Human Rights and Intellectual Property: Conflict or Coexistence?* 2003 54.

¹¹⁴ *Ibid* at 55.

¹¹⁵ *Supra* note 113 at 121.

¹¹⁶ As observed in the case of *Association for Molecular Pathology v. U.S. Patent & Trademark Office* 702 F. Supp. 2d 181 185 (S.D.N.Y. 2010).

¹¹⁷ Article 27(2) states “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”. See https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 08 June 2017).

subject-matter; as members are free to exclude them from patentability. This is the solution that Brazil adopted.¹¹⁸ Article 27(2) opens the door for gene patentability including diagnostic gene patentability, to be interpreted from a bespoke national perspective. Article 27(2) can be criticised for being too broad as the conceptions of morality and *ordre public* differ nationally.¹¹⁹ It may be impossible to find a universal consensus as to what can be construed as a contravention, based on morality.¹²⁰ The Agreement lacks specificity in this aspect. Another negative aspect is that the Agreement was not freely and fairly entered by developing countries. There was an immense lack of information on the part of developing countries and some economic coercion by the US. In addition, African countries, partly of their own accord, barely participated in negotiating the agreement.¹²¹

4.4 The Doha Declaration

As a result of certain flexibilities within TRIPS, member countries interpret the provisions differently and several countries interpret these provisions with the perspective of strengthening intellectual property laws without any consideration for the promotion of public health.¹²² Hence, national legislation is enacted that strengthen the protection of intellectual property rights and fail to consider public health issues facing developing countries.¹²³ Developing countries, including several African countries protest that the TRIPS Agreement consolidates corporate monopolies over the ownership of ideas, exacerbates the north - south technology gap and perversely speeds the transfer of capital from developing to developed countries. They argue that stronger intellectual property standards would harm their development.¹²⁴ Furthermore, as a result of the significant pharmaceutical lobby, developed countries threaten sanctions on countries that endeavour to take benefit from tools such as parallel importing or compulsory licensing provided for by TRIPS.¹²⁵ An example of the latter is the 1997 threat of trade sanctions against South Africa by the US as a response to section 15C of the Medicines and Related Substances Control Amendment Act that allows for compulsory licensing and parallel importing.¹²⁶

In order to take steps to rectify this, Zimbabwe's representative brought the need to clarify the role of intellectual property rights protection to the TRIPS Council's attention at the TRIPS Council session in

¹¹⁸ De Carvalho NP *The Problem of Gene Patents* available at <http://heinonline.org> (accessed 13 March 2015). This is discussed further under section 7.2.

¹¹⁹ The term *ordre public* is associated with "public policy". For more discussion, see Saelens C "*Ordre Public*" and *Morality as a Bar to Obtaining Intellectual Property Rights* Dissertation – Ghent University 2018.

¹²⁰ Ragavan S *Patent and Trade Disparities in Developing Countries* 2012 69. See also Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law 2015 703.

¹²¹ Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips But Not Trips Plus* International Law and Politics 2002 Vol 42 981-1028.

¹²² *Ibid.*

¹²³ Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹²⁴ Nasu H *Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement* ANU College of Law Research study 6 available at <http://ssrn.com/AuthorID=677218> 1 (accessed 02 June 2015).

¹²⁵ *Ibid.* See also Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 317.

¹²⁶ Discussed in detail in section 7.4.3.1. Also discussed in Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal Medicine 2006 Vol 9(2) 152–159. See also Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 400 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> (accessed 19 May 2015).

April 2001. Clarification was needed on protection dealing with pandemics, such as HIV/AIDS and other life-threatening diseases. He argued that even though the TRIPS Agreement allows developing countries the flexibility to apply patents in a way that still enables protecting the health of their people, there were recent legal challenges put forth by the pharmaceutical industry.¹²⁷ It was also brought to the Council's attention that attempts were made by developed countries to acquire developing countries to apply TRIPS Plus measures¹²⁸ or to forego their rights through bilateral and regional agreements.¹²⁹ He notified the council of the AIDS pandemic and other preventable diseases afflicting the continent and the upsurge in the negative public image and public outrage. He also suggested that there is a need to find a way to avoid abusing patent protection; to seek clarity on TRIPS provisions that would enable protecting health, seek to realise the objectives of the TRIPS Agreement and restore confidence in a rule based multilateral trading system.¹³⁰

In the same year an annual ministerial meeting of the WTO was held in Doha, Qatar. The Doha Declaration addresses issues facing developing countries in the domain of public health.¹³¹ The imbalance between that of the patent-holder and the interests of society was re-addressed. Governments of member states agreed on a sovereign declaration relating to the TRIPS Agreement and its role in relieving the global public health crises. The declaration recognises the extent of public health issues afflicting developing countries,¹³² stresses the need for the WTO Agreement on TRIPS to be part of a wider global action¹³³ and recognised that intellectual property protection is vital for developing new medicines.¹³⁴ The Doha round lacked a defect that was present during the negotiations of TRIPS: the 1999 WTO Panel Report declared unilateral trade actions unlawful and that economic coercion through section 301 sanctions was no longer available to the US as a threat to hold over other nations.¹³⁵

The declaration addresses three primary concerns.¹³⁶ The first concern is how member nations should interpret the TRIPS Agreement and whether this is favourable to the advancement of public health. Paragraph 4 of the declaration indicates member nations asserting the compatibility of the agreement with

¹²⁷ Marcellin S *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO* 2010 135.

¹²⁸ TRIPS Plus measures are discussed further in section 4.5.

¹²⁹ *Supra* note 127 at 136. See also Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 1-3 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹³⁰ *Supra* note 127.

¹³¹ Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 48 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹³² Doha Declaration on TRIPS and Public Health paragraph 1: "We recognize the gravity of the public health problems afflicting several developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

¹³³ Doha Declaration on TRIPS and Public Health paragraphs 2: "We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems".

¹³⁴ Doha Declaration on TRIPS and Public Health paragraphs 3: "We recognize that intellectual property protection is important for developing new medicines. We also recognize the concerns about its effects on prices". For more discussion see Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 5-7 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹³⁵ Panel Report *United States Sections 301-310 of the Trade Act of 1974* WT/DS152/R (Dec. 22, 1999). For more discussion on this see Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips but Not Trips Plus* International Law and Politics 2002 Vol 42 981-1028.

¹³⁶ The Doha Ministerial Declaration on TRIPS and Public Health 2001 is available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015).

public health and a member nation's right to interpret the agreement from a perspective aimed at improving public health crises.¹³⁷ The second concern is developing countries being put under pressure to omit from their national legislation any TRIPS measures favourable to public health. The declaration reiterates that nations have the sovereignty to enact their own legislation free from external influence.¹³⁸ Lastly, parallel importing and compulsory licensing and its practicality is addressed. Paragraph 5(c) of the declaration recognises that each member can independently define a national emergency and whether diseases, such as HIV/AIDS, malaria, tuberculosis etc. should constitute such emergencies.¹³⁹ Paragraph 5(d) explained that members have the right to use parallel importing free of external influence.¹⁴⁰ Paragraph 6 of the Declaration addresses the shortfalls of compulsory licensing.¹⁴¹ It states that compulsory licensing is acceptable if used to supply medicines to the authorising country's national market.¹⁴² Developing countries could only use compulsory licences to supply medicines if the proposed product was produced in its jurisdiction.¹⁴³ This is problematic as developing countries rarely have the required infrastructure to

¹³⁷ Doha Declaration on TRIPS and Public Health: paragraph 4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, whilst reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose". World Trade Organization. *Doha Ministerial Declaration on TRIPS and Public Health* 2001 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015). See also Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 48 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015). For further discussion see also Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 328.

¹³⁸ World Trade Organization. *Doha Ministerial Declaration on TRIPS and Public Health* 2001 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹³⁹ Doha Declaration on TRIPS and Public Health sub-paragraph 5 (c): "Accordingly and in the light of paragraph 4 above, whilst maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

...c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency". For further discussion see Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015). See also Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 330.

¹⁴⁰ Doha Declaration on TRIPS and Public Health: sub-paragraph 5 (d): "Accordingly and in the light of paragraph 4 above, whilst maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include: d. The effect of the provisions in the TRIPS Agreement relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4". See Correa CM *Implications of The Doha Declaration on the Trips Agreement and Public Health* 2002 17 http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015). World Trade Organization. *Doha Ministerial Declaration on TRIPS and Public Health* 2001 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159. See also Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law Vol 99 2005 330.

¹⁴¹ Doha Declaration on TRIPS and Public Health paragraph 6: "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002". See Correa CM *Implications of The Doha Declaration on the Trips Agreement and Public Health* 2002 19 http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹⁴² Reichman J & Hasenzahl C *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and an Overview of the Practice in Canada and the USA* UNCTAD/ICTSD Geneva 2003 5 16-18.

¹⁴³ The Doha Ministerial Declaration on TRIPS and Public Health 2001 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015). For further discussion see also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 9(2) 152–159. See also Correa CM *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* World Health Organization 2002 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015). See also Harris DP *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25(1) 119.

maintain a stable pharmaceutical industry. Paragraph 6 allows for the Council to find expeditious solutions to this challenge.¹⁴⁴

Unfortunately, no agreement was reached by the WTO regarding solutions to this challenge.¹⁴⁵ The US rejected the text submitted in December 2002, as in addition to the issue regarding compulsory licences, the US would also not accept the agreement reached by other members regarding diseases and their scope as paragraph 6 of the declaration states that members “recognise” the significance of “public health problems”.¹⁴⁶ The US strived for a limited number of diseases whilst developing countries argued for the inclusion of all major diseases. The reason was that apart from HIV/AIDS there were relatively few new patented medicines for diseases that plagued developing countries. Most of the new patented medicines were for chronic diseases more associated with the developed world, such as cancer, diabetes, heart disease and mental illness. These medicines are responsible for most of the revenue of the pharmaceutical companies.¹⁴⁷ Despite continuous restraint from the US, an agreement was reached at Doha. This was subsequent to an anthrax scare in the US just months before Doha was held. The scare caused shortages of ciprofloxacin, a broad-spectrum antibiotic patented by a German pharmaceutical company, Bayer.¹⁴⁸

Several proposals were made to persuade the US and other WTO members to agree during January and February 2003.¹⁴⁹ Amongst these were proposals to amend Article 31(f) and to remove the export exception under compulsory licences, or to entirely remove export limitations by amending TRIPS and amending national law respectively.¹⁵⁰ Another proposal was to interpret Article 30’s limited exceptions clause to allow export to countries with little or no capacity to manufacture.¹⁵¹

¹⁴⁴ Paragraph 6 is called the Doha assignment. The Doha Ministerial Declaration on TRIPS and Public Health 2001 available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (accessed 15 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159. See also Correa CM *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* World Health Organization 2002 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹⁴⁵ For more discussion see the World Trade Organization Website <http://www.wto.org> (accessed 15 May 2015). See also Harris DP *TRIPS’ Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet back against the United States* Northwestern Journal of International Law & Business 2004 Vol 25 (1) 119.

¹⁴⁶ In making its announcement, the USTR stated that certain WTO members and advocacy organizations did seek to expand the targeted “poor country epidemic” focus of Doha to allow wealthier countries to override a wide range of pharmaceutical patents, for example, Viagra. This approach could seriously undermine the WTO rules on patents providing incentives for development of new pharmaceutical products, including those to treat diseases of a non-epidemic nature”. See Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 331.

¹⁴⁷ Marcellin S *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO* 2010 26. See also Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹⁴⁸ Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 76. See also Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 3-7 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹⁴⁹ Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and The Protection of Public Health* The American Journal of International Law 2005 Vol 99 331.

¹⁵⁰ Article 31 (f) ‘the license use should be “predominantly for the supply of the domestic market”. The Trade Related Aspects of Intellectual Property Rights 1994 available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 15 May 2015). See also Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 31 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

¹⁵¹ Correa CM *Implications of the Doha Declaration on the Trips Agreement and Public Health* 2002 31 available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 19 May 2015).

In August 2003, an agreement¹⁵² was reached whereby less developed countries are exempt from producing patented pharmaceuticals under a compulsory licence and developed countries can issue a compulsory licence to supply a developing country, lacking certain health criteria. Such criteria may include: indication of a major concern for public health; proof that the importer's pharmaceutical industry is either inadequate or non-existent and lastly, proof that the drug will not be used commercially.¹⁵³

In summary the Doha Declaration reaffirmed every member countries' right to use safeguards afforded by TRIPS. Such safeguards include compulsory licences or parallel importation which can be used to overcome patent barriers to promote access to medicines.¹⁵⁴ By 2016 developing countries had to grant and enforce pharmaceutical patents.¹⁵⁵

4.5 Post-TRIPS

Following the negotiation and signing of both the TRIPS Agreement and the Doha Declaration, the US and the EU shifted the focus of their efforts to negotiating multilateral, bilateral¹⁵⁶ and regional¹⁵⁷ free trade agreements (FTAs) with several developing countries, as the latter struggled to implement their obligations under TRIPS.¹⁵⁸ These became known as "TRIPS Plus treaties".¹⁵⁹

The TRIPS Plus treaties further strengthen TRIPS as they:

- Contain intellectual property protection standards higher than the minimum standards found in TRIPS;
- Encourage developing countries to implement TRIPS fully, despite the transition periods offered by TRIPS,¹⁶⁰ or

¹⁵² TRIPS Agreement and Public Health (Decision) World Trade Organization available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 18 May 2015). See also Subhan J *Scrutinized: The TRIPS Agreement and Public Health* McGill Journal of Medicine 2006 Vol 9(2) 152–159.

¹⁵³ *Ibid.*

¹⁵⁴ Report by Access Campaign *TRIPS, TRIPS Plus and Doha* 2011 available at <http://www.msaccess.org/content/trips-trips-plus-and-doha> (accessed at 14 May 2015).

¹⁵⁵ *Ibid.* See also Marcellin S *The Political Economy of Pharmaceutical Patents: US Sectional Interests and the African Group at the WTO* 2010 143. See also http://www.who.int/medicines/areas/policy/doha_declaration/en/ (accessed 03 April 2015).

¹⁵⁶ Bilateral agreements are direct, individual agreements between two or more countries on a range of topics such as trade, investment, scientific research, development cooperation/aid or intellectual property. See Sonderholm J *Intellectual property rights and the TRIPS Agreement: An Overview of Ethical Problems and Certain Proposed Solutions Development Dialogue on Values and Ethics* The World Bank 2010 2. See also Vivas-Eugui D *Regional and Bilateral Agreements and a TRIPS-Plus World: the Free Trade Area of the Americas (FTAA)* Canadian International Development Agency (CIDA) 2003.

¹⁵⁷ Regional agreements allow a group of countries to agree on rules and commitments from simple tariff preferences to full comprehensive bodies of applicable trade and economic law. See Vivas-Eugui D *Regional and Bilateral Agreements and a TRIPS-Plus World: the Free Trade Area of the Americas (FTAA)* Canadian International Development Agency (CIDA) 2003.

¹⁵⁸ Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreements and the WTO Legal System* International Economic Law Series 2006 215. The US alone has signed and approved free trade agreements with Jordan (2001), Singapore (2003), Chile (2003), Morocco (2004), Australia (2004), DR-CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua) (2005), Bahrain (2006), Oman (2006) and Peru (2007). The EU has completed over thirty Bilateral Preferential Agreements with countries in the Middle East and North Africa. See Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips But Not Trips Plus* International Law and Politics 2002 Vol 42 981–1028 available at <http://nyujilp.org/wp-content/uploads/2012/04/42.3-Turk.pdf> (accessed 02 August 2015).

See also Sonderholm J *Intellectual Property Rights and the TRIPS Agreement: An Overview of Ethical Problems and Certain Proposed Solutions Development Dialogue on Values and Ethics* The World Bank 2010 2. See also Collins-Chase CT *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 779.

¹⁵⁹ For more discussion see Helfer LR & Austin GW *Human Rights and Intellectual Property Mapping the Global Interface* 2011 40.

¹⁶⁰ TRIPS gave member states a specific period in which they had to adopt the agreement. Developing states were provided more time to do so than developed states.

- Require such countries to adapt the requirements of additional intellectual property agreements.¹⁶¹

The TRIPS Plus treaties can take one of two forms. The first is that they could require implementing a more extensive standard than TRIPS. This is by either increasing the term of protection or expanding intellectual property protection to new areas.¹⁶² The second form is to eliminate interpretations and flexibilities provided by TRIPS.¹⁶³ With regard to the first form and patent term extension, medical products require lengthy testing periods and regulatory approval. Pharmaceutical companies desiring to apply for patent protection, should wait an extensive period before approval. The patent and regulatory approval process often lasts between eight and twelve years, indicating a company gaining a patent for a pharmaceutical will have a short monopoly period should there be delays.¹⁶⁴ Concerning intellectual property protection expansion, an example is that TRIPS allows member states to exclude plants and animals from their patent laws. However, under bilateral trade agreements with industrialised countries, Jordan, Mongolia, Nicaragua, Sri Lanka and Vietnam are being required to provide patent protection on plants and animals.¹⁶⁵ Another example is that of South Africa and the 78 African Caribbean Pacific (ACP) countries being required to grant patents on biotechnological inventions under bilateral trade agreements with the US and the EU.¹⁶⁶

The second form, eliminating interpretations and flexibilities provided by TRIPS, includes limiting data access for manufacturers seeking to use a patent-holder's clinical test data to obtain faster approval for generics and to prevent registration of generics until after the original drug patent expires.¹⁶⁷ This is achieved in granting exclusive rights over the pharmaceutical test data submitted by companies to regulatory authorities to obtain market authorisation. This results in information concerning a drug's safety and efficiency being kept confidential for a period of approximately five to ten years.¹⁶⁸ Data exclusivity is a way of preventing competition; even when medication is not protected by a patent, a pharmaceutical company will receive a minimum period of market monopoly.¹⁶⁹

¹⁶¹ Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreement and the WTO Legal System* International Economic Law Series 2006 219.

¹⁶² *Ibid.* See also Report by Access Campaign *TRIPS, TRIPS Plus and Doha* 2011 available at <http://www.msfacecess.org/content/trips-trips-plus-and-doha> (accessed at 14 May 2015).

¹⁶³ This can be achieved by introducing provisions that limit using compulsory licences or that restrict generic competition. For discussion see Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 317.

¹⁶⁴ *Supra* note 161. See also Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 59.

¹⁶⁵ For more detail see GRAIN's Report *How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO* (2001) available at <http://www.grain.org/article/entries/5-trips-plus-through-the-back-door> (accessed 02 August 2015).

¹⁶⁶ For more detail see Trade Agreements that South Africa has entered into at <http://www.tips.org.za/publication/south-africas-http://www.oxfam.org/sites/www.oxfam.org/files/Signing%20Away%20the%20Future.pdf> (accessed 14 August 2015). See also *ibid.*

¹⁶⁷ Collins-Chase CT *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 780. See also Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 401 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> (accessed 19 May 2015).

¹⁶⁸ Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreements and the WTO Legal System* International Economic Law Series 2006 229. See also Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 59.

¹⁶⁹ *Ibid.* See also Fink C & Reichenmiller P "Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreement" (editor) Newfarmer R *Trade, Doha and Development a Window into the Issues* The World Bank 2006 291. See also Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 59.

Another instrument used in FTAs is to restrict the permissible grounds for compulsory licensing and limit parallel importation.¹⁷⁰ Concerning the former, as observed in the case of trade agreements between the US and Australia, Jordan and Singapore, grounds for compulsory licences are limited.¹⁷¹ Some of these limitations include cases of anticompetitive practices, private use, situations of national emergency or cases of extreme urgency.¹⁷² Parallel importing occurs when the patent-holder sells a product to a buyer who exports the product to a second buyer in another country. Parallel importation undercuts the ability of a patent-holder to engage in price discrimination across national boundaries and can severely reduce profit levels of global companies.¹⁷³ Once a product is placed on a global market, the intellectual property holders 'rights and control over the product ends. FTA's either prohibit parallel importation or limit the prohibition in cases of restrictions either by indicates of a contract or by an alternative method.¹⁷⁴

TRIPS Plus includes several standards limiting the ability of developing countries to:

- promote innovation of technology and facilitate the transfer of the technology;
- take necessary measures to protect the health of the public;
- take suitable steps to avoid abusing intellectual property rights.¹⁷⁵

The concept of TRIPS Plus agreements covers both those activities aimed at increasing the level of protection for right holders beyond that provided in the TRIPS Agreement and reducing the scope or effectiveness of limitations on rights and exceptions under the TRIPS Agreement. TRIPS Plus agreements increase tension between the international intellectual property and other global regimes, such as human rights, as the treaties indirectly pushes developing countries into not exercising the rights provided for in TRIPS.¹⁷⁶ Several of the bilateral treaties provide that inventions flowing from the North into the South receive the same level of protection that they do back home.¹⁷⁷ For example, an inventor from the US should get the same level of protection for the invention in South Africa as the inventor would in the US. This would mean that South Africa's statutory laws would have to allow for the broadest range of

¹⁷⁰ Collins-Chase Ct *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 780. See also Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 401 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> (accessed 19 May 2015).

¹⁷¹ The Agreement states that "neither party will permit using the subject matter of a patent without the authorisation of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirement, provided that importation will constitute working". See Morin JF *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements* International Journal of Intellectual Property Management 2006 Vol 1(1/2) 47.

¹⁷² Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 401 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> (accessed 19 May 2015). See also Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreements and the WTO Legal System* 2006 International Economic Law Series 231.

¹⁷³ *Supra* note 170.

¹⁷⁴ *Supra* note 170.

¹⁷⁵ For more discussion see Musungu SF & Dutfield G *Multilateral Agreements and a TRIPS-Plus World: The World Intellectual Property Organisation (WIPO)* George Washington University 2003 3.

¹⁷⁶ Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreements and the WTO Legal System* International Economic Law Series 2006 229. See also Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 59.

¹⁷⁷ *Ibid.*

patentable subject-matter. An example provided by the GRAIN¹⁷⁸ indicates that should the US sign a bilateral treaty with Nigeria and if for example Monsanto,¹⁷⁹ has a patent on a provided gene in the US and wants to sell seeds containing that gene in Nigeria, the Nigerian government would have to provide Monsanto the same level of domestic patent protection over the gene, like the US, based on the bilateral investment treaty.¹⁸⁰ GRAIN achieved a limited, sample survey of bilateral agreements between developed and developing countries to observe how TRIPS Plus standards are being pushed on developing countries concerning biodiversity. Table 1 indicates only agreements relating to biotechnology.

Table 1: North-South TRIPS Plus agreements

Northern Proponent	Southern Counterpart	Date	TRIPS Plus Provisions
EU	ACP(Cotonou Agreement)	2000	Both parties must patent biotechnology inventions
EU	South Africa	1999	Both parties must patent biotechnology inventions; apply the highest global standards; and should undertake to go beyond TRIPS standards
US	Sub-Saharan Africa (AGOA)	2000	Trade benefits gauged on extent to which countries go beyond TRIPS standards
US	Andean countries (ATPA)	1991	Trade benefits gauged on extent to which countries go beyond TRIPS standards
US	Caribbean countries (CBTP)	2000	Trade benefits gauged on extent to which countries go beyond TRIPS standards
US	NAFTA ¹⁸¹	2000	Trade benefits gauged on extent to which countries go beyond TRIPS standards
US	DR-CAFTA ¹⁸²	2000	Trade benefits gauged on extent to which countries go beyond TRIPS standards

In the health industry, these agreements have a huge impact on a nation's access to life-saving medicines, such as AIDS antiretroviral (ARV), as a nation's ability to use public health flexibilities under TRIPS is limited.¹⁸³ Thailand is used as a case study to demonstrate this. Facing a fast growing AIDS problem, Thailand required ARV treatments that would be affordable to the majority of the Thai public.¹⁸⁴ In 2005, the Thai government included ARV treatment in the national health insurance system.¹⁸⁵ The latter was

¹⁷⁸ GRAIN is a small international non-profit organisation that works to support small farmers and social movements in their struggles for community-controlled and biodiversity-based food system. See www.grain.org/.

¹⁷⁹ Monsanto is a seed company. More information can be found on the company's website <https://monsanto.com/> (accessed 13 February 2017).

¹⁸⁰ For more discussion see Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 401 available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627342/> (accessed 19 May 2015).

¹⁸¹ North American Free Trade Agreement with Mexico and Canada.

¹⁸² Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua.

¹⁸³ For more discussion see Collins-Chase CT *The Case Against Trips-Plus Protection in Developing Countries Facing Aids* *Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 765.

¹⁸⁴ *Ibid* at 786.

¹⁸⁵ *Supra* note 183 at 786.

mostly possible because of availability of inexpensive generic ARV medicines.¹⁸⁶ Unfortunately, "first-line" treatments such as GPO-vir typically become less effective over time as viruses develop resistance to the medicine.¹⁸⁷ Second and third-line treatments were subject to patent in Thailand and as a result, were too expensive.¹⁸⁸ The Thai government announced its plans to issue a compulsory licence on the ARV drug efavirenz.¹⁸⁹ In response, they received a letter from twenty-two members of Congress pressuring Thailand not to use the licence, through the threat of trade sanctions.¹⁹⁰

The FTA that the US attempted to negotiate with Thailand incorporates the strong level of intellectual property rights and corresponding limitations on the flexibilities for developing countries offered by the TRIPS Agreement.¹⁹¹ The FTA requires Thailand to extend protection to previously non-patentable subject-matter, including biological processes, genes and gene sequences.¹⁹² An important feature of the FTA is that in certain instances, Thailand should allow "second use"¹⁹³ patents on pharmaceuticals that already were protected by a patent and three additional years of patent protection.¹⁹⁴ The FTA continues to further protect test data,¹⁹⁵ requiring Thailand's regulatory body to inform a pharmaceutical patent-holder whenever another company seeks registration of a generic drug and preventing such registration unless it in no way infringes any patents.¹⁹⁶ In addition, the Thai government would be permitted to issue a licence only in certain cases, namely, limiting anticompetitive practices, public non-commercial use and national emergencies.¹⁹⁷ The US advocates for the FTA by citing broad economic benefits for both countries by eliminating US tariff and non-tariff barriers to Thai exports. The FTA could make Thai products more competitive in the US market.¹⁹⁸ The FTA faced strong opposition and concern amongst Thai social movements, farmers and individuals with HIV/AIDS, resulting in no agreement being reached.¹⁹⁹

TRIPS Plus agreements are rapidly becoming a norm rather than the exception. The challenge with these agreements is that they are kept confidential in the drafting stages. Parliament and Congress are not

¹⁸⁶ GPO-vir, a generic product that combined three medicines: stavudine, lamivudine and nevirapine, costs \$31 per person per month, as opposed to \$490 per person per month which is the cost of the branded equivalent. For more details see Collins-Chase CT *The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics* Source University of Pennsylvania Journal of International Law 2008 Vol 29 786.

¹⁸⁷ For more discussion see *ibid* at 765.

¹⁸⁸ *Ibid.* lopinavir syrup costs \$310 per bottle and a lopinavir ritonavir combination costs \$467 for 180 capsules.

¹⁸⁹ See <http://www.cptech.org/ip/health/c/thailand/efavirenz.html> (accessed 27 May 2015).

¹⁹⁰ For more details see <http://www.cptech.org/ip/health/c/thailand/congressional-schwabletter-thailand-10jan06.pdf> (accessed 14 November 2017). See also *supra* note 183 at 787-788.

¹⁹¹ *Ibid.*

¹⁹² *Supra* note 190.

¹⁹³ For more discussion on second use patents see Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability - A Case Study of the Pharmaceutical Industry in Thailand* 2006 available at <http://www.iprsonline.org/unctadictsd/docs/Jakkrit-edited%20final%20draft%2001%20Nov%2006.pdf> (accessed 27 May 2015).

¹⁹⁴ *Supra* note 190.

¹⁹⁵ Preventing the use of disclosed test data strengthens protections under the Thailand FTA beyond those binding on patent applicants in the United States, where public disclosure of a patented product and associated data may preclude patentability after time. See <http://www.thaifta.com/engfta/Home/Agreements/tabid/168/Default.aspx> (accessed 27 May 2015).

¹⁹⁶ For more details see <http://www.cptech.org/ip/health/c/thailand/congressional-schwabletter-thailand-10jan06.pdf> (accessed 14 November 2017). See also Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability A Case Study of the Pharmaceutical Industry in Thailand* 2006 available at <http://www.iprsonline.org/unctadictsd/docs/Jakkrit-edited%20final%20draft%2001%20Nov%2006.pdf> (accessed 27 May 2015).

¹⁹⁷ *Ibid.*

¹⁹⁸ For more on the FTA see http://www.sice.oas.org/TPD/USA_THA/Studies/USTRFactSheet_e.pdf (accessed 27 May 2015).

¹⁹⁹ For more on the FTA see <http://www.bilaterals.org/?-US-Thailand-> (accessed 27 May 2015). See also <http://www.bilaterals.org/?trade-pact-with-the-us-depends-on> accessed 27 May 2015).

consulted and the public opinion is not taken into account. As a result, there is total disregard toward national processes of developing and possibly also developed countries.²⁰⁰ In addition, the treaties stipulate dispute settlement mechanisms that do not involve those embarked by WTO.²⁰¹ It seems that bilateral treaties are a way to secure monopoly rights, compelling the goals of global instruments, such as the TRIPS Agreement, obsolete.

Matthew Turk, in a study for International law and Politics, describes the advantages and disadvantages developing countries face should they refrain from entering bilateral agreements concerning free trade.²⁰² He states that they would benefit from the flexible interpretation of TRIPS in the short-term. He particularly refers to the availability of compulsory licences and parallel importation that would lower the cost of medicine, which would significantly assist with fighting public health crises. The disadvantages of refraining from entering bilateral agreements concerning free trade is that by only implementing the minimum standard of protection offered by TRIPS, the domestic growth of a developing economy is significantly inhibited thus reducing the pace of innovation.²⁰³

In 2011 the International Intellectual Property Institute performed an analysis, examining exactly what the impacts of enhanced intellectual property rights and enforcement of the 14 FTA's signed and implemented by the US would have on developing nations.²⁰⁴ The impact of the enhanced intellectual property rights and enforcement over time on: (1) export of goods from trading partners to the US; (2) US exports to trading partners and royalty and licensing receipts from trading partners; (3) US services trade; (4) investment activity measured through sales by US multinational companies abroad through their foreign affiliates, were analysed.²⁰⁵

The results indicate that improvements in intellectual property protection and enforcement are associated with increased goods trade, royalty and licensing transactions and at least indirectly, through affiliates, services trade. Patents in the pharmaceutical sector indicate less promise. An assumption exists when negotiating TRIPS Plus commitments that strong rules in the pharmaceutical sector will assist innovation. This study claims that it is too simplistic to claim that intellectual property rules alone will stimulate innovation.²⁰⁶ An analysis of the US-Jordan FTA shows that US imports of pharmaceuticals and medicines

²⁰⁰ For more information see GRAIN's Report *How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO* 2001 available at <http://www.grain.org/article/entries/5-trips-plus-through-the-back-door> (accessed on 02 August 2012).

²⁰¹ The WTO Dispute Settlement Body (DSB) adjudicates disputes brought by member states.

²⁰² See Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips but Not Trips Plus* International Law and Politics Vol 42:981-1028. See <http://nyujilp.org/wp-content/uploads/2012/04/42.3-Turk.pdf> (accessed 02 August 2015).

²⁰³ *Ibid.*

²⁰⁴ TRIPS-Plus FTAs with the US include Jordan December 17, 2001; Chile January 1, 2004; Singapore January 1, 2004; Australia January 1, 2005; Morocco January 1, 2006; El Salvador March 1, 2006; Honduras April 1, 2006; Nicaragua April 1, 2006; Guatemala July 1, 2006; Bahrain August 1, 2006; Dominican Republic March 1, 2007; Costa Rica January 1, 2009; Oman January 1, 2009; and Peru February 1, 2009. See Koff AW, Baughman LM, Francois JF *et al Study on the Economic Impact of "TRIPS-Plus" Free Trade Agreements* International Intellectual Property Institute 2011.

²⁰⁵ Koff AW, Baughman LM, Francois JF *et al Study on the Economic Impact of "TRIPS-Plus" Free Trade Agreements* International Intellectual Property Institute 2011.

²⁰⁶ *Ibid* at 37.

from Jordan increased significantly since the FTA was signed.²⁰⁷ The FTA's TRIPS Plus rules are responsible for reducing access to medicine and increasing pharmaceutical prices in Jordan.²⁰⁸ In Chile, with a strong generic market, there were no glaring concerns about a significant decrease in access to medicine and increase in prices but because of the US Chile FTA, data exclusivity issues raise costs for the generic industry, creating a negative perception.²⁰⁹

If FTAs have the affects mentioned above, why would developing countries in need of affordable medicines still enter into these agreements? It is alleged that behind the conclusion of FTAs, such as those above, lies a threat or an actual recourse to trade sanctions under section 301 of the US Trade Act 1974.²¹⁰ Unfortunately, *pacta sunt servanda* and the principles of freedom of contract provide for the presumption that the agreements were fairly entered and should be kept free from judicial intervention. Unless expressed otherwise, the assumption is that developing countries willingly accept the losses and the gains from TRIPS Plus treaties.²¹¹

4.6 Summary and Conclusions

Global instruments are essential in harmonising relevant aspects of law. The Paris Convention of 1883 was the first instrument to globally harmonise the area of intellectual property law.²¹² Subsequently, the TRIPS Agreement set a global minimum standard of intellectual property laws.²¹³ TRIPS serves as a gigantic leap forward in the field of intellectual property by bringing countries with little or no intellectual property protection into the fold of protection. TRIPS offers considerable flexibility to member states to tailor their intellectual property policies to suit national public policy goals.²¹⁴

Instruments such as TRIPS is embedded within a wider context of the imbalanced relationship between developed and developing countries and between creators and users of intellectual property.²¹⁵ Relevant aspects of intellectual property law can encourage innovation and economic growth when used effectively. Conversely, when intellectual property laws are too strict, access to technological inventions and affordable pharmaceuticals can create a challenge.²¹⁶ Unfair bilateral agreements entered into outside of

²⁰⁷ There has been an increase from \$US235,000 in 2000 to \$US20.5 million in 2010. For more discussion see *ibid* at 57.

²⁰⁸ *Supra* note 205 at 49.

²⁰⁹ *Supra* note 205 at 51.

²¹⁰ Nasu H *Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement* ANU College of Law Research study 6 available at <http://ssrn.com/AuthorID=677218> (accessed 02 June 2015).

²¹¹ Details of specific post-trips agreements the include jurisdictions chosen for our comparative study is discussed in chapters 6 and 7. See Turk M *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of Trips but Not Trips Plus* International Law and Politics Vol 42:981-1028. See <http://nyujilp.org/wp-content/uploads/2012/04/42.3-Turk.pdf> (accessed 02 August 2015).

²¹² See chapter 5 of the *WIPO Intellectual Property Handbook* International Treaties and Conventions on Intellectual Property 241.

²¹³ *Trips: A More Detailed Overview of The Trips Agreement* available at https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed 20 May 2015).

²¹⁴ *Ibid*.

²¹⁵ Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 58.

²¹⁶ *Ibid*.

TRIPS further tilt the balance between rewarding innovators and promoting public access.²¹⁷ Bilateral and regional agreements undermine any advantages that developing countries attain in multilateral settings. For example, despite TRIPS providing for countries to exclude inventions that hinder accessibility to that which is against *public ordre*, a provision where diagnostic gene patentability within the broader aspect of access to health would possibly fall under (as it pertains to the general health of the public); several states still do not exercise this right due to TRIPS Plus agreements and economic pressures.²¹⁸

International regulation of intellectual property laws via international instruments indicate that intellectual property, does have a global presence and global standards are necessary. However, differences in economies and infrastructure result in countries having different appropriate standards of intellectual property in order to meet their national needs. A one size fits all solution is not appropriate. These differences are distinct when intellectual property pertains to health care and portrays the need to a global perspective to be applied when interpreting intellectual property laws in the field of biotechnology and pharmaceuticals, specifically in relation to diagnostic gene patents.

²¹⁷ Mercurio B *TRIPS-Plus Provisions in FTAs: Recent Trends in Regional Trade Agreement and the WTO Legal System* International Economic Law Series 2006 215.

²¹⁸ For more discussion see Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability - A case study of the pharmaceutical industry in Thailand* 2006 available at <http://www.iprsonline.org/unctadictsd/docs/Jakkrit-edited%20final%20draft%2001%20Nov%2006.pdf> (accessed 27 May 2015).

Table 2: A summary of global instruments that play a part patent law as it relates to biotechnology

Year	Global Instrument	Content
1883	The Paris Convention of Industrial Property	Established the principle of an independent patent.
1970	Patent Co-operation Treaty (PCT)	Allows a single patent application to indicate all the countries where the inventor would such as patent protection.
1994	Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)	Sets out global requirements and minimum standards for patent protection.
1997	UNESCO Universal Declaration on the Human Genome and Human Rights	Aims to balance the safeguarding of human rights and freedoms and ensuring freedom of research.
2000	HUGO ²¹⁹ Statement on Patenting of DNA sequences – In Particular Response to the European Biotechnology Directive	HUGO confirms that ESTs are research instruments and does not support the patenting of ESTs.
2001	The Doha Declaration	Enabling improved access to medicines.

²¹⁹ Human Genome Organisation. HUGO Statement is available at http://www.who.int/genomics/elsi/regulatory_data/region/international/162/en/ (accessed 9 September 2015).

Chapter 5

5.1 Global Fundamental Rights

Fundamental rights law has become one of the most challenging areas of law as it is continuously evolving to address rising challenges and attempting to ensure future global peace and stability. The aim of this chapter is to answer the third and last sub question to the problem statement - are intellectual property rights, assuming they fall under the umbrella of property rights, fundamental? This chapter first provides a brief observation of the history of the UN and the UDHR, in order to understand the objectives and context of the UDHR and UN conventions, with regards to the recognition, development, status and extent of the right to health as a fundamental right. Even though these instruments are not binding, and is considered soft law, they provide guidance to states on fundamental rights. These instruments are discussed as opposed to regional instruments as these instruments set an international standard upon which regional instruments are based. The chapter then goes on to discuss the international recognition of the right to property (assuming that intellectual property is included within this right) and the right to health individually. Lastly the relationship between intellectual property law and the fundamental rights law regime is analysed in order to determine whether property rights, like the right to health, are fundamental in nature. If so, the value of both rights will need to be evaluated and a justification analysis needs to be applied.

5.2 The History and Development of the UN

Before World War II, global law only provided rules to the treatment of foreigners that their home countries could appeal to. It did not regulate the treatment of individuals by their home countries as this was internally regulated. After World War II, this changed.¹ Since World War I, the League of Nations signified the global organisation providing a forum for resolving global disputes. The need for its replacement was first stated officially in 1943 during the Moscow declaration.² Specific proposals for a charter of a new organisation was drafted by China, Great Britain, the United States and the USSR³ in the 1944 Dumbarton Oaks Conference. In 1945 further agreement was reached regarding the charter at the Yalta Conference.⁴

¹ For more discussion see Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* 2007 80.

² The League of Nations was created by the Treaty of Versailles in 1919 and disbanded in 1946. For more detail see <http://www.britannica.com/topic/United-Nations> (accessed 24 July 2015). See also <https://history.state.gov/milestones/1914-1920/league> (accessed 30 December 2015). The main organs of the UN include the General Assembly, the Security Council, the Economic and Social Council, the Trusteeship Council, the International Court of Justice and the UN Secretariat <http://www.un.org/en/aboutun/history/> (accessed 24 July 2015).

³ The Union of Soviet Socialist Republics.

⁴ For more detail see <http://www.infoplease.com/encyclopedia/history/united-nations-history.html> (accessed 25 July 2015).

The UN was established in 1945,⁵ creating a new era for international law. A main purpose of the UN is to promote fundamental rights and fundamental freedoms for all.⁶ The purposes and principles contained in the founding Charter guide the mission and work of the UN.⁷ The Charter was drafted in 1945 when 50 countries met in San Francisco at the UN conference on International Organisation. The representatives of the 50 countries signed the Charter in June 1945.⁸ According to the Charter, members of the UN are required to commit to promoting better living standards, solutions of global economic, social and health challenges and a universal respect for human rights.⁹ Objectives include maintaining global peace and security,¹⁰ promoting sustainable development,¹¹ protecting human rights,¹² upholding global law¹³ and delivering humanitarian aid.¹⁴

The provisions of the UDHR were drafted in the context of the extensive reaction to the brutality of World War II where science and technology formed a significant part whilst serving as an instrument of the Holocaust.¹⁵ It was drafted within the context that science had to be protected from misuse. The UDHR provides a globally agreed set of standards which serves as a guide and assesses conducting governments through an extensive range of sectors that have a bearing on medicine, public health and the strengthening of health systems.¹⁶ Legal obligations under the UDHR binds member states to take action to achieve higher standards of living, conditions of economic and social development, solutions of global health challenges and universal respect for human rights.¹⁷

Article 2 of the UDHR establishes that all rights and freedom set by the declaration are without distinction of any kind. The status of an individual would not matter, whilst Article 25 of the UDHR states that “everyone has the right to a standard of living adequate for the health and wellbeing of himself and his

⁵ The name “United Nations” was designed by United States President Franklin D. Roosevelt and was first used in the Declaration by United Nations of 1 January 1942, during World War II. For more detail see <http://www.un.org/en/aboutun/history/> (accessed 24 July 2015).

⁶ Preamble and Article 1(3) of UN Charter.

⁷ See <http://www.un.org/en/about-un/index.html> (accessed 24 July 2015).

⁸ For more detail see <http://www.un.org/en/aboutun/history/> (accessed 24 July 2015).

⁹ For more information see <http://www.un.org/en/about-un/index.html> (accessed 24 July 2015).

¹⁰ The UN works toward preventing conflict; helping parties in conflict make peace; peacekeeping; and creating the conditions to allow peace to hold and flourish.

¹¹ The UN aims to “achieve international co-operation in solving international problems of an economic, social, cultural, or humanitarian character and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion.” See the Preamble of the UN Charter.

¹² See the discussion below on the UDHR.

¹³ This is completed in several ways - by courts, tribunals, multilateral treaties - and by the Security Council, which can approve peacekeeping missions, impose sanctions, or authorize using force when there is a threat to international peace and security, if it deems this necessary.

¹⁴ See Article 2 of the UN Charter <http://www.un.org/en/about-un/index.html> (accessed 24 July 2015). See also <http://www.britannica.com/topic/United-Nations> (accessed 24 July 2015).

¹⁵ Chapman AR *A Human Rights Perspective on Intellectual Property, Scientific Progress and Access to the Benefits of Science* study delivered at the Panel Discussion on Intellectual Property and Human Rights 1998 1- 44. See also Morsink J *The Universal Declaration of Human Rights: Origins, Drafting and Intent* 2010 1- 88. See also Tobin J *The Right to Health in International Law* 2012 30.

¹⁶ Backman G, Hunt P, Khosla R et al *Health Systems and the Right to Health: An Assessment of 194 Countries* Lancet 2008 Vol 372 2047.

¹⁷ Articles 55 and 56 of the UN Charter. See also Helfer LR & Austin GW *Human Rights and intellectual property, Mapping the Global Interface* 2011 68. See also <http://www.un.org/en/documents/udhr/> (accessed 25 July 2015). See also Morsink J *The Universal Declaration of Human Rights: Origins, Drafting and Intent* 2010 1-88. See also Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 96-107.

family, including food, clothing, housing and medical care...”.¹⁸ This corresponds with Article 12 of the ICESCR¹⁹ and the preamble of the Constitution of the World Health Organisation (WHO)²⁰ stating that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions”.²¹

Article 27 provides that each individual “has the right freely to participate in the cultural life of the community” and to “enjoy the arts and to share in scientific development and the benefits that come of these developments”²² and that each individual has “the right to protecting the moral and material interests that result from any scientific, literary or artistic production of which he is the author”.²³

Article 29(2) discusses the limitation of rights contained within the UDHR and provides that in order for one right to be limited in favour of another the following must be accomplished:²⁴

a. The limitation must be provided by the law

This condition requires the limitation to have a clear legal basis. The law authorising the limitation of the right must be a) publicly accessible; b) sufficiently precise to enable people to regulate behaviour and c) it must not confer unfettered discretion on the state to prevent risk of abuse and arbitrary exercise of discretion.

b. The limitation must serve a legitimate aim

The legitimate aims refer to the interests of the state and the rights of others. Some of the enumerated aims include:

- respect for the rights and reputations of others;
- respect for public morals;
- protection of public order;
- promoting the general welfare in a democratic society.

c. Proportionality between end and means

¹⁸ Article 25 of the Universal Declaration of Human Rights.

¹⁹ See <http://www.escr-net.org/docs/i/425251> (accessed 04 July 2017) see paragraph 5.3.1 below.

²⁰ Both of these also stemming from the UN. WHO was set up to control the prevention and control of disease.

²¹ The “right to the highest attainable standard of health encompasses medical care, access to safe drinking water, adequate sanitation, education, health-related information and other underlying determinants of health; it includes freedoms, such as the right to be free from discrimination and involuntary medical treatment and entitlements, such as the right to essential primary health care”. See Backman G, Hunt P, Khosla R et al *Health Systems and the Right to Health: An Assessment of 194 Countries* Lancet 2008 Vol 372 2047. See also http://www.who.int/governance/eb/who_constitution_en.pdf.0 (accessed 17 October 2015). See also Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 96-160.

²² Article 27(1) of the Universal Declaration of Human Rights. See also [ww.un.org/en/documents/udhr/](http://www.un.org/en/documents/udhr/) (accessed 25 July 2015).

²³ Article 27(2) of the Universal Declaration of Human Rights. See also [ww.un.org/en/documents/udhr/](http://www.un.org/en/documents/udhr/) (accessed 25 July 2015).

²⁴ Article 29(2) of the Universal Declaration of Human Rights. See also [ww.un.org/en/documents/udhr/](http://www.un.org/en/documents/udhr/) (accessed 25 July 2015).

The proportionality principle demands that the means used by a state to limit a right must be proportional to the aim sought. Note 4, paragraph 35 of the UN's General Comment 34 states that:

"[w]hen a State party invokes a legitimate ground for restriction of freedom of expression, it must demonstrate in specific and individualized fashion the precise nature of the threat, and the necessity and proportionality of the specific action taken, in particular by establishing a direct and immediate connection between the expression and the threat."²⁵

There are a number of considerations that need to be taken into account to justify that the means used by a state to limit a right is proportional to the aim sought suitability²⁶, subsidiarity²⁷ and proportionality in the narrow sense^{28, 29}.

5.3 Global Covenants

In the atmosphere of the cold war between the West and the former Soviet Union, newly emergent sovereign African and Asian states shaped the drafting of two covenants³⁰ with a view to emphasising the rights of self-determination, national authority over resources and freedom from racial discrimination.³¹ In 1966 these two global fundamental rights treaties, the ICESCR and the ICCPR (International Covenant on Civil and Political Rights), were adopted by the UN.³² Together with the UDHR, these are known as the International Bill of Rights.³³ The treaties are designed to bring the general principles contained within the UDHR into treaty obligations.³⁴ The ICESCR provisions relating to health is discussed below.

5.3.1 ICESCR

Article 12 and 15 deal with the right to health. Article 12 states that:

"The State Parties to the present Covenant recognise the right of each one to the enjoyment of the highest attainable standard of physical and mental health."³⁵

²⁵ General Comment 34 can be available at <https://www.opensocietyfoundations.org/publications/un-human-rights-committee-general-comment-no-34> (accessed 17 January 2019).

²⁶ Suitability requires that the limitation should in principle lead to the legitimate aim which is sought after.

²⁷ The subsidiary test reviews whether there are other alternative less restrictive means to reach the legitimate aim.

²⁸ Proportionality in the narrow sense requires a reasonable relationship between the infringement and the legitimate aim.

²⁹ General Comment 34 can be available at <https://www.opensocietyfoundations.org/publications/un-human-rights-committee-general-comment-no-34> (accessed 17 January 2019).

³⁰ The International Covenant of Economic Social and Cultural Rights and the International Covenant on Civil and Political Rights.

³¹ For discussion, see Drahos P *The Universality of Intellectual Property Rights: Origins and Development* a study delivered at the Panel Discussion on Intellectual Property and Human Rights 1998 1-36.

³² These covenants can be accessed at

<http://www.ohchr.org/EN/ProfessionalInterest/Pages/UniversalHumanRightsInstruments.aspx> (accessed 04 July 2017). See also Grosheide W *Intellectual Property and Human Rights, A Paradox* 2010 38.

³³ For more discussion see Grosheide W *Intellectual Property and Human Rights, A Paradox* 2010 38.

³⁴ Helfer LR & Austin GW *Human Rights and Intellectual Property, Mapping the Global Interface* 2011 8.

³⁵ Article 12(1) of the International Covenant of Economic Social and Cultural Rights.

Considering the historical drafting context and the explicit wording of Article 12, it is most definitely not confined to the right to health care, but also a range of socio-economic factors aimed at promoting environments encouraging healthy lifestyles. It extends to food and nutrition, housing, safe and portable water and sanitation, healthy working conditions and a healthy environment.³⁶ In the opinion of Hestermeyer the word “recognise” determines state obligations and is defined as “acknowledge the existence, validity, character or claims of...”.³⁷ If this interpretation is accepted, a state that recognises a right should therefore then guarantee it.³⁸ A confirmation of this interpretation is found in Article 12(2) providing that steps are to be taken by the state parties to realise this right, including those necessary for (amongst others) “(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases...”.³⁹

Article 12(2) of the treaty encompasses how state parties may achieve full recognition of this right. This includes the right to “maternal, child and reproductive health; healthy natural and workplace environments; prevention, treatment and control of disease; and creating conditions assuring to all medical service and medical attention in the event of sickness”.⁴⁰ The UN’s General Comment 14 establishes that Article 12(2)(c) of the Covenant, quoted above.⁴¹ This includes the right to the creation of a system of urgent medical care in cases of accidents, epidemics and similar health hazards and the provision of disaster relief and humanitarian assistance in emergency situations.⁴²

It is further established in the UN’s General Comment 14 that the right to health has the following vital components, applicable depending on the conditions that prevail a particular state party:⁴³ The components are

³⁶ General comment 14: *The Right to the Highest Attainable Standard of Health: The Economic and Social Council*.08/11/2000. E/C.12/2000/4. See also Saul B, Kinley D, Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 977. See also Leary VA *The Right to Health in International Human Rights Law* Health and Human Rights 1994 Vol 1(1) 41.

³⁷ Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2007)108.

³⁸ *Ibid.* See also Kinney ED *The International Human Right to Health: What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1457. See also Leary VA *The Right to Health in International Human Rights Law* Health and Human Rights 1994 Vol 1(1) 41. See also Evans T A *Human Right to Health?* Third World Quarterly 2002 Vol 23(2) 199–200. See also Hans V Hogerzeil, Melanie Samson, Jaime Vidal Casanovas et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11.

³⁹ See <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015). See also Saul B, Kinley D, Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 977. See also de Campos TC *Health as a Basic Human Need: Would This Be Enough?* Journal of Law, Medicine & Ethics 2012 252. See also Evans T A *Human Right to Health?* Third World Quarterly 2002 Vol 23(2) 199–200.

⁴⁰ Article 12 (2) of the ICESCR. For more discussion see Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11.

⁴¹ UN General Comments serve as guidance when interpreting UN Conventions. See <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015). For discussion see also de Campos TC *Health as a Basic Human Need: Would This Be Enough?* Journal of Law, Medicine & Ethics 2012 251. See also Kinney ED *The International Human Right to Health: What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1457.

⁴² General comment 14: *The Right to the Highest Attainable Standard of Health: The Economic and Social Council*.08/11/2000. E/C.12/2000/4. For more discussion see also Riggirozzi P *Human Rights to Health: a case for regional pro-poor approaches* 2014 PRARI Policy Brief 5 The Open University available at (<http://www.open.ac.uk/socialsciences/prari/>) (accessed 16 November 2015).

⁴³ Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11. See also de Campos TC *Health as a Basic Human Need: Would This Be Enough?* Journal of Law, Medicine & Ethics 2012 252. See also Kinney ED *The International Human Right to Health: What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1457.

- (a) Availability;
- (b) Accessibility.

Concerning availability, there needs to be working health care facilities, medicines, services and health programmes. Concerning accessibility, the above-mentioned facilities and services have to be equally accessible within each jurisdiction.⁴⁴ For example, access to essential medicines is a part of the right to health and is indispensable.⁴⁵ Medicines should also be accessible in rural areas and in urban centres. This will have implications for the design of medicine supply systems.⁴⁶ Medicines also need to be affordable to all provided the fundamental human rights principles of non-discrimination and equality.⁴⁷

From the provisions of Article 12(2), that the covenant aims to accomplish the full realisation of the right to health for all individuals and prompts states to take measures to accomplish this. It is the opinion of Hestermeyer that a state also has an obligation to protect third parties from interfering with this fundamental right.⁴⁸ It must therefore ensure that pharmaceutical manufacturers do not limit access to medicines.⁴⁹ This was already confirmed by General Comment 14 indicating that: “States have a special obligation to provide those who do not have sufficient indicates with the necessary health insurance and health care facilities and to prevent any discrimination on globally prohibited grounds in the provision of health care and health services, especially concerning the core obligations of the right to health”.⁵⁰ It continues to state that state parties have a specific and ongoing obligation to realise the rights of Article 12 and that the right to health, such as all fundamental rights, imposes three levels of obligation on state parties: The obligation to respect, protect and fulfil.⁵¹ These were explained as follows:

- States should refrain from directly or indirectly interfering with an individual’s enjoyment of the right to health to fulfil the obligation to respect;
- The obligation to protect requires states to initiate preventing interference of the right by third parties; and
- Finally, the obligation to fulfil involves states to implement suitable measures, to promote the full realisation of the right to health.⁵²

⁴⁴ Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11. See also de Campos TC *Health as a Basic Human Need: Would This Be Enough?* Journal of Law, Medicine & Ethics 2012 252. See also Kinney ED *The International Human Right to Health: What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1457.

⁴⁵ Article 12(2)(d) provides for essential drugs as defined by the WHO action programme on Essential Drugs: “those that satisfy the priority health care needs of the population. Essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety and comparative cost-effectiveness”. Backman G, Hunt P, Khosla R et al *Health Systems and the Right to Health: An Assessment of 194 Countries* Lancet 2008 Vol 372 2047.

⁴⁶ Backman G, Hunt P, Khosla R et al *Health Systems and the Right to Health: An Assessment of 194 Countries* Lancet 2008 Vol 372 2047.

⁴⁷ *Ibid.*

⁴⁸ Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* 2007 109. See also Saul B, Kinley D, Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 977. See also Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* Lancet 2006 Vol 368 305–11.

⁴⁹ *Ibid.*

⁵⁰ General comment 14: *The Right to the Highest Attainable Standard of Health: The Economic and Social Council*.08/11/2000 E/C.12/2000/4. See also Chinkin C *The Protection Of Economic, Social And Cultural Rights Post-Conflict* http://www2.ohchr.org/english/issues/women/docs/Paper_Protection_ESCR.pdf (accessed 25 July 2015).

⁵¹ Toebes B *Towards an Improved Understanding of the International Human Right to Health* Human Rights Quarterly 1999 Vol 21 661.

⁵² *Ibid.*

Failure to initiate towards ensuring the realisation of the right to health amounts to a violation of the obligation to fulfil.⁵³

Article 15 also relates to health. It can be observed in the history of the fundamental rights regime that the right in Article 15 was meant to benefit more than just the author.⁵⁴ The terms “author” and “scientific” implies that the protection is offered only to writers of scientific tractates.⁵⁵

Article 15(1) (a), (b) and (c) encompasses each person’s right to:

“(a) take part in cultural life;

(b) to enjoy the benefits of scientific progress and its applications; and

(c) to protecting the moral and material interests resulting from any scientific, literary, or artistic production of which he is the author, as a human right”.⁵⁶

The rights under (a) and (b) are to unite with the objectives which are contained in the WTO agreement and Article 7 of TRIPS which emphasises public interest.⁵⁷ States are urged to make these rights available to all individuals.

Article 15(1)(c) is discussed in General Comment 17.⁵⁸ The Covenant uses the term “creator’s rights” and extends protection to the “literary, scientific and artistic sphere”.⁵⁹ General Comment 17, illustrates certain of the differences between intellectual property rights and fundamental rights. The latter are, as their name suggests, fundamental, as they are integral to each individual person, whereas intellectual property rights are a way for a state to provide incentives for innovation and are temporary.⁶⁰ In 2009, The *Venice Statement on the Right to Enjoy Benefits of Scientific Progress and its Applications*⁶¹ further analysed Article 15(1). It was held that the right to “enjoy benefits of scientific progress” can conflict with the intellectual property regime that as mentioned above, is a short-term monopoly to be monitored to prevent profit prioritisation.⁶² It states further that science is not only about evolving knowledge of a specific subject-

⁵³ Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* 2007 109.

⁵⁴ Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* 2007 155.

⁵⁵ For discussion see Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 247-254. See also Saul B, Kinley D & Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 1175.

⁵⁶ <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015).

⁵⁷ TRIPS Article 7 reads: “The protection and enforcement of intellectual property rights should contribute to promoting technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations”. See also Saul B, Kinley D & Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 1175.

⁵⁸ See <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015). See also Saul B, Kinley D & Mowbray J *The International Covenant on Economic, Social and Cultural Rights: Commentary, Cases and Materials* 2014 1175. Helfer LR, Austin GW *Human Rights and intellectual property, Mapping the Global Interface* (2011) 234. See also Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* *Indiana Journal of Global Legal* 1998 Vol 6(1) 3 66.

⁵⁹ Article 15(1)(c) of the ICESCR. For discussion see Helfer LR & Austin GW *Human Rights and intellectual property, Mapping the Global Interface* 2011 174 see <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015).

⁶⁰ *Ibid* at 188. See Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 247-254.

⁶¹ Sponsored by UNESCO, the expert’s meeting held in Venice in 2009. The meeting was attended by leading experts and representatives of intergovernmental organizations and bodies (OHCHR, WIPO, WTO and EU), three members of the Committee on Economic, Social and Cultural Rights (CESCR) and the United Nations Special Rapporteur on the right to food and representatives of UNESCO Chairs and nongovernmental organizations. See unesdoc.unesco.org/images/0018/001855/185558e.pdf (accessed 04 July 2017).

⁶² See Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 247-254.

matter, but is also about improving the conditions for further scientific and cultural activity.⁶³ This pertains to the scope of protection permitting or restricting third parties to experiment with the patented invention.⁶⁴

Articles 4 and 5 of the Convention address limitation of rights and further enforce the limitation test provided in the UDHR.⁶⁵

5.3.2 Post ICESCR

Since the two global covenants were adopted in 1966, there has been substantial changes regarding global health since. Formerly unknown diseases, such as HIV/AIDS and cancer, and rapid population growth, created new impediments for the realisation of the right to health.⁶⁶ The issue of health is now put on the frontline and is finally receiving the attention that it deserves. It emphasises that states must use all available resources to realise the right. This includes taking legislative measures. It can be argued that states that have adopted patent laws which thereby raise pharmaceutical prices and interfere with access to medicines, are in violation of their obligation to protect the right.⁶⁷ In contrast with civil and political rights (as those contained in the ICCPR), the rights contained in the ICESCR, with the exception of the labour-related articles, are not grounded in significant bodies of domestic or global jurisprudence.⁶⁸ Unfortunately until this occurs, these instruments will remain as mere guidelines that countries.

5.4 The Right to Property

The general right to property diverts back to the UDHR of the French Revolution and the Bill of Rights of the US.⁶⁹ The right to property is essential for the right holder as it contributes to the realisation of economic and social rights including the right to housing, food and social security.⁷⁰ The term “property” refers to tangible and intangible property, including intellectual property.⁷¹

⁶³ See Sage R *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* 2002 247-254. See also Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) Article 3 66.

⁶⁴ Helfer LR & Austin GW *Human Rights and Intellectual Property, Mapping the Global Interface* 2011 237.
<http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx> (accessed 25 July 2015).

⁶⁵ Article 4 of the ICESCR states that “The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society”.

⁶⁶ General comment 14: *The Right to the Highest Attainable Standard of Health: The Economic and Social Council*.08/11/2000 E/C.12/2000/4 (article 12 of the International Covenant on Economic, Social and Cultural Rights). See also Chinkin C *The Protection Of Economic, Social And Cultural Rights Post-Conflict*
http://www2.ohchr.org/english/issues/women/docs/Paper_Protection_ESCR.pdf (accessed 25 July 2015).

⁶⁷ Hestermeyer H *Rights and the WTO: The Case of Patents and Access to Medicines* 2007 109.

⁶⁸ Chapman AR *A Human Rights Perspective on Intellectual Property, Scientific Progress and Access to the Benefits of Science* study delivered at the Panel Discussion on Intellectual Property and Human Rights on 9 November 1998 1- 44.

⁶⁹ The Declaration of the French Revolution states in Article 1 that “men are born and remain free and equal in rights” which were specified as the rights of liberty and private property. The fifth amendment of the US Bill of Rights enshrines the right to property. See <https://www.aclu.org/united-states-bill-rights-first-10-amendments-constitution> (accessed 05 July 2017).

⁷⁰ Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 29.

⁷¹ This includes rights that relate to: literary and artistic works; inventions in all fields of human endeavour; industrial designs; semiconductor mask works; trade secrets; know-how and confidential business information; and trademarks, service marks,

In 1948 the UDHR proclaimed in Article 17 that “one has the right to own property alone and in association with others” and that “no one will be arbitrarily deprived of his property”.⁷² The right to property did not make it into the ICCPR or the ICESCR, except that it appears in both covenants as part of the non-discrimination clause.⁷³ Several other core human rights treaties adopted after 1966, refer to property rights. Most of these instruments require state parties to ensure equality concerning property ownership.⁷⁴

Even though the UDHR does not expressly refer to intellectual property rights, Article 27(2) states that “Everyone has the right to the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author”.⁷⁵ At the same time Article 27(1) states that each one has “the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.”⁷⁶ During negotiations relating to Article 27 of the UDHR, controversy arose over the inclusion of the right to benefit from the moral and material interests of the author. Certain members of the Commission on Human Rights argued that it was not a right applicable to every individual and that patents and copyrights could sometimes prevent others from enjoying the benefits of scientific progress and its applications.⁷⁷

Article 27 includes a tension familiar to intellectual property law; the tension between rules, protecting the creators of subject-matter and information and those enabling the use of subject-matter and diffusion of information. Recognising the interests of authors in the UDHR is complemented by the proclamation in Article 17⁷⁸ of a general right of property.⁷⁹

and trade names. For more discussion see Kriebaum U & Schreuer C *The Concept of Property in Human Rights Law and International Investment Law* 2007 http://www.univie.ac.at/intlaw/wordpress/pdf/88_concept_property.pdf (accessed 18 August 2015).

⁷² Article 17 of the Universal Declaration of Human Rights. For discussion see Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 3. See also Sprankling JG *The Global Right to Property* 2013 <http://ssrn.com/abstract=2245765> (accessed 14 August 2015).

⁷³ Article 2(1) of the ICCPR provides that: “Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.” Article 2(2) of the ICESCR states: “The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.” For discussion see Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 4.

⁷⁴ Articles 15(2) and 16(1)(h) of the International Convention on the Elimination of All Forms of Discrimination against Women, The Convention on the Rights of Persons with Disabilities contains clauses on property rights under Articles 5(3) and 30(3) and the International Labour Organization Convention No. 169 concerning Indigenous and Tribal Peoples in article 14. For discussion see Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 4-5. Equality is defined as the right of different groups of people to have a similar social position and receive the same treatment. See <https://dictionary.cambridge.org/dictionary/english/equality> (accessed 21 December 2018).

⁷⁵ Article 27(2) of the Universal Declaration of Human Rights.

⁷⁶ Article 27(1) of the Universal Declaration of Human Rights.

⁷⁷ Note that tension between intellectual property protection and accessibility was present at the time of drafting. For more discussion see Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

⁷⁸ Article 17:

- (1) “Everyone has the right to own property alone and in association with others
- (2) No one will be arbitrarily deprived of his property”.

⁷⁹ Drahoš P *The Universality of Intellectual Property Rights: Origins and Development* study delivered at the Panel Discussion on Intellectual Property and Human Rights 1998 1-36.

Few countries have a treaty based obligation to protect property, though certain regional fundamental right instruments.⁸⁰ These include the Charter of Fundamental Rights of the European Union,⁸¹ EU directives, and the African Charter on Human and Peoples' Rights.⁸² The latter guarantees the right to property in Article 14; although it then continues to recognise that the right may be infringed upon in the "interest of public need or in the general interest of the community".⁸³

The American Convention on Human Rights of 1969, in Article 21(1), also recognises a right of property being a right that no one is to be deprived of "except upon payment of just compensation".⁸⁴ Most recently, member states of the Association of Southeast Asian Nations (ASEAN) adopted the ASEAN Human Rights declaration⁸⁵ which also recognises the right to property in Article 17.⁸⁶

The review of provisions of global instruments and regional treaties reveal the universal recognition of the fundamental right. As observed above, most states are consistent in their reflection of the first paragraph of Article 17 of the UDHR.⁸⁷ There is also a trend towards including a global right to property in regional human rights treaties. It is reasonable to assume that this momentum will continue in coming decades, as more nations become members of such treaties.⁸⁸ It is reasonable to consider whether characterising the right to property as a "fundamental right" rather than simply as a "right" significantly affects its nature or content.⁸⁹ The implication of this view is that fundamental rights occupy a hierarchical superior position amongst the norms of international law and will thereby prevail over other norms.⁹⁰

The above-mentioned trend of the right of property raises concerns. It seems uncontroversial to suggest that the right of property forms part of the norms of international law.⁹¹ Even though states recognise the

⁸⁰ Please note that only regional instruments of regions of comparative study of this study were observed. Regional treaties are not discussed in detail as they are based on the fundamental values of international instruments discussed within this chapter. For more discussion see Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicine* 2013 515.

⁸¹ The charter can be accessed at http://www.europarl.europa.eu/charter/pdf/text_en.pdf (accessed 25 February 2018).

⁸² The African Charter on Human and Peoples' Rights is available at <http://www.achpr.org/instruments/achpr/> (accessed 15 September 2017).

⁸³ For more see Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 6.

⁸⁴ Article 21(2) The American Convention on Human Rights 1969. *Ibid.* See also Kriebaum U & Schreuer C *The Concept of Property in Human Rights Law and International Investment Law* 2007 http://www.univie.ac.at/intlaw/wordpress/pdf/88_concept_property.pdf (accessed 18 August 2015).

⁸⁵ ASEAN Human Rights Declaration 2012.

⁸⁶ Article 17 states: "Every person has the right to own, use, dispose of and provide that person's lawfully acquired possessions alone or in association with others. No person will be arbitrarily deprived of such property." For discussion see Sprankling JG *The Global Right to Property* 2013 <http://ssrn.com/abstract=2245765> (accessed 14 August 2015).

⁸⁷ Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

⁸⁸ For discussion see Sprankling JG *The Global Right to Property* 2013 <http://ssrn.com/abstract=2245765> (accessed 14 August 2015).

⁸⁹ *Ibid.*

⁹⁰ Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

⁹¹ Drahos P *The Universality of Intellectual Property Rights: Origins and Development* study delivered at the Panel Discussion on Intellectual Property and Human Rights 1998 1-36.

property rights of their citizens and those of other states and their nationals, the difficulty arises regarding the nature and scope of the right and the ranking of the right amongst other fundamental rights.⁹²

There is an argument supporting intellectual property rights as fundamental rights simply because intellectual property rights are widespread in international law.⁹³ The basis of this view is that all intellectual property rights are fundamental rights by their universal recognition.⁹⁴ This is problematic as having an individual's invention copied cannot be compared to being stripped of bedding, food, medicines or other essentials needed for basic living.⁹⁵ The understanding is that fundamental human rights are "human rights of such importance that their global protection includes the right, possibly even the obligation, of global enforcement".⁹⁶

An issue that rises is whether the protection afforded by a fundamental right to property, applies only to natural individuals or whether it extends to legal individuals, such as corporations and other entities.⁹⁷ A vital component of the basic definition of a "human right" is that it is a right held by a human being, not by an entity.⁹⁸ A more substantial issue is that private and public global law recognises the right of a state to regulate property rights and modify these rights to suit the economic and social circumstances of the state, in contrast to regulating other fundamental rights, such as those prohibiting genocide, torture and slavery.⁹⁹ If intellectual property had to fall within the category of fundamental rights regime, it would require that the level of protection be raised to promote scientific progress in a manner that will broadly benefit members of society individually and collectively.¹⁰⁰ It would also establish a higher standard for evaluating patent applications by ensuring that the proposed invention also be consistent with the inherent dignity of the human being and with fundamental rights norms.¹⁰¹ Finally, as a result of fundamental rights being a universal entitlement, its application should be measured by the degree to which it benefits the public.

In a discussion study by the Centre for International Environmental Law,¹⁰² the process of creating intellectual property law is described as follows:

"Intellectual property laws are defined through closed, secretive international negotiations dominated by industry – and are then brought to national legislatures as *faits accomplis*,

⁹² Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 15.

⁹³ *Ibid.*

⁹⁴ *Supra* note 91.

⁹⁵ For more discussion see Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

⁹⁶ *Ibid.*

⁹⁷ *Supra* note 95.

⁹⁸ For more discussion see Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 10.

⁹⁹ *Supra* note 95.

¹⁰⁰ *Supra* note 95.

¹⁰¹ *Supra* note 91.

¹⁰² The Centre for International Environmental Law (CIEL) aims to strengthen and use international law and institutions to protect the environment, promote human health and ensure a just and sustainable society. More information on the centre and its activities is available at <http://www.ciel.org/> (accessed 09 September 2015).

without democratic deliberation. Combined with the technical, arcane nature of intellectual property legal specialty, this assisted corporate interests to avoid public scrutiny and expand their control over developments in applications, such as electronic information, biotechnology or pharmaceuticals. Industrial country governments promote corporate interests in expanded intellectual property rights in the name of maximising national competitiveness in a global marketplace".¹⁰³

Science and technology have a substantive economic impact. It is well-known that less developed countries are primarily recipients, rather than sources of basic scientific research and innovative technologies. They rarely have the infrastructure required to undertake comprehensive research.¹⁰⁴ Products manufactured in only certain countries find their way globally, into technologically less sophisticated populations. Decisions to strengthen a country's competitive position are in line when dealing with intellectual property rights but cannot be equated with a fundamental rights approach.¹⁰⁵

5.5 The Right to Health

5.5.1 The historical position of the right

Historically well-known charters and declarations, such as the Magna Carta of 1215, the English Bill of Rights in 1689, the American Declaration of Independence in 1776 and the French Declaration on the Rights of Man and of the Citizen in 1789, all failed to make reference to the right to health.¹⁰⁶ As mentioned above, the end of the Cold War created opportunity for recognising the interdependence of civil, political and social rights.¹⁰⁷ Global strategies were considered to provide opportunity for including the right to health within global law as it was linked with maintaining peace and security.¹⁰⁸ European states realised that they had to co-operate through global law to control the spread of cholera and other infectious diseases. The 1851 International Sanitary Conference was held, with subsequent conferences in the latter half of the nineteenth century and early twentieth century.¹⁰⁹ Subsequently four global health organisations were created namely; the Pan American Sanitary Bureau,¹¹⁰ the *Office International d'Hygiene Publique*,¹¹¹ the Health Organisation of the League of Nations,¹¹² and the *Office International des Epizooties*.¹¹³ As mentioned earlier, the League of Nations was absorbed and replaced by the UN after World War II.¹¹⁴

¹⁰³ The discussion study is available at <http://www.ciel.org/Publications/WTOReviewofLPunderTRIPS.pdf> (accessed 09 September 2015).

¹⁰⁴ For more discussion see Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 15.

¹⁰⁵ *Ibid.*

¹⁰⁶ Tobin J *The Right to Health in International Law* 2012 16.

¹⁰⁷ *Ibid* at 1.

¹⁰⁸ *Supra* note 104 at 15.

¹⁰⁹ Fidler DP *International Law and Global Public Health* The University of Kansas Law Review 1999 Vol 48 16.

¹¹⁰ Formed in 1902. *Ibid.*

¹¹¹ Formed in 1907.

¹¹² Formed in 1923.

¹¹³ Formed in 1924.

¹¹⁴ Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 23.

After the UN established the WHO and adopted the UDHR in 1948, the right to health was finally recognised.¹¹⁵ Since then it seems that the right to health moved to the centre of political debate featuring in UN debates to national courts and national constitutions.¹¹⁶

In 1978, the Declaration of Alma-Ata was adopted, sustaining the right to the highest attainable standard of health. In 1986 the Ottawa Charter of Health Promotion also reflects the connections between public health and human rights.¹¹⁷ Unlike the right to property, the right to health is mentioned in several global instruments and is explicitly recognised as a fundamental right.¹¹⁸ WHO defines health as “a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity”¹¹⁹ whilst the right to health was described by the UDHR in Article 25: “everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family”.¹²⁰

As mentioned above,¹²¹ the right is also mentioned in the ICESCR. More than 150 countries became state parties to the ICESCR and 83 have signed regional treaties incorporating the right.¹²² Additionally, more than 100 countries have incorporated the right to health in national constitutions.¹²³

5.5.2 Subsequent steps

As discussed in section 4.5, several trade and investment agreements undermine the right to health by enabling price increases of medicines, thereby making them unavailable to most of the public. TRIPS was identified as one of these agreements in 2000 by the UN sub-committee on Human Rights issued Resolution 2000/7, titled *Intellectual Property Rights and Human Rights*. The resolution expressed concern on restrictions on access to patented pharmaceuticals, amongst other factors.¹²⁴ It concluded the

¹¹⁵ The right to health is also recognized in numerous other international human rights treaties which include the International Convention on the Elimination of All Forms of Racial Discrimination of 1965, the Convention on the Elimination of All Forms of Discrimination against Women of 1979, and the Convention on the Rights of the Child of 1989. For more discussion see Kinney ED *The International Human Right to Health: What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1457. See also Bishai DM *Right to Health and the Universal Declaration of Human Rights* The Lancet 2005 Vol 37 13.

¹¹⁶ Tobin J *The Right to Health in International Law* 2012 2.

¹¹⁷ Hunt P & Backman G *Health Systems and the Right to the Highest Attainable Standard of Health* Health and Human Rights 2008 Vol 10(1) 80. See also Leary VA *The Right to Health in International Human Rights Law* Health and Human Rights 1994 Vol 1(1) 32.

¹¹⁸ The right is mentioned in many international instruments including: the European Convention for the Protection of Human Rights and Fundamental freedoms, African Charter on Human and People's rights, American Convention on Human rights, the UDHR and the ICESCR. See Leary VA *The Right to Health in International Human Rights Law* Health and Human Rights 1994 Vol 1(1) 32.

¹¹⁹ This definition is found in the Constitution of the World Health Organisation. See <http://www.who.int/about/mission/en/> (accessed 10 July 2017).

¹²⁰ Article 25 of the UDHR. For discussion see de Campos TC *Health as a Basic Human Need: Would This Be Enough?* Journal of Law, Medicine & Ethics 2012 251.

¹²¹ Refer to section 5.3.1.

¹²² For more information see Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* Lancet 2006 Vol 368 305–11.

¹²³ These include amongst others: Brazil, Bolivia, Columbia, Costa Rica, Ecuador, Nigeria, Panama, San Salvador, South Africa and Venezuela. *Ibid.* See also Gruskin S, Mills EJ & Tarantola D *History, Principles and Practice of Health and Human Rights* The Lancet 2007 Vol 370 449. See also Bishai DM *Right to Health and the Universal Declaration of Human Rights* The Lancet 2005 Vol 37 13.

¹²⁴ See Leary VA *The Right to Health in International Human Rights Law* Health and Human Rights 1994 Vol 1(1) 51. See also ED Kinney *What Does This Mean for Our Nation and World?* Indiana Law Review 1997 Vol 34 1457.

essentiality and indivisibility of all fundamental rights is not reflected by implementing TRIPS. Subsequently in 2004, the Geneva declaration on the future of the WIPO was held.¹²⁵ It occurred in conjunction with an initiative led by Argentina and Brazil to have WIPO adopt a Development Agenda whereby focus is on the health concerns of developing nations.¹²⁶

The declaration announced that “humanity faces a global crisis in the governance of knowledge, technology and culture” and that manifestation can be observed in several ways, including lack of access to essential medicines, anticompetitive practices that impose increased costs on consumers and retard innovation and private interests dominating public interests.¹²⁷ In addition to other things, the declaration advocates for a grant on new treaties and a harmonisation of intellectual property standards and calls for more attention to be provided alternative methods encouraging innovation. It demands consideration of the needs of the public.¹²⁸ The Commission calls on states to “refrain from taking measures that would deny or limit equal access for all individuals to such pharmaceuticals and medical technologies,”¹²⁹ thereby discouraging aggressive pharmaceutical patent protection. The only state to oppose an otherwise unanimous adoption of the resolution was the US.¹³⁰ An analogous situation to the above-mentioned US-Brazil dispute, was a local dispute taken to the Constitutional Court between the Pharmaceutical Manufacturers Association of South Africa and the South African government.¹³¹

As can be observed from above, the right to health has held an important status in global law for several years and was in the foresight of recent global discussions. Since most of the covenants, declarations and global agreements discussed above, deal with so-called “soft law”, there are no sanctions for non-compliance.¹³²

5.6 The Inter-Relationship between Intellectual Property and Fundamental Rights

There are two events that have caused intellectual property law to be put on the fundamental rights law agenda. The first related to the rights of indigenous individuals and the second that related to intellectual property and trade as reflected in the TRIPS Agreement.¹³³ Both events revealed deficiencies in the law

¹²⁵ <http://www.futureofwipo.org/futureofwipodeclaration.pdf> (accessed 08 September 2015).

¹²⁶ Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 44.

¹²⁷ *Ibid* at 45.

¹²⁸ *Supra* note 126 at 46.

¹²⁹ D Weissbrodt & K Schoff *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub Commission Resolution 2000/7* 5 Minnesota Intellectual Property Review 2003.

¹³⁰ *Ibid*.

¹³¹ *Pharmaceutical Manufacturers Association of South Africa v President of the Republic of South Africa* Case No. 4183/98 (High Court of South Africa 1998) <http://www.cptech.org/ip/health/sa/pharmasuit.html>. The plaintiffs alleged that the amendment to the Medicines and Related Substances Control Act infringed on a manufacturers' property rights and conflicted with the provisions of TRIPS. The case is discussed in further detail in section 7.4.3 of this thesis.

¹³² Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 46.

¹³³ Helfer HR *Human Rights & Intellectual Property: Conflict or Coexistence* 2007 available at https://scholarship.law.duke.edu/faculty_scholarship2007 (accessed on 04 October 2015).

of intellectual property when observed from a fundamental rights law perspective.¹³⁴ The consequence of these deficiencies is as follows:

- An increased incentive to develop fundamental rights norms by re-examining treaty and national texts;
- An emergence in the treatment of intellectual property product users/consumers. Since inventors are the holders of the rights from an intellectual property law perspective, whilst from a fundamental rights law perspective, the users will be granted a status equal to that of inventors as fundamental rights are universal; and
- The articulation of maximum standards of intellectual property protection. From the Berne Convention, to the Paris Convention, to the TRIPS Agreement, the concern is minimum standards of protection.¹³⁵

Even if intellectual property rights are accepted as fundamental rights, there are certain aspects of the right that differ from the conventional fundamental rights. In contrast to conventional fundamental rights, intellectual property rights can be revoked, licenced, or assigned to a third party and are temporary in nature.¹³⁶ These rights can be traded, amended and limited in time and scope. Conventional fundamental rights, conversely, are timeless.¹³⁷ Table 3 reflects the main differences between the two regimes.¹³⁸

Table 3: Differences between fundamental rights and intellectual property

FR Characteristics	IP Characteristics
Public law	Private law
Ex persona	Ex lege
Universal	Territorial
Individual rights	Individual rights and corporate rights
Immaterial interests	Material interests
Unlimited term	Limited term
Not assignable	Assignable
Non-exploitable	exploitable

Two theories regulate the relationship between the intellectual property law and the fundamental rights law regimes. With regard to the theory that the two regimes are in conflict, there is a need to identify the nature of the conflict before one right can supersede the other. The legal justification for this should be analysed.¹³⁹

¹³⁴ *Ibid.*

¹³⁵ Hestermeyer H *Human Rights and the WTO: The Case of Patents and Access to Medicines* 2007 105.

¹³⁶ Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 16.

¹³⁷ *Ibid.*

¹³⁸ *Supra* note 135 at 21.

¹³⁹ Helfer LR & Austin GW *Human Rights and Intellectual Property, Mapping the Global Interface* 2011 65.

In the year 2000 the UN and the sub-committee on the Promotion and Protection of Human Rights formed a resolution entitled *Intellectual Property Rights and Human Rights*. The following conflicts were noted in the resolution:¹⁴⁰

- Impediments relating to the transmission of technology to developing countries;
- The concerns relating to the food or plant variety and patenting of genetically modified organisms' bio-piracy;¹⁴¹
- The lack of control over an individual's own genetic and natural resources;
- Limitations over access to patented pharmaceuticals.¹⁴²

The sub-committee advises states, inter-governmental organisations and NGOS to distinguish between fundamental rights and economic policy agreements and the superiority of the former.¹⁴³ The UN Charter confirms that fundamental rights law enjoys supremacy in stating: "In the event of a conflict between the obligations of the member of the UN under the present Charter and their obligations under any other global agreement, their obligations under the present Charter will prevail".¹⁴⁴

According to Helfer and Austin, the conflict approach entails a broad notion of inconsistency. They explain that if national legislation encourages a state to perform in a certain way, but a subsequent global agreement prohibits that same conduct, then it can be taken as the state renouncing the earlier authority by ratifying the later one.¹⁴⁵ They suggest and this author concurs, that instead of identifying conflicting rules and justifying them one should rather interpret those rules in a manner that harmonises the values and policies that underlie them. Global treaties and regulations pertaining to a particular topic should not be interpreted in isolation.¹⁴⁶ This leans towards the 'compatible theory'.

The compatible theory observes that the two areas of law are compatible and a balance is needed. Both serve to enhance welfare and benefit society, and both regimes equally attempt to define the appropriate scope of private rights, whilst safe guarding public interest.¹⁴⁷ The theory is confirmed by General Comment 17 on creator's rights¹⁴⁸ and is further addressed in the high Commissioner's report on the TRIPS Agreement.¹⁴⁹ The basis of theory is that because both the regimes have the same objectives, they are compatible.

¹⁴⁰ The resolution is available at: http://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf.

¹⁴¹ Bio-piracy is the exploitative appropriation of indigenous forms of knowledge by commercial actors and the search for previously unknown compounds in organisms that have never been used in traditional medicine.

¹⁴² For a full discussion see D Weissbrodt & K Schoff *Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub Commission Resolution 2000/7* 5 Minnesota Intellectual Property Review 2003.

¹⁴³ *Ibid.*

¹⁴⁴ Article 103 of the UN Charter.

¹⁴⁵ Helfer LR & Austin GW *Human Rights and Intellectual Property, Mapping the Global Interface* 2011 66. See also Yu PK *Intellectual Property and Human Rights 2.0* University of Richmond Law Review 2019 Vol 53 1375.

¹⁴⁶ *Supra* note 145 at 67.

¹⁴⁷ Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 237.

¹⁴⁸ General Comment 17 E/C.12/GC/17 see <http://tb.ohchr.org/default.aspx?Symbol=E/C.12/GC/17> (accessed 23 January 2015).

¹⁴⁹ See Human Rights Commission - Report of the High Commissioner *Impact of the Agreement on Trade-Related of Intellectual Property Rights on Human Rights* U.N.Doc. E/CN.4/Sub.2/2001/13 – 27 June 2001

5.7 Fundamental Aspects in the Intellectual Property Regime

Whether using the compatible or the conflict approach, it cannot be denied that there are certain aspects of fundamental rights law influencing intellectual property law. An example of this is the concept of morality. The patent system has been connected to morality for a long time but was not explored until the recent rise of the biotechnology industry. Morality cannot be defined as it indicates entities different to each individual and each state. As patent systems are territorial, each patent jurisdiction has to produce its own legal answers in relation to patenting and morality. It seems that in countries holding large biotechnology industries, the role of morality (at least in relation to biotechnology) is diminished.¹⁵⁰

The discussion has already touched on the concept of morality within the context of the provisions of the TRIPS Agreement¹⁵¹ and provisions of international covenants¹⁵² and despite *prima facie* seeming otherwise, moral standards play a part in patent systems. When patent laws are enacted, the moral standards of the community where they belong are factors that affect the content of national patent laws.¹⁵³ Morality usually enters the interpretive process involved in judicial decision-making on patent law. When the majority in *Diamond v Chakrabarty*¹⁵⁴ decided that it was for Congress to decide to exclude from patent protection genetically engineered organisms, they expressly endorsed a political morality that allocated matters of "high policy" to Congress.¹⁵⁵ Since the custodians are caught up in a structural predicament of global dimensions, the scope of patentability is expanding, whilst the role of moral standards in the operation of the patent system is increasingly limited. Ironically, this is happening at a time when the moral debate over patentability, at least in the field of biotechnology, has never been greater.

Another fundamental concept also linked to the patent system and the recent biotechnology controversy, is that of dignity, well established in the global arena but the connection between dignity and patents is more recent due to growth in human genetics.¹⁵⁶ The European Group on Ethics in Science and New Technologies conducted a study on the relationship between patents and the fundamental right to human dignity and the ethical implications of biotechnology in Europe.¹⁵⁷ Their opinions seem to support integrating fundamental rights law into the patents law regime, particularly in the context of human genetics. The study observed the principles that the EU was founded on. These include liberty, democracy, respect for fundamental rights and freedoms and the rule of law.¹⁵⁸ They hold the opinion that if the nature

<https://www.ohchr.org/en/issues/globalization/pages/reportshc.aspx> (accessed 19 September 2017). For more discussion see also Yu PK *Intellectual Property and Human Rights 2.0* University of Richmond Law Review 2019 Vol 53 1375.

¹⁵⁰ Drahos P *Biotechnology Patents, Markets and Morality* European Intellectual Property Review 1999 21(9) 441.

¹⁵¹ See section 4.3.2 and section 4.3.4.

¹⁵² See section 5.3 and 5.4.

¹⁵³ *Supra* note 149.

¹⁵⁴ *Diamond v Chakrabarty* 447 U.S. 303 313 (1980).

¹⁵⁵ *Supra* note 150.

¹⁵⁶ Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 244.

¹⁵⁷ Human Dignity is defined as an individual or group's sense of self-respect and self-worth, physical and psychological integrity and empowerment. See <http://www.duhaime.org/LegalDictionary/H/HumanDignity.aspx> (accessed 21 December 2018). See also *ibid* at 247.

¹⁵⁸ *Supra* note 157.

of the biotechnological invention contains elements of human origin, the European Directive should guarantee the refusal of the patent on grounds of human dignity.¹⁵⁹ This notion appeared for the first time in the European Community in the proposal for an EU Biotechnology Directive in 1988. The European parliament rejected the proposal. It was then implemented in the final EU Directive of 1998 but only as a recital.¹⁶⁰

5.8 Summary and Conclusions

World War II led to developing the UN and promoting fundamental rights and freedoms. The International Bill of Rights including the UDHR and the international Covenants (the ICESCR and ICCPR) were drafted in the post war context aiming to protect science from misuse and to promote a standard of adequate health and socio-economic care.

The fundamental status of the two rights in issue, the right to health and the right to property, need to be established. The covenants and the UDHR expressly mention the right to health¹⁶¹ with provision for individuals to enjoy the benefits of scientific advancement.¹⁶² The UDHR also mentions the right to property¹⁶³ but does not make specific reference to intellectual property. However, Article 27(2) of the UDHR provides that an author has the right to material interests resulting from any scientific, literary, or artistic production.¹⁶⁴

Assuming that intellectual property rights are included within the wider category of property rights, should the latter not be considered as a fundamental right, the right to health would supersede it. Instruments will then need to be used to strike an optimal balance of incentivising private innovation, enriching the wellbeing of the public since Article 27 of the UDHR and Article 15 of the ICESCR both obligate governments to reward human creativity and innovation, but also ensuring public access to the fruits of such creativity and innovation.¹⁶⁵ However, should property rights, including intellectual property rights, be considered as a fundamental right, it would need to be without distinction? Just as the right to health needs to be of equal status to each individual, intellectual property rights would need to benefit both the creator and the consumer.¹⁶⁶

¹⁵⁹ *Supra* note 157.

¹⁶⁰ For more discussion, see chapter 6. See Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 245.

¹⁶¹ Article 25 of the Universal Declaration of Human Rights. See www.un.org/en/documents/udhr/ (accessed 25 July 2015).

¹⁶² Article 27(1) of the Universal Declaration of Human Rights. See www.un.org/en/documents/udhr/ (accessed 25 July 2015).

¹⁶³ Article 17 and 27 (2) of the Universal Declaration of Human Rights. See www.un.org/en/documents/udhr/ (accessed 25 July 2015).

¹⁶⁴ Article 27(2) of the Universal Declaration of Human Rights. See www.un.org/en/documents/udhr/ (accessed 25 July 2015).

¹⁶⁵ Article 27 of the Universal Declaration of Human Rights and Article 15 of the International Covenant of Economic Social and Cultural Rights. For discussion see Hein W & Moon S *Informal norms in Global governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 507. See also Saez C “No Human Right to Patent Protection,” Says UN Rapporteur on Cultural Rights Intellectual Property Watch <https://www.ip-watch.org/2015/10/08/no-human-right-to-patent-protection-un-rapporteur-on-cultural-rights-says/> (accessed 24 January 2020).

¹⁶⁶ For discussion see Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 507.

To be consistent with fundamental rights norms, the inventions would have to meet the following requirements:¹⁶⁷

- Intellectual property rights need to be consistent with the understanding of human dignity in the various global fundamental rights instruments and the norms defined therein;
- Intellectual property rights related to science should promote scientific progress and affordable access to its benefits;
- Intellectual property regimes should respect scientific research and creative freedoms;

Intellectual property regimes should encourage global contact development and scientific and cultural field co-operation.¹⁶⁸

This ideal would allow the relationship between the two regimes to be compatible, at least in so far as biotechnology is concerned. A pathway consistent with fundamental rights needs to be formed whereby pharmaceutical innovation is rewarded but the innovation is accessible to all. At face value, the two regimes seem to be in conflict.¹⁶⁹ Even during the negotiations of the UDHR, Article 27(1) was recognised to be in conflict with Article 27(2).¹⁷⁰ This conflict is evident in the area of diagnostic genes.¹⁷¹ In order for compatibility to be reached between these regimes interpretation of treaties, like the TRIPS Agreement, and relevant intellectual property legislation, should be guided.

The interpretation of intellectual property legislation with the above mentioned fundamental right norms, highly increases the probability of achieving an optimal balance of incentivising private innovation and enriching the wellbeing of the public. To fulfil the provisions of Article 15 of the ICESCR, the level of protection afforded to intellectual property holders, should also protect broad society at an individual and collective level. This approach will establish balance between the rights of the patent rights holders and the interests of the wider society.¹⁷²

¹⁶⁷ Chapman AR *A Human Rights Perspective on Intellectual Property, Scientific Progress and Access to the Benefits of Science* study delivered at the Panel Discussion on Intellectual Property and Human Rights 1998 1- 44.

¹⁶⁸ *Ibid.*

¹⁶⁹ See table 3 in section 5.6.

¹⁷⁰ Article 27(2) states that “Everyone has the right to the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author”. At the same time Article 27(1) states that each one has “the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.” See the Universal Declaration of Human Rights. See also www.un.org/en/documents/udhr/ (accessed 25 July 2015).

¹⁷¹ This is clear from section 2.2.2's discussion on the lack of public benefit in this regard.

¹⁷² For more discussion see Chapman AR *Approaching Intellectual Property as a Human Right* 2001 77.

Chapter 6

Comparative study

6.1 Patenting of Diagnostic Genes in Developed Countries

In this age of globalisation and intertwinement of global public and private law, it is increasingly important to understand foreign legal systems especially regarding the aims of global harmonisation and unification of laws.¹ Different jurisdictions deal with a particular legal issue in different ways as a result of various factors including the political history and culture of that particular jurisdiction.² An example used by Siems to explain this is that of an individual being jailed for certain crimes in Saudi Arabia, whilst in Europe the same crime may only result in a fine.³ This may be indicative of varying standards of morality or values. For example, in the US capital punishment still stands, whilst in South Africa the criminal law is more focussed towards retribution.⁴ Regarding intellectual property laws, certain inventions may be patentable in particular jurisdictions and not in others, or it may be that an invention is patentable in both jurisdictions but for different reasons.

This chapter deals with the legal position regarding diagnostic gene patentability in developed countries specifically, the US and the EU, the latter with specific focus on Germany. As suggested in chapter 2, genes are a form of data making patenting eligibility different from the eligibility of other biological compounds.⁵ This issue is particularly relevant in the case of diagnostic gene tests, as the gene used in these tests serve as only an association between a gene variant and a disease and not an invention.⁶ The association between the gene and the mutation is used by applying the gene as a standard to identify the gene in the patient. The description of an association between a naturally occurring gene and a disease, extends to no more than just a discovery.⁷ Despite this, legal regimes of most countries allow patent applications on gene sequences, as long as they are useful in a general sense. Most countries hold similar limitations and exclusions regarding patentability, though interpreted differently. For example, most countries have an exclusion based on morality. Morality is a concept that can be perceived differently within various jurisdictions. As Drahos puts it: “Tests of morality that depend on the patent being “abhorrent to the overwhelming majority of the public, a contravention of the ‘totality of the accepted norms’ or a

¹ Michaels R *The Functional Method of Comparative Law* 2006 340 available at http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2033&context=faculty_scholarship (accessed 07 September 2015).

² For more discussion see Siems M *Comparative Law* 2014 7- 8.

³ *Ibid* at 103.

⁴ *Supra* note 2 at 103.

⁵ De Carvalho NP *The Problem of Gene Patents* available at <http://heinonline.org> (accessed 13 March 2015). See also Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 733.

⁶ Nuffield Council on Bioethics: *The Ethics of Patenting DNA a discussion study* 2002 available at <http://www.nuffieldbioethics.org.uk/the-ethics-of-patenting-dna-a-discussion-study> (accessed 03 October 2015).

⁷ A discovery is the act of detecting entities that already exists and has been around over a long period of time, whilst an invention uses objects, ideas or theories that already exist to create a new object, idea or theory that does not yet exist. A gene as it is naturally found would be a discovery.

‘weighing up’ of advantages and disadvantages” provide a patent office minded to do so with plenty of scope to narrow the scope of operation of the morality criterion”.⁸

This chapter aims to provide an understanding of the development, objectives and status of patent laws within the US and the EU as developed countries with strong biotechnology and pharmaceutical industries. Elements compared within both jurisdictions include applicable legislation, case discussions relevant to the progression of genes being acceptable as patentable subject matter and the effect of diagnostic genes being patentable. The role of each of these jurisdictions in TRIPS Plus agreements is also discussed as it elaborates on the main objectives of each of these jurisdictions.

6.2 Biotechnology in the US

The US has one of the largest biotechnology industries globally. In just a few decades, biotechnology in the US became a major industry with a market capitalisation of over \$400 billion and payroll of over 130,000 individuals.⁹ With the up rise of the industry came an up rise of the number of related patent applications. It began in the 1970s when inventors began securing significant numbers of patents, with claims on the complex organic molecules of life. In 1971 two patents were issued claiming a “polypeptide” and “protein”.¹⁰ In 1972, the first claim to a “peptide”¹¹ appeared in the US and by 1973 “DNA” was included as an element of a patent claim.¹² Finally, in 1982, a patent was issued including claims on “recombinant DNA transfer vector[s]” comprising of a specified nucleotide sequences of codons.¹³ From this period to 2001, the United States Patents and Trademark Office (USPTO) granted patents to over 8,000 genes, genetic material, or gene sequences.¹⁴ In order to obtain an understanding of the American position on biotechnology patents, including diagnostic gene patents, federal US law is analysed. This section details the development of US patent law and attitude of US courts toward genes as patentable subject matter. The effect of a patent on the breast cancer genes, BRCA 1 and 2, is also analysed. Lastly, this section discusses FTA’s from an American perspective to create an understanding of the objectives of these agreements.¹⁵

⁸ P Drahos *Biotechnology Patents, Markets and Morality* European Intellectual Property Review 1999.

⁹ C Barfield & JE Calfee *Biotechnology and the Patent System: Balancing Innovation and Property Rights* 2007 available at <http://www.aei.org/book/health/biotechnology-and-the-patent-system/> (accessed 08 July 2015).

¹⁰ US Patent Numbers 3,607,370 and 3,619,206 respectively. For more information see Torrance AW *Gene Concepts, Gene Talk and Gene Patents* Minnesota Journal of Law, Science & Technology 2010 Vol 11(1) 157-191.

¹¹ Patent Number 3,645,689.

¹² The term “gene” first appeared as a claim element in the US Patent No 3,710,511.

¹³ US Patent No. 4,363,877 (“the ‘877 patent”). For more information see Torrance AW *Gene Concepts, Gene Talk and Gene Patents* Minnesota Journal of Law, Science & Technology 2010 Vol 11(1) 157-191.

¹⁴ The increase was after the case of *Diamond v Chakrabarty* 447 U.S. 303, 313 (1980).

¹⁵ FTA’s and their global effects are discussed in detail in section 4.5.

6.2.1 History of American patent law

The first US Patent Act of 1790 was a short Act with seven sections entitled *An Act to Promote the Progress of Useful Arts*.¹⁶ In 1793 this Act was repealed and replaced by a slightly longer Act; the drafting, largely attributed to Thomas Jefferson, defining a patentable object as being: "any new and useful art, machine, manufacture or composition of matter and any new and useful improvement on any art, machine, manufacture or composition of matter".¹⁷ The Act was amended several times after this, expanding the category of potential patentees,¹⁸ requirements for novelty, grace periods, double patenting and various other aspects. The basic structure of the present law was adopted in 1952. Since then amendments continued to develop by way of case law.¹⁹

The primary feature of the US patent system indicates that examinations are carried out for all applications for conformity. All questions relating to validity of patents are left to district courts, with the power to set in motion a process that could end in the repeal of the patent.²⁰ In the early 1980s, the Court of Appeals for the Federal Circuit was created to unify regional circuit courts of appeal in dealing with patent cases. The latter demonstrated a tendency to rule in favour of the patent-holders, aiming to enhance the value of a patent as protection for an innovation.²¹ The Federal Circuit also conveyed a certain antipathy towards the doctrine of misuse.²²

Under the US patent system "the first and true inventor" is the individual who is issued the patent.²³ Hence, a patent would be granted to the first inventor, irrespective of who was the first to file. The USPTO would have to conduct an investigation in order to determine the first inventor in cases of more than one claim on the same invention.²⁴ Initially, US statutes also restricted patents to US citizens or to residents who declared that they intended to become citizens. In 1836, the Patent Office was established and authorised to examine all applications.²⁵ In addition, stipulations on citizenship or residency were removed and replaced with discriminatory patent fees. Foreigners could obtain a US patent for a fee of three hundred dollars.²⁶ It was only after 1861 that patent rights (except for caveats) were offered to all applicants on the same basis, regardless of nationality.²⁷

¹⁶ <http://www.ladas.com/Patents/USPatentHistory.htm> (accessed 17 February 2015).

¹⁷ The US Patent Act of 1793. *Ibid.* See also O Mills *Biotechnological Inventions (Revised Edition) Moral Restraints and Patent Law* 2010 42.

¹⁸ So that it included resident foreigners.

¹⁹ Lauzon ED *Patentability of Diagnostic Methods Concerning Human Genes, Cells, Blood and DNA* American Law Reports 2014 Vol 90 235.

²⁰ *Ibid.*

²¹ Reichman J & Hasenzahl C *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the USA* UNCTAD/ICTSD Geneva 2003 5 176.

²² *Ibid* at 178.

²³ This indicates the first and true inventor globally and not just in the US. For more discussion see Khan Z & College B *An Economic History of Patent Institutions* available on <https://eh.net/encyclopedia/an-economic-history-of-patent-institutions/> (accessed 18 September 2015).

²⁴ Page J *First to Invent* Integrity Intellectual Property 2010 <http://integrityip.com/GGL/Patent/First-To-Invent.aspx> (accessed 24 January 2020).

²⁵ *Supra* note 21.

²⁶ Khan Z & College B *An Economic History of Patent Institutions* available on <https://eh.net/encyclopedia/an-economic-history-of-patent-institutions/> (accessed 18 September 2015).

²⁷ Reichman J & Hasenzahl C *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under*

The law was next amended in 1994 to comply with TRIPS,²⁸ imposing on all member states minimum standards of patent protection, requiring the US to amend domestic legislation relating to the minimum duration of a patent and to prevent discrimination between protecting inventions in the US and those invented elsewhere.²⁹

In 2011 the Leahy-Smith America Invents Act was signed into law.³⁰ The latter updates the patent system to encourage innovation, job creation and economic growth.³¹ The Act implements a first-to-file standard for patent protection replacing the previous first-to-invent standard. The Act also creates a post-grant review system to weed out bad patents and assists the Patent and Trademark Office (PTO) to address the backlog of patent applications. Its enactment is a victory for America's innovators and job creators who rely on patent system to develop new products and grow their businesses.³²

The most recent legislative development in June 2018, introduced the Restoring American Leadership in Innovation Act of 2018 into parliament.³³ The Act is presented in the form of a Bill and seeks to repeal certain provisions of the Leahy-Smith America Invents Act including the first-to-file standard for patent protection and reverting back to the first-to-invent system. As the name suggests, the aim of the Act is to strengthen protection of inventors.³⁴

6.2.2 Applicable legislation

6.2.2.1 The US Constitution

The first Constitution of the US is the Articles of Confederation adopted by 13 colonies in 1781.³⁵ These colonies became the first states of the US and included: Delaware, Georgia, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, South Carolina, Pennsylvania, Rhode Island and Virginia.³⁶ The articles allowed each state to collect their own taxes, issue its own currency and even establish its own army. The second and final constitution amended this and was adopted in 1788.³⁷

TRIPS and an Overview of the Practice in Canada and the USA UNCTAD/ICTSD Geneva 2003 5 176.

²⁸ See section 4.3 for a full discussion on TRIPS.

²⁹ <http://www.ladas.com/Patents/USPatentHistory.html> (accessed 17 February 2015).

³⁰ Leahy-Smith America Invents Act 112-29 of 2011. See http://judiciary.house.gov/issues/issues_patentreformact2011.html (accessed 05 June 2015).

³¹ http://judiciary.house.gov/issues/issues_patentreformact2011.html (accessed 05 June 2015).

³² *Ibid.*

³³ The proposed Bill can be found at <https://cdn.patentlyo.com/media/2018/07/FinalPatentBill.pdf> (accessed 23 October 2018).

³⁴ For more discussion on the Bill see Lund D *Rep. Massie Introduces New Legislation to Restore America's Patent System* Centre for the Protection of Intellectual Property Law at Antonin Scalia Law School 2018 available at <https://cpip.gmu.edu/2018/06/29/rep-massie-introduces-new-legislation-to-restore-americas-patent-system/> (accessed 23 October 2018).

³⁵ Billings R *The American Legal System* 2015 1.

³⁶ Today the US comprises 50 states including these original states.

³⁷ For more discussion see *supra* note 34.

The founding fathers of the US gave much thought to the encouragement of innovation when drafting the Constitution.³⁸ Article 1, section 8, clause 8 of the US Constitution establishes the basis for protecting invention in the US: "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries".³⁹ The clause is intended to reward an individual for creating an invention and sharing new knowledge. This concept is the constitutional basis for the intellectual property system that currently exists in the US.⁴⁰ Thomas Jefferson expressed concern over monopolies in science stating: "Considering the exclusive right to invention as provided not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent and those which are not".⁴¹ He wrote that ideas should spread freely across the globe, "for the moral and mutual instruction of man and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, such as fire, expansible over all space, without lessening their destiny in any point and such as the air where we breathe, move and have our physical being, incapable of confinement or exclusive appropriation".⁴² The US Constitution does not guarantee the right to health care.⁴³

6.2.2.2 The US Patent Act

Chapter 10 of the Act⁴⁴ deals with the patentability of inventions and the grant of patents. A patent provides the inventor exclusive rights to prevent others from making, using, selling, offering for sale, or importing the claimed invention within the US. The US government grants a twenty-year monopoly to the inventor. In exchange, the inventor makes information regarding the manufacture and function of the invention available to the public.⁴⁵ The American patent system is a three-party give-and-take system. The system includes the USPTO, the courts and Congress, all of which have active roles in guaranteeing the goals of the patent system are met.⁴⁶ The USPTO issues utility patents, design patents and plant patents. Genes

³⁸ Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) June 539.

³⁹ This clause is known as the progress clause. See http://judiciary.house.gov/issues/issues_patentreformact2011.html (accessed 05 June 2015). See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* 2011 Duke Law Journal 2011 Vol 61 736. Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The "Useful Arts"* Albany Law Journal of Science & Technology 1997 312.

⁴⁰ Billings R *The American Legal System* 2015 1.

⁴¹ See *ibid* for discussion.

⁴² Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 539. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The "Useful Arts"* Albany Law Journal of Science & Technology 1997 312. See also Feldman R *Rethinking Patent Law* 2012 99.

⁴³ States constitutions do however expressly recognize a right to health. For discussion see ED Kinney *What Does This Mean for Our Nation and World?* Indiana Law Review 2001 Vol 34 1 465. See also Golden JM *Biotechnology, Technology Policy and Patentability: Natural Products and Invention in the American System* 2001 Vol 50. See also Rai AK *Intellectual property and Biotechnology* 2011 194. See also Matsuura H *Does the Constitutional Right to Health Matter? A Review of Current Evidence* CESifo DICE Report 2014 12(2) 35-41 <https://www.cesifo-group.de/DocDL/dicereport214-rr1.pdf> (accessed 05 September 2018).

⁴⁴ The US Patent Act 35 USC.

⁴⁵ http://judiciary.house.gov/issues/issues_patentreformact2011.html (accessed 05 June 2015).

⁴⁶ For more discussion see Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 539.

and gene fragments most usually fit in the utility patent framework.⁴⁷ Within this framework an invention should comply with the requirements of novelty, non-obviousness and utility.⁴⁸ The invention should also fall within the ambit of what is patentable by statute.⁴⁹ With regards to the requirement of novelty, an invention should be "new". Section 102 lists the situations where a novelty can be refuted.⁵⁰ The purpose of the novelty requirement is to prevent duplicity of patents.⁵¹

The statutory requirement of non-obviousness enquires whether the invention is clear to an individual who is skilled in the field. An analysis examines all relevant information prior to determining whether the claimed invention represents a significant advancement in the field.⁵²

The court address the requirement of non-obviousness in the Supreme Court case of *Hotchkiss v. Greenwood*,⁵³ where it is held that "unless more ingenuity and skill... (is applied in the new invention)...than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention".⁵⁴

In 1965, the US Supreme Court set forth the modern test for obviousness in *Graham v. John Deere Co*⁵⁵ which imposes three requirements:

- The court should survey the scope and content of the prior art;
- The court should examine the differences between the prior art and the claimed invention;
- The court should determine the level of originality.⁵⁶

Another case where the requirement of obviousness was an issue was in *Amgen v. Chugai*,⁵⁷ where the Federal Circuit focusses on the availability of scientific methods. The case deals with the discovery of the DNA sequences, encoding the human protein erythropoietin (EPO).⁵⁸ The court held that a DNA sequence could not be conceived as an invention until the gene containing the sequence is isolated. By limiting the definition of "conception," the court's reasoning focusses on the *availability* of DNA sequences and procedures. The court treats the scientific process of gene discovery as bearing on the issue of

⁴⁷ Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The "Useful Arts"* Albany Law Journal of Science & Technology 1997 311.

⁴⁸ The US Patent Act 35 USC. For more discussion see Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284. Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 707.

⁴⁹ Refer to chapter 2 sub-section 2.1.1.

⁵⁰ The US Patent Act 35 USC.

⁵¹ For discussion see Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284.

⁵² The US Patent Act 35 USC. For more discussion see Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 745. See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 737.

⁵³ *Hotchkiss v. Greenwood* US 248 (1850).

⁵⁴ *Ibid.*

⁵⁵ *Graham v. John Deere Co* 383 US 1 (1966).

⁵⁶ *Supra* note 51.

⁵⁷ *Amgen Inc. v Chugai Pharmaceutical Co. Ltd.* 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

⁵⁸ Erythropoietin (EPO) is a protein that boosts red blood cell production. Patients with anaemia have a red blood cell deficiency and some respond to treatment with erythropoietin. Through innovative cloning techniques, Amgen scientists isolated and purified the stretch of human DNA that codes for erythropoietin. This isolated DNA code constitutes the patent. See Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 754.

obviousness.⁵⁹ In conclusion, the court decided that “since conception of a DNA invention cannot occur until the actual sequence is discovered, the invention cannot be obvious until the sequence is conceivable”.⁶⁰

Concerning utility, the last requirement, “specific, substantial and credible” utility is required.⁶¹ Apart from this, the statute does not explain this requirement. Courts had to formulate standards on a case by case basis. In 1966 the US Supreme Court laid down the criteria for patent utility in the case of *Brenner v. Manson*⁶² where the court upheld the Patent Board's rejection of a claim for lack of utility.⁶³ The respondent claimed a patent for a synthesised compound. The class of compound that includes his was tested for tumour inhibiting effects and held that “current testing” did not meet the utility requirement. The court stated that in respect of biotechnology inventions, it firstly, did not believe that Congress intended the term “useful” to include “any invention not positively harmful”.⁶⁴ Secondly, that simply being the object of scientific inquiry did not establish utility and thirdly; concern was expressed about the “quid pro quo” of granting a monopoly for a compound with an unknown function.⁶⁵ Generally, courts construe the utility requirement to mandate three separate tests: firstly, courts need to establish whether the invention has any purpose, secondly, courts need to establish whether the invention can be used for its intended purpose and thirdly, courts need to establish whether the intended purpose is beneficial to society.⁶⁶

In 2005 the court addresses the requirement of utility again in the case of *In re Fisher*⁶⁷ the claim is pertinent to purified expressed sequence tags (“ESTs”)⁶⁸ corresponding with fragments of specific genes. The precise structure or function of these genes were unknown.⁶⁹ The court again held that to meet the utility standard, the gene sequence should “correlate to an underlying gene of known function”.⁷⁰

⁵⁹ Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 754.

⁶⁰ Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 755. For more on US cases on the requirement for non-obviousness see *Hybritech, Inc. v Monoclonal Antibodies, Inc.* 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987) and *In re Vaeck* 947 F.2d 488 (Fed. Cir. 1991).

⁶¹ Utility Examination Guidelines Federal Regulations 66 1092 (accessed 05 January 2001). See Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284. See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1057.

⁶² *Brenner v. Manson* 383 U.S. 519 (1966).

⁶³ *Ibid.*

⁶⁴ For more discussion see Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law & Technology Review 2013 434.

⁶⁵ The requirement of utility was also dealt with by the courts in the case of *Nelson v Bowler* 206 USPQ 881 (CCPA 1980) where it was stated that data submitted from “rough screens”, as it were in this case, which were uncorrelated with actual utility and was still found to be patentable because data on “pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use”. See also <http://www.ladas.com/Patents/Biotechnology/Biotechnology.USA.html> (accessed 14 February 2015).

⁶⁶ Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 465.

⁶⁷ *In re Fisher* 421 F3d 1365 (Fed. Cir. 2005).

⁶⁸ An EST is a short nucleotide sequence that represents a fragment of the nucleotide sequence encoding a protein. It is useful for identifying full-length genes and serves as a landmark for mapping. See <http://www.medicinenet.com/script/main/art.asp?articlekey=3328> (accessed 02 July 2015). See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 741.

⁶⁹ *Supra* note 66.

⁷⁰ This is in line with the 1910 case of *Kuehmsted v. Farbenfabriken of Elberfeld Co* that considered whether the purification of an aspirin compound would convey sufficient patentable weight to distinguish it from compound in its impure state as prior art. The purified compound was found patentable. The court stated that “the one is therapeutically available and the others were therapeutically unavailable”. The court also stated that the inventor “produced a medicine indisputably beneficial to mankind

With reference to gene sequences it is insufficient to simply assert that a claimed sequence can be used to detect complementary sequences. Any genetic sequence holds this property. However only certain sequences, for example, have the specific utility of being useful for forensic purposes as they are associated with portions of the genetic code that differ significantly between individuals.⁷¹

In addition to the requirements discussed above, section 101 of the Patent Act and the progress clause⁷² in the Constitution, require an assessment that the invention is not an abstract idea, law of nature, or product of nature. The invention does not only have to meet the requirements of novelty, non-obviousness, and utility, products of nature⁷³ may meet all three of the requirements listed above and yet may not be an “invention” concerning the Act.⁷⁴ Section 101 of the Act also broadly defines patentable subject-matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”.⁷⁵ None of these limitations are explicit in the statutory language of the Act leading to courts questioning several principles.⁷⁶

6.2.3 Progression of US courts towards accepting gene sequences as patentable subject matter

As mentioned in the previous section, abstract ideas, laws of nature, products of nature, or materials isolated from products of nature that behave in the same way they would in nature, is unpatentable.⁷⁷ In 1911, in the case of *Parke-Davis & Co v. HK Mulford Co*⁷⁸ Judge Hand was tasked with distinguishing molecules as they exist in nature from molecules manipulated through processes, such as purification and

something new in a useful art, such as our patent policy was intended to promote”. *Kuehms v. Farbenfabriken of Elberfeld Co* 179 F. 701 (7th Cir. 1910). See Kane EM *Splitting the Gene: DNA Patents and the Genetic Code* Tennessee Law Review 2004 Vol 71 718-738. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 742. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The “Useful Arts”* Albany Law Journal of Science & Technology 1997 Vol 7 314.

⁷¹ The USPTO released the Utility Examination Guidelines in 2001 which explains that isolated and purified DNA are different from naturally occurring genes as it experienced a process whereby the gene and molecules naturally associated with the gene are separated. See Regulation 1094. See Chawla HS *Patenting of Biological Material and Biotechnology* Journal of Intellectual Property Rights 2015 Vol 10 48. See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review 2011 Vol 89 1050.

⁷² Article 1 section 8 clause 8 of the US Constitution.

⁷³ This is articulated in the case of *Funk Brothers Seed Co. v Kalo Inoculant Co* which holds that products of nature cannot be patented, since nothing novel was ever created. See also Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The “Useful Arts”* Albany Law Journal of Science & Technology 1997 313.

⁷⁴ Andrews LB *The “Progress Clause”: An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 545. See also Cannon BC *Toward a Clear Standard of Obviousness for Biotechnology Patents* Cornell Law Review 1994 Vol 79 741. See also Golden JM *Patentable Subject Matter and Institutional Choice* Texas Law Review Vol 89 1041. See also Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 284. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 737.

⁷⁵ US Courts confirmed these by specifically stating that “a scientific truth, or the mathematical expression of it, is not a patentable invention,” and that “patents cannot issue for the discovery of the phenomena of nature”. The court has also stated that “[p]henomena of nature, though just discovered, mental processes and abstract intellectual concepts are not patentable, as they are the basic instruments of scientific and technological work”. See Olsen BV *The Biotechnology Balancing Act: Patents for Gene Fragments and Licensing The “Useful Arts”* Albany Law Journal of Science & Technology 1997 313.

⁷⁶ For further discussion see Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski* Case Western Reserve Journal of Law, Technology & the Internet 2012 26.

⁷⁷ *O'Reilly v Morse* 56 US 62 (1853). See Andrews LB *The “Progress Clause”: An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 540.

⁷⁸ *Parke-Davis v. HK Mulford* 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

isolation. The claim concerned a patent for glandular adrenaline requiring the isolation of adrenaline from the body and subsequent laboratory purification. The purification was “for every practical purpose a new object commercially and therapeutically”.⁷⁹ In *casu*, Judge Hand did not view the claimed chemical composition as merely a purer version of the natural chemical, but as a distinct compound, as the claimed compound did not include a salt, whilst the natural compound existed in a salt form, making the claimed compound distinctly different.⁸⁰

In 1928 the third circuit addressed the issue of isolation and purification in *General Electric Co v. De Forest Radio Co.*⁸¹ The patent claim regarded tungsten and the method of making it for use as filaments of incandescent electric lamps and for other purposes. The patent was granted initially as it was believed that tungsten found in nature was highly brittle and incapable of being turned into wires. The patentee took the natural tungsten and processed it creating a metal with new properties not found in natural tungsten.⁸² It was later found that the tungsten that occurred naturally was in actuality an oxide of tungsten, WO₃ and that the patentee merely managed to separate the tungsten from the oxide form. The court held that if the metal occurs naturally, a patent could not be held over the metal as it then constitutes a discovery, product of nature, or a chemical element. The applicant simply discovered the natural properties of tungsten and did not create anything.⁸³

In 1948 this issue was expanded on in *Funk Bros Seed Co v. Kalo Inoculant Co*⁸⁴ In *casu*, the court had to determine whether a patent for combining naturally occurring strains of bacteria was patent-eligible. The bacterium is a naturally occurring root nodule⁸⁵ bacteria that aid leguminous plants in the fixing of nitrogen from the air which is later converted in the plant for organic nucleic acid compounds.⁸⁶ It is known that there were six such species of these root nodules and that one had to select the strains strongest to produce a culture placed in a liquid or powder and sold to be used to inoculate seeds. It is believed that the varied species in the early mixtures were mutually inhibitive upon another, thereby nullifying the benefit of creating the mixture.⁸⁷ The applicants discovered new strains that did not cause the mutually inhibitive properties present in the earlier generation mixtures. The applicant’s patent claim provided for a novel mixture of root nodule bacteria strains, capable of inoculating multiple types of seeds, a feature that prior mixtures could not accomplish. The court rejected the mixture as patentable, claiming it to be a product of nature.⁸⁸

⁷⁹ *Parke-Davis v. HK Mulford* 189 F. 95, 103 (C.C.S.D.N.Y. 1911). See [http://www.pubpat.org/assets/files/brca/mats/Parke-Davis,%20189%20Fed%2095%20\(1911\).pdf](http://www.pubpat.org/assets/files/brca/mats/Parke-Davis,%20189%20Fed%2095%20(1911).pdf) (accessed 23 September 2017).

⁸⁰ *Ibid.* For case discussion see also Brazil C *You Didn't Build That: The Case against Patentability of Isolated Organisms* University of Kansas Law Review 2015 767.

⁸¹ *General Electric Co v. De Forest Radio Co.* 28 F.2d 641 (3d Cir. 1928).

⁸² *Ibid.*

⁸³ *Supra* note 80. This case is available at <https://law.justia.com/cases/federal/appellate-courts/F2/28/641/1502452/> (accessed 23 September 2017).

⁸⁴ *Funk Bros. Seed Co. v Kalo Inoculant Co.* 333 U.S. 127, 131-32 (1948).

⁸⁵ For more information on root nodules see <https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/root-nodule> (accessed 13 February 2018).

⁸⁶ Brazil C *You Didn't Build That: The Case Against Patentability of Isolated Organisms* University of Kansas Law Review 2015 770.

⁸⁷ *Ibid.*

⁸⁸ Brazil C *You Didn't Build That: The Case Against Patentability of Isolated Organisms* University of Kansas Law Review 2015

The 1980 case of *Diamond v. Chakrabarty*,⁸⁹ discussed in chapter 2, confirmed that the exemption was just as applicable in the modern biotech age.⁹⁰ This was once again reiterated in *Mayo Collaborative Servs v. Prometheus Labs*,⁹¹ *Bilski v. Kappos*⁹² and most recently in *AMP v. USPTO*.⁹³ The *Mayo* and *AMP* cases are discussed in the next section.

6.2.4 Effect of diagnostic gene patents in the US – the BRCA case

In 2009 the court saw the case of *AMP v. USPTO* concerning the BRCA1 and BRCA2 genes which relate to breast cancer.⁹⁴ Breast cancer was first discovered to be hereditary in 1991 and the general location of the gene was mapped by Mary-Claire King's research team in the same year.⁹⁵ Mark Skolnick and his colleagues at Myriad Genetics managed to isolate the location of the BRCA1 gene in 1994.⁹⁶ The team identified mutations within the coding regions of the gene, mostly introducing stop codons within the reading frame.⁹⁷ This results in a non-functional BRCA protein. These proteins are involved in DNA repair and cells containing defective proteins experience damage to double-stranded DNA.⁹⁸ Challenges can arise when the BRCA gene develops mutations that affect its ability to repair DNA efficiently resulting in an increase of the number of mutations throughout the genome and increasing the likelihood of cancer.⁹⁹

The location of the second gene, BRCA2, was discovered at the Institute of Cancer Research in Sutton, Surrey, by a team led by Professor Michael Stratton.¹⁰⁰ The team had been collaborating with Skolnick at

770. See also <https://www.law.cornell.edu/supremecourt/text/333/127> (accessed 23 September 2017).

⁸⁹ *Diamond v. Chakrabarty* 447 U.S. 303, 313 (1980). See chapter two for further details on this case.

⁹⁰ For example Einstein's law of $E=mc^2$ could not be patented; nor can Newton's law of gravity. Such discoveries are "manifestations of... nature, free to all men and reserved exclusively to none." See Andrews LB *The "Progress Clause": An Empirical Analysis Based on the Constitutional Foundation of Patent Law* North Carolina Journal of Law & Technology 2014 Vol 15(4) 541.

⁹¹ *Prometheus Labs. v Mayo Collab. Servs.*, 581 F.3d 1336, 1340 (Fed. Cir. 2009) and *Mayo Collaborative Servs. v Prometheus Labs* 132 S. Ct. 1289, 1305 (2012). See Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski* Case Western Reserve Journal of Law, Technology & the Internet 2012 24.

⁹² *Bilski v Kappos* 561 U.S. 593 (2010).

⁹³ *Association for Molecular Pathology v Myriad Genetics, Inc.*, 569 U.S. 576 (2013). Section 6.2.4 discusses this case in detail.

⁹⁴ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) see https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017).

⁹⁵ For more discussion see Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

⁹⁶ This gene is located on chromosome 17. For discussion on the BRCA case Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 930. See also Jervis HH *Seduced by the Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics, Inc.* Florida Coastal Law Review 2014 69. See also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

⁹⁷ Stop codons are sequences of DNA and RNA that are needed to stop translation or the making of proteins by stringing amino acids together. For further explanation see <https://www.news-medical.net/life-sciences/START-and-STOP-Codons.aspx> (accessed 19 December 2018).

⁹⁸ For discussion see Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 931. See also Oliver AM *Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research* Southern Methodist University Law Review 2015 537.

⁹⁹ Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics, Inc.* Florida Coastal Law Review 2014 69.

¹⁰⁰ This gene is located on chromosome 13.

the University of Utah. Skolnick located the gene and applied for a patent on it.¹⁰¹ The claim includes a “composition of matter” patent on the gene and a “method-of-use” patent for applying BRCA1 and BRCA2 in diagnostic and therapeutics.¹⁰² Myriad then produced a breast cancer test for hereditary breast cancer and ovarian cancer, based on the DNA sequences of BRCA1 and BRCA2. The test detects deleterious mutations and is marketed as BRCAanalysis. The latter is the yardstick for genetic testing as each base pair in the coding region is checked and deleterious mutations identified. The test detects missense mutations and most frame shift or nonsense mutations^{103, 104} Each test costs more than \$3,000.¹⁰⁵

The first BRCA1 patent is a use patent granted and asserts rights over the diagnostic use of the BRCA1 gene.¹⁰⁶ The second BRCA1 patent is a product patent and asserts the rights over the isolated BRCA1 gene and a handful of mutations found to be causative for familial breast and ovarian cancer whilst the third BRCA 1 patent is a product patent covering an additional set of mutations that is related to breast and ovarian cancer and their use in a method for diagnosing a predisposition to it.¹⁰⁷ The first BRCA2 patent is a product patent on the most frequent allelic variant of the BRCA2 gene. It identifies several disease mutations in the BRCA2 gene and the method for determining variation of the nucleotide sequence of a suspected mutant BRCA2 allele linked with predisposition to breast cancer in reference to this most frequent allelic variant of the BRCA2 gene.¹⁰⁸ The second BRCA2 patent asserts the rights over the gene in all its allelic variants through a product-by-process claim.¹⁰⁹

Myriad holds patents in several countries over both the BRCA1 and BRCA2 genes.¹¹⁰ The company currently has a monopoly over breast cancer testing. The Myriad business model is to license the test exclusively to a few commercial genetic laboratories in specific areas, creating a diagnostic monopoly on breast cancer testing.¹¹¹ Their patent blocks complete gene testing for a heterogeneous disease.¹¹² An

¹⁰¹ For discussion see Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 931. See also Oliver AM *Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research* Southern Methodist University Law Review 2015 537.

¹⁰² *Ibid.*

¹⁰³ For more explanation on these mutations see <https://ghr.nlm.nih.gov/primer/mutationsanddisorders/possiblemutations> (accessed 19 December 2018).

¹⁰⁴ For discussion see Williams - Jones B *History of the Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 133.

¹⁰⁵ Morrison AJ *Rethinking the Gene Patent* Biotechnology Law Report 2010 Vol 29(6) 609.

¹⁰⁶ The main claim of the patent reads as follows: “A method for diagnosing a predisposition for breast and ovarian cancer in human subject which comprises determining in a tissue sample of said subject whether there is a germline alteration in the sequence of the BRCA1 gene coding for a BRCA1 polypeptide having the amino acid sequence set forth in sequence ID no 2 or a sequence with at least 95% identity to that sequence, said alteration being indicative of a predisposition to said cancer”. See Matthijs G *The European Opposition Against the BRCA Gene Patents* Springer Familial Cancer 2006 5 95–102.

¹⁰⁷ The claim reads as follows: isolated nucleic acid which comprises a coding sequence for the BRCA1 polypeptide defined by the amino acid sequence in sequence ID no 2, or an amino acid sequence with at least 95% identity to the amino acid sequence of sequence ID. no 2. For more information see Matthijs G *The European Opposition Against the BRCA Gene Patents* Springer Familial Cancer 2006 5 95–102.

¹⁰⁸ Matthijs G *The European Opposition Against the BRCA Gene Patents* Springer Familial Cancer 2006 5 95–102.

¹⁰⁹ *Ibid.*

¹¹⁰ Walpole IR, Dawkins HJS, Sinden PD *et al Human Gene Patents: The Possible Impacts on Genetic Services Health care* 2007 203–205. See also Oliver AM *Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research* Southern Methodist University Law Review 2015 537.

¹¹¹ Walpole IR, Dawkins HJS, Sinden PD *et al Human Gene Patents: The Possible Impacts on Genetic Services Health care* 2007 203–205. See also Oliver AM *Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research* Southern Methodist University Law Review 2015 537.

¹¹² Breast cancer is a heterogeneous disease. For more discussion see Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 127.

exclusive licence to one or a few common genes or mutations drives testing to one provider, regardless of whether licenced patents cover all varieties of this disease.¹¹³

In the years after the first BRCA patent was issued, Myriad established a history of anticompetitive, exclusive behaviour, refusing to grant research licences and enforcing their patents ensuring the exclusivity of their BRCA gene diagnostic tests. The patent restricts equitable access to health care in the following ways:¹¹⁴

- Limiting access to testing by limiting it to certain commercial laboratories;
- The licence terms are projected to result in a two to threefold increase in genetic testing costs, making it unaffordable to the majority of the public;
- Performing all full-sequence testing at one overseas commercial laboratory bypasses national jurisdiction and procedures for ensuring quality control and peer review; and
- The licence terms disregard the development and use of any other technologies for testing for BRCA mutations which currently may not be identified by the patented technology.¹¹⁵

Initially, a lawsuit was filed in May 2009 with the US District Court of Southern New York.¹¹⁶ The plaintiffs¹¹⁷ claim that Myriad patents¹¹⁸ violate the Patent Act 35 of the United States Code (USC) 101 and is unconstitutional because the subject matter is not patentable.¹¹⁹ The practice of the USPTO of granting 'composition of matter claims' on genes if they were "isolated" from surrounding cellular material was also challenged as 'isolating' the gene does not change its function or informational value. Method claims on the act of analysing a claimed DNA sequence, or of comparing a DNA sequence to one claimed by a Myriad patent was also challenged. The plaintiffs argue that without specifying a method of analysis, the patent is on an abstract thought process that only amounts to scientific inquiry and cannot be patentable.¹²⁰

¹¹³ Cook-Deegan R, Chandrasekharan S & Angrist M *The Dangers of Diagnostic Monopolies* Nature 2009 Vol 458(7237) 405. See also Rai AK *Intellectual property and Biotechnology* 2011 547. See also Baltatzis A & Martin S *Recent Pharmaceutical Decisions in the United States* Journal of Intellectual Property Rights 2014 Vol 19 18-26.

¹¹⁴ *Ibid.*

¹¹⁵ Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 917.

¹¹⁶ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Graff GD, Phillips D, Lei Z et al *Not a Myriad of Gene Patents* Nature Biotechnology 2013 Vol 31(5) 404. See also Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 132.

¹¹⁷ The Plaintiffs include medical professional societies, geneticists, cancer patients and health-related advocacy groups. The cancer patients include six women, between the ages of thirty-two and fifty-two, who were adversely affected by Myriad's exclusive right to provide BRCA1/2 diagnostic testing as they were denied access to information about their own predisposition to aggressive cancers because the BRCA gene patent claims excluded other clinicians from performing additional tests or the same tests at lower cost. See Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8 (15) <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015).

¹¹⁸ Claims related to 7 of Myriad's patents: USPTO no. 5,747,282; 5,693,473; 5,709,999; 5,710,001; 5,753,441; 5,837,392; 6,033,857.

¹¹⁹ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017).

¹²⁰ *Ibid.* See also Cho M *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics* Trends in Biotechnology 2010 Vol 28(11) 548. See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Brazil C *You Didn't Build That: The Case Against Patentability of Isolated Organisms* University of Kansas Law Review 2015 773.

The plaintiffs also argue that the patents violate article 1, section 8 of the Constitution,¹²¹ as the patents impede rather than promoted “the progress of science and the useful arts” by inhibiting research and clinical practice.¹²² They claim that gene patenting discourages related research and prevents other companies from providing diagnostic tests for these genes. Subsequently, patients who are provided a certain result are unable to legally find a different test providing them with a better answer.¹²³

The defendants¹²⁴ in the matter claim that the patent protection is crucial to drive investment in areas such as biopharmaceutical innovation. It allows investors to recover the cost of research and provides them with an incentive to pursue new research.¹²⁵ They argue that invalidating the Myriad patents would be the same as overruling the famous *Chakraborty* case¹²⁶ and several other patents granted by the USPTO.¹²⁷ In addition they argue that DNA is chemical in nature rather than informational and that isolated DNA is in a form that does not exist in nature and as such, is patentable. They cite the research of over 18 000 scientists on BRCA genes and the clinical testing of over 400 000 patients as evidence that research and clinical practice had not been impeded.¹²⁸

In *casu*, Judge Lourie characterised three types of DNA: native DNA,¹²⁹ isolated DNA,¹³⁰ and cDNA^{131, 132}. It was held that cDNA constitutes patentable subject-matter as it requires extensive human intervention and modification. The court then compared genomic isolated DNA to its native counterpart from a chemical perspective and not an informational content perspective.¹³³ Native DNA contains constitutes fragments of exorbitantly large strands of DNA but isolated DNA such as the BRCA and BRCA 2 strands each are

¹²¹ See section 6.2.2 for discussion on this clause.

¹²² *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Cho M *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics* Trends in Biotechnology 2010 Vol 28(11) 548.

¹²³ For case discussion see <http://www.globalization101.org/landmark-gene-patenting-ruling/> (accessed 06 August 2015).

¹²⁴ The USPTO, Myriad Genetics and officials of the University of Utah Research Foundation.

¹²⁵ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 918. See also Salzberg SL *The Perils of Gene Patents* Clinical Pharmacology & Therapeutics 2012 Vol 91(6) 911.

¹²⁶ *Diamond v Chakrabarty* (1980) In 447 US.

¹²⁷ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See Also Cho M *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics* 2010 Trends in Biotechnology Vol 28(11) 548.

¹²⁸ *Ibid.*

¹²⁹ This is DNA as it is found in nature. Natural DNA contains both coding exon and non-coding intron regions.

¹³⁰ This is isolated DNA with histones removed. For more information on histones see <https://www.nature.com/scitable/definition/histone-histones-57> (accessed 08 March 2018).

¹³¹ This is a form of synthetic DNA and is made in a laboratory. This type of DNA only contains protein coding regions.

¹³² *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Bowman A *Genes 101: Are Human Genes Patentable Subject Matter?* Richmond Journal of Law & Technology 2008 Vol 8(15) see <http://jolt.richmond.edu/v18i4/article15.pdf> (accessed 19 June 2015). See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 731.

¹³³ *Ibid.*

only respectively about 7,000 and 11,000 base pairs long. The court states that this chemical structural difference makes isolated DNA decidedly different from that of native DNA.¹³⁴

The court considered the *Prometheus* decision¹³⁵ where the plaintiffs challenge the validity of defendant's patent claims that consist of a method by which autoimmune diseases can be treated using *thiopurine* drugs.¹³⁶ The claim in issue states that a physician could improve treatment by taking the following steps:

- Administering a small amount of 6-thioguanine;
- Monitoring the extent to which a patient's body metabolises the drug; and
- Giving either more or less of the drug in a subsequent dose to keep the amount of the drug in the patient's blood stream below a toxicity level and above a minimum efficacy level.¹³⁷

The court found that the relationship between concentrations of specific metabolites in the blood and the view that a thiopurine drug dosage will not be useful or may even cause harm, are not patentable as laws of nature. They can only be patentable if they have additional features that provide practical promise that the processes are applications of those laws as opposed to drafting efforts intended to monopolise the correlations.¹³⁸ The "determining step" did not limit the doctors in any way, because they could "determine the level of the relevant metabolites... through whatever process" they chose to use.¹³⁹ When considering all the claim elements together, the three steps in combination added "nothing to the laws of nature that is not already present when the steps are considered separately" and that the steps are routine steps that the scientific community already understand and use.¹⁴⁰

The court in *Myriad* held that in the *Prometheus* decision the court was silent on claims relating to genes as compositions of matter, dealing instead with method claims in applying drugs, the consequence of which is that the holder of a patent on an isolated gene has the right to exclude "anyone from working with" the claimed isolated gene.¹⁴¹ The lower court focusses on the chemical rather than the informational nature of DNA. Justice Lourie, held that breaking the covalent bonds to isolate a gene from the rest of the

¹³⁴ *Association for Molecular Pathology v US Patent & Trademark Office* 669 F.Supp.2d 365 (2009) See https://scholar.google.co.uk/scholar_case?case=2593898733653316804&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Cho M *Patently Unpatentable: Implications of the Myriad Court Decision on Genetic Diagnostics* 2010 Trends in Biotechnology Vol 28(11) 548.

¹³⁵ *Prometheus Labs Inc. v Mayo Collab. Servs* 132 S. Ct. at 1294-95, *Prometheus Labs Inc. v Mayo Collab. Servs.* 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted sub nom.* See also Graff GD, Phillips D, Lei Z et al *Not a Myriad of Gene Patents* Nature Biotechnology 2013 Vol 31(5) 404. See also Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 909.

¹³⁶ For more discussion see Lauzon ED *Patentability of Diagnostic Methods Concerning Human Genes, Cells, Blood and DNA* American Law Reports 2014 Vol 90 235.

¹³⁷ For more discussion see Baltatzis A & Martin S *Recent Pharmaceutical Decisions in the United States* Journal of Intellectual Property Rights 2014 Vol 19 18-26.

¹³⁸ *Supra* note 135.

¹³⁹ For case discussion see Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law & Technology Review 2013 434.

¹⁴⁰ *Ibid.* See also *Prometheus Labs v Mayo Collab Servs* 581 F.3d 1336, 1340 (Fed. Cir. 2009). See also Liddicoat J, Whitton T & Nicol D *Are the Gene-Patent Storm Clouds Dissipating? A Global Snapshot* Nature Biotechnology 2015 Vol 33(4).

¹⁴¹ For case discussion see Grosheide W *Intellectual Property and Human Rights. A Paradox* (2010)15. See also Lauzon ED *Patentability of Diagnostic Methods Concerning Human Genes, Cells, Blood and DNA* American Law Reports 2014 90 235.

DNA molecule is enough to constitute an invention with markedly different characteristics from those that occur in nature.¹⁴² The court held the patent to be valid.¹⁴³

In March 2010, on appeal, Judge Sweet ruled in favour of the applicants, invalidating the claims BRCA1 and BRCA2.¹⁴⁴ Claims to diagnostic methods using DNA samples for BRCA1 and 2 mutations were also invalidated.¹⁴⁵ The court's reasoning is that purifying native DNA did not alter its fundamental characteristics essential to both the gene's biological function in a cell and the gene's utility outside of the body.¹⁴⁶ This time the court focusses on the informational nature of genes which indicate that breaking the covalent chemical bonds is not enough to constitute an invention as the gene provides the same information before and after the covalent bonds are broken.¹⁴⁷

In February of 2012, after the *Prometheus* case,¹⁴⁸ the US Supreme Court remanded the *Myriad* issue and sent it to the federal court for reconsideration.¹⁴⁹ Justice Thomas began by framing the patent law issue in question: "This case requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent-eligible under section 101 of the US 35 USC § 101 by its isolation from the rest of the human genome".¹⁵⁰ The Court observed whether cDNA was patent-eligible. The claims relate to isolated DNA molecules encoding either the BRCA1 or BRCA2 proteins or to alleles thereof, or to fragments of any of those DNA molecules.¹⁵¹ The Federal Circuit's 2012 decision in *Myriad Genetics*

¹⁴²For case discussion see Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study No.08 2014 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015).

¹⁴³ *Association for Molecular Pathology v US Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017).

¹⁴⁴ *Association for Molecular Pathology v US Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). For more discussion on the case see Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski Case* Western Reserve Journal of Law, Technology & the Internet 2012 Vol 3(1) 1-65. See also Scola A *Uncommon Genes, Unpatentable Subject Matter* Seattle University Law Review 2011 Vol 34 909. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 749.

¹⁴⁵ *Ibid.*

¹⁴⁶ Lauzon ED *Patentability of Diagnostic Methods Concerning Human Genes, Cells, Blood and DNA* American Law Reports 2014 Vol 90 235. See also Schilling SH *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents* Duke Law Journal 2011 Vol 61 749. See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre For Law And Genetics Occasional study No.08 2014 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Robertson AS *The Role of DNA Patents in Genetic Test Innovation and Access - BIO* Northwestern Journal of Technology and Intellectual Property 2011 Vol 9(7) 278.

¹⁴⁷ *Association for Molecular Pathology v US Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Nicol D, Nielsen J, Liddicoat J et al *The Innovation Pool in Biotechnology: The Role of Patents in Facilitating Innovation* Centre for Law and Genetics Occasional study No.08 2014 available at <http://ssrn.com/abstract=2503314> (accessed 26 June 2015). See also Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: A Comparison Under Current European and US patent law* European Journal of Human Genetics 2011 19 1104–1107.

¹⁴⁸ *Prometheus Labs v Mayo Collab Servs* 581 F.3d 1336, 1340 (Fed. Cir. 2009).

¹⁴⁹ The court also considered the *Bilski* case involving a risk hedging method. *Bilski v Kappos* 561 U.S. 593 (2010). See <https://supreme.justia.com/cases/federal/us/561/593/> (accessed 24 September 2017). The case is discussed further in Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods after In re Bilski Case* Western Reserve Journal of Law, Technology & the Internet 2012 Vol 3(1) 24. *Association for Molecular Pathology v. Myriad Genetics Inc.* 133 S. Ct. 2107 (2015).

¹⁵⁰ For case discussion see Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics Inc.* Florida Coastal Law Review 2014 65.

¹⁵¹ Claims 1, 2, 5, 6 and 7 of the US Patent 5,747,282 (the "282 Patent"). See Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Pathology v. Myriad Genetics, Inc.* Florida Coastal Law Review 2014 65.

consists of three separate opinions. Judge Lourie, in his majority opinion, concludes that all product/composition claims in issue constitute patentable subject-matter; he believes all the isolated DNA segments were substantially different from the DNA found in humans and were “man-made”.¹⁵² Judge Moore and Judge Bryson agree with this, but Judge Moore does not agree that the longer strands of isolated DNA in claim 1 function differently than the native DNA,¹⁵³ but agrees that the smaller, isolated DNA segments did have markedly different characteristics and functions than those of native DNA.¹⁵⁴ Judge Bryson dissents stating: “from the courts holding that Myriad's BRCA gene claims and its claims to gene fragments [were] patent-eligible”.¹⁵⁵ He also argues that the isolated DNA segments of claim 1 are not substantially different in characteristics and utility than those of the DNA found in nature.¹⁵⁶ The judges divide on various aspects including the pre-emptive effect of the claim, chemical composition of the subject-matter and the concept of invention.¹⁵⁷

In August of the same year the Federal Circuit rejected the Myriad patents' claims to methods of comparing gene sequences from patients against the sequences of its isolated molecules.¹⁵⁸ In response to the question relating to claims on isolated DNA molecules as compositions of matter, the Federal Circuit reaffirms its earlier decision that, to the extent that they are new and “markedly different” in characteristics from what exists in nature in chromosomal form, they are eligible subject-matter.¹⁵⁹ It was held by the panel that the method claims relating to “comparing” or “analysing” gene sequences do not fall within the scope of section 101 as only abstract mental processes are claimed. There is inconsistency within the panel as to whether segments of the isolated DNA were from chromosomes, but were otherwise unaltered, remaining unpatentable as they are products of nature.¹⁶⁰

¹⁵² *Association for Molecular Pathology v. Myriad Genetics Inc.* 133 S. Ct. 2107 (2013) 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) see https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law & Technology Review 2013 434.

¹⁵³ The first claim refers to a specific BRCA1 polypeptide amino acid sequence, which contemplates every DNA molecule that is capable of encoding the designated amino acid sequence. This was an attempt to provide breadth to the claim by increasing the number of molecules that the claim encompassed rather than limiting the invention to a single molecule with the specific DNA sequence. *Association for Molecular Pathology v U.S. Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). For more discussion see Jervis HH *Seduced by the Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics Inc.* Florida Coastal Law Review 2014 65.

¹⁵⁴ Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law Review 2013 434.

¹⁵⁵ *Ibid.*

¹⁵⁶ *Association for Molecular Pathology v U.S. Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law Review 2013 434.

¹⁵⁷ *Ibid* at 475 – 486.

¹⁵⁸ Graff GD, Phillips D, Lei Z et al *Not a Myriad of Gene Patents* Nature Biotechnology 2013 Vol 31(5) 404.

¹⁵⁹ *Ibid.* *Association for Molecular Pathology v U.S. Patent & Trademark Office* 702 F. Supp. 2d 181 (S.D.N.Y.) (2010) See https://scholar.google.co.uk/scholar_case?case=14116333141117279245&q=association+for+molecular+pathology+v.+uspto&hl=en&as_sdt=2006&as_vis=1 (accessed 24 September 2017). See also Brazil C *You Didn't Build That: The Case Against Patentability of Isolated Organisms* University of Kansas Law Review 2015 773.

¹⁶⁰ This is discussed in detail in Eisenberg RS *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski* Case Western Reserve Journal of Law, Technology & the Internet 2012 Vol 3(1) 53.

Another petition for *certiorari* was filed by the plaintiff and in November of 2012 and the Supreme Court agreed once again to hear the *Myriad* case.¹⁶¹ In 2013 US Supreme Court provides a final decision on the *AMP v. USPTO* case.¹⁶² The Court rules that human genes cannot be patented, reversing the decision of the court *a quo*.¹⁶³ It was held that the separation of the gene from its surrounding genetic material does not amount to an act of invention. According to the Court, Myriad's patent claim "fell squarely within the law of nature exception".

The 2013 decision contrasts more than 30 years of US patent cases and has global implications.¹⁶⁴ Naturally occurring genes isolated are now no longer patentable in the US, whilst synthetic ones can be patented. The Court stresses that "creation of a cDNA sequence ... results in an exons-only molecule that is not naturally occurring" and as such "cDNA is not a product of nature and is patent-eligible".¹⁶⁵ The Supreme Court held that section 101 is not unlimited concerning the patent eligibility of naturally occurring things and the court indicates that patent protection strikes a gentle balance between creating "incentives that lead to creation, invention and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention".¹⁶⁶ The court applies this standard in determining whether Myriad's patents claim a "new and useful.....composition of matter".¹⁶⁷

The court discusses the differences between naturally occurring chromosomes, genomic DNA encompassing the BRCA1 and 2 genes and the exon-only cDNAs. The court held that isolated BRCA1 and BRCA2 genes differ from DNA as it is found in the body.¹⁶⁸ The Court proclaims that synthesising a portion of the native chromosomal DNA sufficed as human intervention and provided the product isolated DNA with a chemical identity that is distinctive from that which it possessed as native DNA.¹⁶⁹

The decision represents a major challenge to the way the USPTO grants patents on genes as several patents on genes were granted based on the assumption that DNA is a chemical entity with purification renders that transform it into a patentable object.¹⁷⁰ The decision received criticism comprising claims that

¹⁶¹ Graff GD, Phillips D, Lei Z et al *Not a Myriad of Gene Patents* Nature Biotechnology 2013 Vol 31(5) 404.

¹⁶² *Association for Molecular Pathology v U.S. Patent & Trademark Office* 702 F.Supp.2d 181.

¹⁶³ This was a unanimous 9-0 decision.

¹⁶⁴ *Association for Molecular Pathology v Myriad Genetics Inc.* 569 U.S. 576 (2013). See https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf (accessed 24 September 2017). See also <http://www.globalization101.org/landmark-gene-patenting-ruling/> (accessed 06 August 2015).

¹⁶⁵ *Association for Molecular Pathology v Myriad Genetics Inc.* 569 U.S. 576 (2013). See https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf (accessed 24 September 2017). For case discussion see also Stern R *Association for Molecular Pathology v Myriad Genetics: sieving the gene pool* European Intellectual Property Review 2013 Vol 35 (11) 685-690.

¹⁶⁶ *Supra* note 163. "[w]hoever 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 therefor, subject to the conditions and requirements of this title." 35 USC section 101.

¹⁶⁷ Haag T & Kilger C *Myriad Ruling v Biotech Patent Eligibility in Europe* available at <http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (accessed 18 September 2015).

¹⁶⁸ *Association for Molecular Pathology v Myriad Genetics Inc.* 569 U.S. 576 (2013). See https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf (accessed 24 September 2017). See also Stern R *Association for Molecular Pathology v Myriad Genetics: Sieving the Gene Pool* European Intellectual Property Review 2013 Vol 35 (11) 685-690.

¹⁶⁹ *Supra* note 166.

¹⁷⁰ Haag T & Kilger C *Myriad Ruling v Biotech Patent Eligibility in Europe* available at <http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (accessed 18 September 2015).

DNA by virtue of its isolated form, forms a vital part in medicine as a diagnostic instrument.¹⁷¹ It was also criticised as no precedent was followed.¹⁷² With the court's focus in *Myriad* is on the chemical nature of DNA, it fails to acknowledge the unique characteristics of DNA that differentiates it from other chemical compounds.¹⁷³

6.2.5 Trade agreements

Over 25 per cent of US exports in the 1980s contain a high intellectual property component compared to a mere 10 per cent in the post war period.¹⁷⁴ This increase in intellectual property exports brought opportunities for global trade in knowledge-based goods, but also increased opportunities for imitation, copying and unauthorised use of technologies. Pharmaceutical companies now face threats from cheaper generic versions of medicines in countries that have manufacturing capabilities.¹⁷⁵

In 1988 the Process Patents Amendment Act provided that buyers importing any products into the US domestic market made in violation of US intellectual property laws would be liable to civil suits. Also, in 1988, the Omnibus Trade and Competitiveness Act introduced further changes. The partial amendment to section 337 allows for the complete exclusion from the US of any import manufactured in a way that has violated an intellectual property right held by US legal subjects.¹⁷⁶ The provisions of section 301 of the Act allows the government to apply pressure on countries for violations of intellectual property rights protected under domestic US laws by using trade sanctions.¹⁷⁷ In line with the provisions of 301, the US Trade Regulatory conducts annual reviews of the intellectual property practices of all US trading partners to identify countries failing to provide adequate and effective intellectual property protection.¹⁷⁸ Countries that the US deem to have most onerous policies with the greatest adverse impact on US intellectual property right holders or products, are placed on the priority watch list.¹⁷⁹

¹⁷¹ Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law Review 2013 508. See also Stern R *Association for Molecular Pathology v Myriad Genetics: Sieving the Gene Pool* European Intellectual Property Review 2013 Vol 35(11) 685-690. See also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 25(1) 20-33. See also Kurts A *Consequences of the US Supreme Court decision on gene patenting* European Intellectual Property Review 2013 629-639. See also Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics, Inc.* Florida Coastal Law Review 2014 114.

¹⁷² Even with the latter being parallel to the *Merck* case which was found to be consistent with the principle set forth in *Funk Brothers* case.

¹⁷³ Rogers DL *After Prometheus, Are Human Genes Patentable Subject Matter?* Health and Biotechnology Patent and Technology Duke Law Review 2013 508. See also Stern R *Association for Molecular Pathology v Myriad Genetics: sieving the gene pool* European Intellectual Property Review 2013 Vol 35(11) 685-690. Jervis HH *Seduced by The Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics, Inc.* Florida Coastal Law Review Fall 2014 94.

¹⁷⁴ Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 46.

¹⁷⁵ *Ibid.*

¹⁷⁶ Section 337 of the Omnibus Trade and Competitiveness Act of 1988. See also *supra* note 173 at 49.

¹⁷⁷ *Supra* note 173 at 49.

¹⁷⁸ *Supra* note 173 at 46.

¹⁷⁹ Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 46.

Once the TRIPS Agreement came into force allowing less developed countries time to adapt their domestic law to be in line with the minimum standard that it sets out, the US undertook its own measures to ensure that its trade partners adopt stricter laws relating to intellectual property.¹⁸⁰ After the signing of the TRIPS Agreement, the US entered into FTA's with several countries.¹⁸¹

These bilateral FTAs were entered with unprecedented vigour with around 25 developing countries signing FTAs with the US. The US has called its approach "competitive liberalisation".¹⁸² These agreements are entered into with several countries sufficiently developed to produce generic drugs locally but that do not have enough bargaining power to counter bilateral pressure. The threat of trade sanctions and a lack of access to American markets convince them to sign the TRIPS plus agreements.¹⁸³ FTAs negotiated between the US and its trade partners are constructed based on the provisions of the North American Free Trade Agreement (NAFTA).¹⁸⁴ NAFTA constitutes the basic rules exemplified in US intellectual property and trade laws.¹⁸⁵ NAFTA was initiated in 1994 and focusses on expanding opportunities for new investments, acquiring property and opening services to competition by private corporations in the US, Canada and Mexico.¹⁸⁶ The objective of these agreements, based on NAFTA, is to "reduce distortions in trade in the American hemisphere and promote and ensure adequate and effective protection to intellectual property rights. In this negotiating process, changes in technology were considered".¹⁸⁷ The initiative of the US Trade Representative (USTR) mandated by the US Trade Act of 2000, sets out the principle negotiating objects to promote sufficient protection of intellectual property rights through, negotiating bilateral trade agreements.¹⁸⁸

As mentioned in section 4.5, TRIPS Plus agreements use several ways to strengthen intellectual property rights of the inventor. These include amongst others, the extension of the scope of patentability achieved by requiring patents for new uses of known products, extension of the patent term, mandating patent

¹⁸⁰ TRIPS came into force in 1994. For a full discussion on the relevant TRIPS provisions, see section 4.3.

¹⁸¹ These include Jamaica, Lithuania, Latvia, Trinidad and Tobago, Cambodia, Laos, Nicaragua and Vietnam. After 2002 trade agreements were also signed with Singapore (Singapore-US FTA, signed 6 May 2003), Chile (Chile-US FTA, signed 6 June 2003), Central American countries, the Dominican Republic, Australia (Australia-US Free-Trade Agreement (AUSFTA), signed 18 May 2004, Morocco (Morocco-US FTA, signed 15 June 2004), Bahrain (Bahrain-US FTA, signed 14 September 2004), Oman (Oman-US FTA, signed 19 January 2006), Peru (Peru-US Trade Promotion Agreement, signed 14 December 2007), Colombia (Columbia-US FTA, signed 22 November 2006), Panama (Panama-US Trade Promotion Agreement, signed 28 June 2007) and Korea (Korea-US FTA (KOR), signed 30 June 2007).

¹⁸² *Signing Away the Future: How Trade and Investment Agreements Between Rich and Poor Countries Undermine Development* Oxfam Briefing study 2007.

¹⁸³ For more discussion on this see Morin JF *Multilateralizing TRIPS-Plus Agreements: Is the US Strategy a Failure?* The Journal of World Intellectual Property 2009 Vol 12(3) 175. See also Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 399. See also Nasu H *Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement* ANU College of Law Research study No 10-53 available at <http://ssrn.com/AuthorID=677218> (accessed 02 June 2015).

¹⁸⁴ For more on the NAFTA see <http://www.fas.usda.gov/itp/agreements.asp> (accessed 01 October 2015).

¹⁸⁵ *Ibid.* See also Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability: A Case Study of the Pharmaceutical Industry in Thailand* 2006 9.

¹⁸⁶ Ellen R, Shaffer ER, Waitzkin H et al *Global Trade and Public Health Ethics in Public Health Research* American Journal of Public Health 2005 Vol 95(1) 27.

¹⁸⁷ Vivas-Eugui D *Regional and Bilateral Agreements and a TRIPS-Plus World: the Free Trade Area of the Americas (FTAA)* Canadian International Development Agency (CIDA) 2003 3.

¹⁸⁸ Nasu H *Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement* ANU College of Law Research study No 10-53 <http://ssrn.com/AuthorID=677218> accessed 02 June 2015).

protection for life forms, excluding exemptions on plants and animals from patentability.¹⁸⁹ In summary, they remove flexibilities offered by TRIPS by taking advantage of the unclear language used in TRIPS. For example, Article 27(1) of TRIPS allows for patents for products or processes in the field of technology; it is flexible determining whether a new use of a known product is patentable.¹⁹⁰ Bilateral agreements also contain provisions, particularly in medicines, containing limitations on introducing competition from generic producers.¹⁹¹ In accordance with TRIPS,¹⁹² government's issuance of compulsory licences is limited to situations of emergency, antitrust remedies and non-commercial use.¹⁹³

Despite this, three US FTAs restrict the grounds upon which a compulsory licence can be granted. The first is the FTA signed with Jordan, specifying a restrictive list of legitimate grounds¹⁹⁴ FTAs signed with Singapore and Australia also prohibit using compulsory licences based on failure to meet working requirements. These agreements also state that if a party uses a compulsory licence in the case of a national emergency, the party "may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention authorised for use".¹⁹⁵ Table 4 provides a brief summary patent related provision in US TRIPS Plus agreements.

Table 4: Brief summary patent related provision in US TRIPS plus agreements

<u>Provisions</u>	<u>Australia-US (AUSFTA)</u>	<u>Vietnam - US</u>	<u>Jordan – US</u>	<u>Singapore-US</u>	<u>Chile - US</u>	<u>Morocco-US</u>	<u>Thailand-US (TUSFTA)</u>
<u>Exclusions</u>	Moral, health and safety exclusions only	Particular plants and animals may be exempt from exclusion	No general exclusion of plants and animals from patentability	No general exclusion of plants and animals from patentability	No provision relating to exclusion	Reasonable efforts to provide for plant patentability	Exclusion on new use or ways of using an already known product patents
<u>Compulsory licences</u>	Limited to national	Limited to national	Limited to national	Limited to national			Limited to national

¹⁸⁹ For more see Correa CM *Implications of Bilateral Free Trade Agreements on Access to Medicines* World Health Organisation Bulletin 2006 401. See also Fink C & Reichenmiller P "Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements" (editor) Newfarmer R Trade, Doha and Development A Window into the Issues The World Bank 2006 292.

¹⁹⁰ FTAs concluded by the US with Australia, Morocco and Bahrain excluded such flexibility. The latter two FTAs also go a step further and specifies that treatment of humans and animals are included under the provisions of patentability of new uses of known products. Morin JF *Tripping up TRIPS Debates IP and Health in Bilateral Agreements* International Journal of Intellectual Property Management 2006 Vol 1(1/2) 41.

¹⁹¹ Fink C & Reichenmiller P "Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements" (editor) Newfarmer R Trade, Doha and Development A Window into the Issues The World Bank 2006 292.

¹⁹² Article 31 of the TRIPS Agreement.

¹⁹³ Specifically, the agreements with Australia, Jordan, Singapore and Vietnam.

¹⁹⁴ The trade agreement states that "neither party will permit using the subject matter of a patent without the authorisation of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirement, provided that importation will constitute working". See Morin JF *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements* International Journal of Intellectual Property Management 2006 Vol 1(1/2) 47.

¹⁹⁵ See Morin JF *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements* International Intellectual Property Management 2006 Vol 1(1/2) 47.

	emergencies and antitrust remedy, & for public non-commercial use	emergencies, antitrust remedy & non-commercial use	emergencies, antitrust remedy & non-commercial use	emergencies and antitrust remedy, & for public non-commercial use	TRIPS standards apply	TRIPS standards apply	emergencies and antitrust remedy, & for public non-commercial use
<u>Parallel importing</u>	Limitation of parallel imports of pharmaceutical products through licensing contracts	No specific provision	Standards of TRIPS apply	Limitation of parallel imports of pharmaceutical products through licensing contracts	Standards of TRIPS apply	No specific provision	No specific provision

In 1997, states facing serious health issues, in the form of accessing medicines, decided to take a stand against the US by utilizing TRIPS flexibilities despite a TRIPS Plus agreements being in place. The US threatened to enforce sanctions on Thai exports if Thailand did not drop its plan to use compulsory licensing provisions. In 1998, 40 pharmaceutical manufacturers sued the South African's government in relation to a law on compulsory licensing¹⁹⁶ and in 2000; the US filed a claim under the WTO dispute settlement mechanism against Brazil for its use of compulsory licences.¹⁹⁷

The aims of FTA negotiations may suit developed nations, but it does not suit the requirements of developing nations. These agreements generate substantial economic and social costs for developing countries; but FTA's are observed as a way of accessing developed markets and are therefore willingly entered into, fully aware of the negative effects.¹⁹⁸ Several governments believe that FTAs are beneficial and that compromise in the pharmaceuticals sector may be required to gain in other areas.¹⁹⁹

¹⁹⁶ See section 7.4.3 for more detail. See also Müller-Langer F *Creating R&D Incentives for Medicines for Neglected Diseases: an Economic Analysis of Parallel Imports, Patents and Alternative Mechanisms to Stimulate Pharmaceutical Research* doctoral thesis - Hamburg University 2008.

¹⁹⁷ In addition, countries that most seriously threaten the interests of American intellectual property right holders, such as China, Russia, Egypt and India have been placed on the US "301 Priority watch list". Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 49. See also Morin JF *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements* International Journal Intellectual Property Management 2006 Vol 1(1/2) 40.

¹⁹⁸ Kuanpoth J *Harmonisation of TRIPS-Plus IPR Policies and Potential Impacts on Technological Capability: A Case Study of the Pharmaceutical Industry in Thailand* 2006 9. See also Morin JF *Tripping Up TRIPS Debates IP and Health in Bilateral Agreements* International Journal Intellectual Property Management 2006 Vol 1(1/2) 40.

¹⁹⁹ For more discussion, see Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and The Protection of Public Health* The American Journal of International Law 2005 Vol 99 359. See also Koff AW, Baughman LM, Francois JF *Study on the Economic Impact of "TRIPS-Plus" Free Trade Agreements* International Intellectual Property Institute 2011 343.

6.2.6 Summary

The US, as a country with a strong biotechnology industry, supports the granting of patents as the financial aspect is advantageous.²⁰⁰ It is estimated that in the US, since 1998, 3,000 new gene patents are issued annually with over 40,000 of these patents granted till date.²⁰¹

The 2013 Supreme Court decision in *AMP v. USPTO*²⁰² has affected claims to new methods or processes, claims to a new machine, claims to a new article of manufacture and claims to a new composition of matter.²⁰³ Studies indicate other companies have a similar business model to Myriad's, proving that anti-competitiveness is on its way to becoming a norm in the US. An example is that of Athena Diagnostics and PGxHealth, who refused to allow laboratories of higher education institutions from offering testing for long-QT syndrome and Alzheimer's disease.²⁰⁴ In June 2013 the US Patent Office in a memorandum to the Patent Examining Corporation from the Deputy Commissioner for Patent Examination Policy, advised that examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof whether isolated or not.²⁰⁵ This is based on it being ineligible subject to section 101 of 35 USC. In addition, the memorandum also advises that further directives will emerge once the decision was reviewed in detail.²⁰⁶ The reaction suggests that the decision will not necessarily ensure patients access to more affordable testing, while there are claims that the decision will lead to greater innovation and improved patient-care.²⁰⁷ The decision has also given effect to pro-patent legislative changes also being proposed.²⁰⁸

6.3 Biotechnology in Europe

Europe, like the US, has a substantial biotechnology industry and a large number of patents related to biotechnology. In 2012, the sector was valued to be worth 220 billion euros.²⁰⁹ A difference between European patent law and that in the US is that in Europe, even though gene patents are allowed, the

²⁰⁰ According to WIPO data, the US has approximately four times more patents in force as compared to Germany, 23 times more than Mexico and 33 times more than Italy. For more detail see Liddicoat J, Whitton T & Nicol D *Are the Gene-Patent Storm Clouds Dissipating? A Global Snapshot* Nature Biotechnology 2015 Vol 33(4).

²⁰¹ Caulfield T, Cook-Deegan RM, Kieff FS et al *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies* Nature Biotechnology 2006 Vol 24(9) 1091.

²⁰² Association for Molecular Pathology v Myriad Genetics Inc. 569 U.S. 576 (2013).

²⁰³ Graff GD, Phillips D, Lei Z et al *Not a Myriad of Gene Patents* Nature Biotechnology 2013 Vol 31(5) 404.

²⁰⁴ Long QT syndrome is a disorder of the heart's electrical activity. It can cause sudden, uncontrollable, problems with the rate or rhythm of the heartbeat. GeneDx (Gaithersburg, MD) and university laboratories ceased stopped testing after the enforcement of the patent in 2002 despite a commercial test only becoming available in 2004. For more discussion on this see Carbone J, Gold ER, Sampat B et al *DNA Patents and Diagnostics: Not a Pretty Picture* Nature Biotechnology 2010 Vol 28(8) 784-791.

²⁰⁵ For more on this see Kurts A *Consequences of the US Supreme Court Decision on Gene Patenting* European Intellectual Property Review 2013 629-639.

²⁰⁶ *Ibid.*

²⁰⁷ *Supra* note 204.

²⁰⁸ The Restoring American Leadership in Innovation Act of 2018. The proposed Bill can be found at <https://cdn.patentlyo.com/media/2018/07/FinalPatentBill.pdf> (accessed 23 October 2018).

²⁰⁹ See the European Commission's website http://ec.europa.eu/growth/sectors/health_care_en. For more details of the industry see The European Federation of Pharmaceutical Industries and Associations *The Pharmaceutical Industry in Figures 2017* available at https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf (accessed 02 November 2018).

standard for inventiveness is slightly higher than in the US. Note that when reference is made to Europe it refers to the member states of the EU.²¹⁰ The EU operates under what is known as supranational laws.²¹¹ EU law is supreme over the national laws of EU member countries, indicating that it has a direct effect upon the national legal systems of these countries. EU law is also interpreted and enforced through the co-operation of EU courts and the courts of EU member countries.²¹²

In order to obtain a full understanding of the European position on biotechnology patents, including diagnostic gene patents, both supranational and national (specifically Germany) laws are analysed in order to understand the legal structure and content in relation to intellectual property laws in the EU. German laws are analysed in order to illustrate an example of how an EU member country can adapt national laws to suit national needs. This section discusses the attitude of the courts toward genes as patentable subject matter and the effects of diagnostic genes being patentable. Lastly, this section discusses FTA's from a European perspective to create an understanding of the objectives of these agreements within Europe.²¹³

6.3.1 History of European patent law

The first milestone in European patent history was the Paris Convention in 1883, formulating the basic tenants of patent law in Europe.²¹⁴ In 1949, the Council of Europe started to work on plans for a European Patent Office. The latter produced the European Convention, relating to the formalities required for patent applications and the European Convention on the International Classification of Patents for Invention.²¹⁵ In 1957 the Treaty of Rome was signed creating a European Economic Community. In 1960, six-member states created a working group to draft a European Convention relating to a European patent law. The draft was published in early 1962 and provided for the creation of a supranational European Patent Office operating in English, French and German, granting unitary and autonomous European patents. It also provides for the creation of a European Patent Court.²¹⁶

The second milestone in European patent history is the Strasbourg Convention, adopted to provide a common market in Europe by harmonising substantive laws for aspects such as novelty and inventive step and the third was the EPC in 1973 providing for a common patent granting system in European

²¹⁰ At present EU member states are: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Sweden, Slovakia, Slovenia, Spain, United Kingdom, but not Switzerland. It should be noted that the United Kingdom is negotiating its way from the European Union and should exit the Union by the end of March 2019. For more on the UK exit of the EU see Wheeler B & Hunt A *Brexit: All You Need to Know About the UK Leaving The EU* <http://www.bbc.co.uk/news/uk-politics-32810887> (accessed 14 September 2016).

²¹¹ Supranational laws are defined in the Oxford dictionary as "Having power or influence that transcends national boundaries or governments: *supranational law*" <http://www.oxforddictionaries.com/definition/english/supranational> (accessed 15 October 2015).

²¹² <http://www.britannica.com/topic/European-law> (accessed 18 September 2015).

²¹³ FTA's and their effects are discussed more generally in section 4.5.

²¹⁴ For more information see Sreenivasulu NS & Raju CB *Biotechnology and Patent Law: Patenting Living Beings* 1st edition 2008 37. See also Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 38.

²¹⁵ <http://www.cipa.org.uk/pages/journal/article?35DC374C-278B-4E30-9A9A-9FC679FD27C6> (accessed 16 October 2015).

²¹⁶ For more on the European Patent Court see sub-section 6.3.3. See also <http://www.cipa.org.uk/pages/journal/article?35DC374C-278B-4E30-9A9A-9FC679FD27C6> (accessed 16 October 2015).

countries.²¹⁷ The Convention provides a platform for an autonomous legal system for granting European patents.²¹⁸ The EPC established the European Patent Office as a central granting authority for European patents, which acts as a bundle of national patents.

6.3.2 The European Patent Office

In Europe, patent protection can be secured by obtaining a patent from the EPO, validating the patent in specific countries of interest. The EPO governs the prosecution and grant of the initial patents.²¹⁹ The EPO is headquartered in Munich, Germany and is the executive body of the European Patent Organisation. The Administrative Council acts as its supervisory and legislative bodies. The EPO allows three different routes for patent applications: global, national and European. Most European patents contain two-part claims, including a preamble and a characterising section, dealing with features of the invention notable in the closest prior art. The average term for a European patent is twenty years, with patents, such as medical patents, eligible for extensions.²²⁰

Concerning gene patents, the EPO will not grant a patent over a gene involving an isolated DNA sequence, unless the process to identify the sequence involves ingenuity or if the sequence has surprising characteristics, identified by the inventor.²²¹

6.3.3 The European Patent Court

To obtain patent protection in Europe separate applications have to be made to each of the national patent offices within each EU country.²²² In 2003, a draft European Patent Litigation Agreement was published providing for a European Patent Court as a court of first instance and a court of appeal.²²³ In 2006 the European Commission proposed a Community Patent Regulation.²²⁴ The latter would create a community patent granted by the EPO including provision for a centralised community patent court with an appeal to a specialist chamber of the general court. It also included provisions for further appeal to the ECJ.

²¹⁷ The European Patent Convention was finally signed in Munich in October 1973. Six European countries, including Germany and the United Kingdom, signed the European Patent Convention, which went into effect in 1977. For more discussion see Sreenivasulu NS & Raju CB *Biotechnology and Patent Law: Patenting Living Beings* 1st edition 2008 38. See also <http://www.cipa.org.uk/pages/journal/article?35DC374C-278B-4E30-9A9A-9FC679FD27C6> (accessed 16 October 2015).

²¹⁸ <http://info.articleonepartners.com/international-patent-history-and-laws-europe/> (accessed 17 September 2015).

²¹⁹ Brinckerhoff CC *Dispelling The Myriad Gene Patent Harmonization Myth* 30 April 2013 available at <http://www.pharmapatentsblog.com/2013/04/30/dispelling-the-myriad-gene-patent-harmonization-myth/> (accessed 19 September 2015).

²²⁰ Gampp M *European Patent Law: Fundamental Reform Ahead* <https://www.dlapiper.com/en/uk/insights/publications/2014/12/ipt-news-q4-2014/european-patent-law-fundamental-reform-ahead/> (accessed 14 October 2016).

²²¹ Sreenivasulu NS & Raju CB *Biotechnology and Patent Law: Patenting Living Beings* 1st edition 2008 38.

²²² Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 436.

²²³ The provisions of substantive law were based on the CPC and the jurisdictional provisions were based on the Brussels I Regulation. <http://www.cipa.org.uk/pages/journal/article?35DC374C-278B-4E30-9A9A-9FC679FD27C6> (accessed 16 October 2015).

²²⁴ For more information see *ibid*.

The agreement on the Unified Patent Court (UPC) was signed in Brussels in 2013. A preparatory committee was established to set up the UPC.²²⁵ This was in accordance with Article 118 of the Treaty on the Functioning of the EU (TFEU), providing that the Union lawmakers "shall establish measures for creating European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union".²²⁶ Based on this provision, Regulation 1257/2012 (the Unitary Patent Regulation) was adopted, establishing unitary patent protection that aims to improve the level of patent protection by making it possible to obtain uniform patent protection in the participating member states.²²⁷

From a legal and economic perspective, the new system is a complete game changer in European patent law in history.²²⁸ Under the new system, it will be possible to obtain an injunction against an infringing product valid across the entire EU with just one legal action.²²⁹

The aim of the reform is to offer an alternative by simplifying the existing system and support a cost-effective route to patent protection and dispute settlement. It will still be possible to use the national route for those who prefer to seek protection in an individual member state.²³⁰ Inventors seeking patents with unitary effect could, after grant of the patent in a member state, file a request for unitary effect. If the formal requirements are met,²³¹ the European patent will then benefit from unitary effect in all the participating member states.²³² The unified patent offers an additional option to the European patent system. The new patent package will consequently provide users with a choice between a classical European patent,²³³ or

²²⁵ Jurisdiction is granted to the UPC under the Brussels Ibis Regulation. De Miguel Asensio: Regulation (EU) No. 542/2014 and the International Jurisdiction of the Unified Patent Court (IJC 2014, 868). See also *An Enhanced European Patent System* as prepared by The Select Committee and The Preparatory Committee.

See also <http://english.rvo.nl/topics/innovation/patents-other-ip-rights/patents> (accessed 17 September 2015).

²²⁶ Article 118 of the Treaty on the Functioning of the EU.

²²⁷ For a transition period of initially seven years, the UPC and the national courts will have alternative jurisdiction. The patentee may declare to opt from the jurisdiction of the UPC, either for individual patents or entire portfolios. By declaring to opt out, the patentee can prevent the patent from being declared invalid by the UPC. This will have an effect in all member states. Conversely, the patentee thereby also deprives of the possibility to obtain an injunction for infringement of the patent with pan-European effect. *An Enhanced European Patent System* as prepared by The Select Committee and The Preparatory Committee. See Gampp M *European Patent Law: Fundamental Reform Ahead* <https://www.dlapiper.com/en/uk/insights/publications/2014/12/ipt-news-q4-2014/european-patent-law-fundamental-reform-ahead/> (accessed 14 October 2016). Aerts RJ *The Unitary Patent and the Biotechnology Directive: Is Uniform Protection of Biotechnological Inventions Ensured?* *European Intellectual Property Review* 2014 Vol 36(9) 584-587.

²²⁸ Gampp M *European Patent Law: Fundamental Reform Ahead*

<https://www.dlapiper.com/en/uk/insights/publications/2014/12/ipt-news-q4-2014/european-patent-law-fundamental-reform-ahead/> (accessed 14 October 2016).

²²⁹ *Ibid.*

²³⁰ *An Enhanced European Patent System* as prepared by the Select Committee and the Preparatory Committee.

²³¹ To gain unitary patent the European patent should have been granted with the same set of claims for all the participating member states, the request for unitary effect will be filed at the EPO in the language of proceedings within one month from the publication of the grant in the European Patent Bulletin. As from the date of application of the UPP regulations there will be a transitional period of six to a maximum of twelve years during which the patent holder will need to file a translation of the patent specification into one additional language. If the patent is granted in German or French the translation will be into English. If the patent is granted in English, the translation will be into any other official language of the EU at the choice of the patent holder. These translations are for information purposes only and do not have any legal effect. After the transitional period no translations will be required. See *An Enhanced European Patent System* as prepared by the Select Committee and the Preparatory Committee.

²³² The patent will have uniform protection and equal effect in all member states. See Gampp M *European Patent Law: Fundamental Reform Ahead* <https://www.dlapiper.com/en/uk/insights/publications/2014/12/ipt-news-q4-2014/european-patent-law-fundamental-reform-ahead/> (accessed 14 October 2016).

²³³ A national patent.

a unified patent.²³⁴ The European patent is not a single uniform intellectual property right providing protection across the entire EU but should be validated with each respective national patent office, only existing as a bundle of national patents.²³⁵ In the event of an infringement, the patentee should bring separate actions before courts in every relevant jurisdiction.²³⁶

6.3.4 Relevant supranational legislation

6.6.4.1 The European Patent Convention (EPC)

As mentioned above, in 1973, 16 European countries signed the EPC,²³⁷ which went into effect in 1977. This convention provides a platform for an independent legal system for granting European patents.²³⁸ The Patent Convention sets out the requirements of a patent as follows:²³⁹

- Novelty – the claimed subject-matter should be new.²⁴⁰
- Inventive step – the invention should not be obvious for a skilled individual working in the relevant field of technology and should solve a technical challenge.²⁴¹
- Industrial application – the claimed subject-matter should be made or used in any kind of industry.²⁴²

The implementing regulations to the EPC specify that the invention should have technical features, related to a technical field, whereby a technical challenge is addressed.²⁴³ Additionally the invention should be disclosed fully in the application and should be described clearly enough for “an individual skilled in the art” to be able to reproduce it.²⁴⁴ The EPC Implementing Regulations (EPC IRs) recommends that the

²³⁴ *An Enhanced European Patent System* as prepared by the Select Committee and the Preparatory Committee.

²³⁵ The patent will have uniform protection and equal effect in all member states. *Ibid.*

²³⁶ Similarly, the defendant should endeavor to have the patent invalidated separately in every jurisdiction.

<https://www.dlapiper.com/en/netherlands/insights/publications/2014/12/ipt-news-q4-2014/european-European-patent-law-fundamental-reform-ahead> (accessed 14 October 2015).

²³⁷ The EPC can be accessed at: <http://www.epo.org/law-practice/legal-texts/epc.html> (accessed 28 October 2015).

²³⁸ <http://info.articleonepartners.com/international-patent-history-and-laws-japan/> (accessed 24 February 2015).

²³⁹ For full discussion see O Mills *Biotechnological Inventions (Revised Edition) Moral Restraints and Patent Law* 2010 32. See also Schertenleib D *The patentability and protection of living organisms in the European Union* European Intellectual Property Review 2004 26(5) 203-213. See also Gibson J *The Discovery of Invention: Gene Patents and the Question of Patentability* Journal of Intellectual Property Rights 2007 Vol 12 38-44.

²⁴⁰ Article 54 EPC. Patent protection cannot be granted for a known material even where a new use or application of the material is found. In the medical field a divergent rule is applied when faced with such a case. The EPC stipulates that the general rules “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 Art. 53 (c) EPC [surgical, therapeutic, or diagnostic method], provided that its use for any such method is not comprised in the state of the art”. This rule is extended to known substance which are used for second medical indications. The EPC can be accessed at: <http://www.epo.org/law-practice/legal-texts/epc.html> (accessed 28 October 2015). See Van Overwalle G *Policy Levers Tailoring Patent Law Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 451. See also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4448586/#FN7> (accessed 05 September 2018).

²⁴¹ Article 56 EPC. The isolation or characterization of DNA, does not amount to an ‘invention’. Sequences isolated, cloned and replicated are patentable, though genes expressed in the human body cannot be patented. The EPC can be accessed at: <http://www.epo.org/law-practice/legal-texts/epc.html> (accessed 28 October 2015). For discussion see Soini S, Aymé S & Matthijs G *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues* European Journal of Human Genetics 2008 Vol 16 10–50.

²⁴² Article 57 EPC. <http://info.articleonepartners.com/international-patent-history-and-laws-europe/> (accessed 17 September 2015). See also <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4448586/#FN7> (accessed 05 September 2018).

²⁴³ (Rule 43(1)) and Rule 42(1)(c)). For further discussion see Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: Comparison Under Current European and US Patent Law* European Journal of Human Genetics 2011 Vol 19 1104–1107.

²⁴⁴ Articles 83 and 84 of the EPC. See also Matthijs G, Huys I, Van Overwalle G & Stoppa-Lyonnet D *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines* Nature biotechnology 2013 Vol 31(8) 705.

description specifies the field or area of the invention in Rule 42 (1) (a) EPC IRs. The description of the claim should also make the technical challenge and its solution known;²⁴⁵ and the claims should define the matter concerning the technical features of the invention.²⁴⁶

Article 53(a) clarifies exclusions to patentability and excludes inventions that are opposing to “*ordre public*” or morality. Article 53(b) excludes “essentially biological processes [to produce] plants or animals” and 53(c) excludes “methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body....” rule 28 of the EPC analyses Article 53 and more specifically excludes:²⁴⁷

- cloning of human beings;
- modifying the human germ line;
- use of human embryos whether industrial or commercial; and
- generating genetically modified animals if their production causes suffering without substantial medical benefit.

European patent law contains an explicit morality test. The EPC sets out that European patents will not be granted over immoral inventions or inventions contrary to *ordre public*.²⁴⁸ The ethics of gene patenting was questioned in the *Howard Florey Institute* case²⁴⁹ claiming a patent coding for human relaxin.²⁵⁰ In *casu* it was concluded by the EPO Opposition Division that claims concerning a human gene was acceptable and not exempt from to patentability as DNA is a chemical particle and cannot be construed as “life”.²⁵¹

6.6.4.2 The European Convention on Human Rights

In 1998 the ECHR was adopted under the council. The first protocol of the ECHR recognises a provision on protecting property but makes no reference to intellectual property. It reads as follows:

- “Every natural or legal individual is entitled to the peaceful enjoyment of his possessions. No one will be deprived of his possessions except in the public’s interest and subject to the conditions provided for by law and by the general principles of global law.

²⁴⁵ Rule 42 (1) (c) EPC IRs.

²⁴⁶ Rule 43 (1) EPC IRs. See also Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 436.

²⁴⁷ The EPC can be accessed at <http://www.epo.org/law-practice/legal-texts/epc.html> (accessed 28 October 2015). Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 436. See also <http://info.articleonepartners.com/international-patent-history-and-laws-europe/> (accessed 17 September 2015). See also Schertenleib D *The Patentability and Protection of Living Organisms in the European Union* European Intellectual Property Review 2004 26(5) 203-213.

Schrell A, Bauser H & Brunner H “*Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*” (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

²⁴⁸ Article 53 (a) EPC. For further discussion see Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 450.

²⁴⁹ *Howard Florey Institute’s Application/Relaxin* (OJ EPO 1995, 388) (V 0008/94).

²⁵⁰ Decision of the European Patent Office, Board of Appeal, Case V 8/94 (Aug. 30, 1984) O.J. E.P.O. 388 (1995). For a brief discussion of the case see section 6.3.6.

²⁵¹ For more discussion see Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 450.

- The preceding provisions will not in any way impair the right of a state to enforce such laws as it deems necessary to control using property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties".²⁵²

The Convention does not make mention of the right to health care. Matters such as health and socio-economic rights are traditionally more appropriately addressed in instruments such as the European Social Charter²⁵³, the European Code of Social Security²⁵⁴ or, at a more global level, the ICESCR^{255, 256}.

Therefore, most health-related cases that have arisen before the Commission have been brought under Articles 2, 3, 8 and 14 of the Convention. These articles relate to life, torture, privacy and discrimination respectively.²⁵⁷ The case of *Smith Kline*²⁵⁸ did relate to biotechnology and access but as the case was not defended under the right to health care (as the latter is not protected by the ECHR) it was addressed solely under Protocol 1 of the ECHR. In the *Smith Kline* decision, the European Commission of Human Rights decided on a matter pertaining to the protection of a patent right over the grant of a compulsory licences in order to produce a related substance. The compound in question known as H2 antagonists and are of particular value in treating gastric and duodenal ulcers.²⁵⁹

6.6.4.3 The EU Directive 1998

The EU Directive operates on the European-EU level and all member states must adhere to it.²⁶⁰ The EU Biotechnology Directive's primary objective is to harmonise existing rules on biotechnology type inventions for all EU member states and to remove any discrimination based on the field of technology.²⁶¹ It was enacted as a market harmonisation instrument based on Article 100(a) of the Treaty Establishing the European Community.²⁶² The Directive also has other goals, including market interests and non-market interests.²⁶³ The latter includes acknowledging the important part of biotechnology research and protecting the financial risks inherent in this research,²⁶⁴ eliminating differences between national laws to clarify the

²⁵² Protocol 1 of the ECHR.

²⁵³ The European Social Charter can be found at <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cde2> (accessed 21 November 2018).

²⁵⁴ The European Code of Social Security can be accessed at <https://www.coe.int/en/web/conventions/full-list/conventions/treaty/048> (accessed 27 November 2018).

²⁵⁵ The International Covenant on Economic, Social and Cultural rights is discussed in detail in section 5.3 of this thesis.

²⁵⁶ The European Council's Thematic Report on *Health-Related Issues in the Case-Law of the European Court of Human Rights* https://www.echr.coe.int/Documents/Research_report_health.pdf (accessed 27 November 2018).

²⁵⁷ *Ibid.*

²⁵⁸ *Smith Kline and French Laboratories Ltd v The Netherlands* (1990) 66 DR 70. See <http://echr.ketse.com/doc/12633.87-en-19901004/view/> (accessed 26 September 2018).

²⁵⁹ *Ibid.*

²⁶⁰ The Directive is supranational law with the EU.

²⁶¹ Directive 98/44/EC can be accessed at

<https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (accessed 24 September 2018).

²⁶² It is now known as article 114 of the Treaty on the Functioning of the EU (TFEU).

²⁶³ Andrea FA *Judicial Activism, the Biotech Directive and its Institutional Implications: Is the Court Acting as a Legislator or a Court When Defining The "Human Embryo"?* European Law Review 2015 40(4) 613-627.

²⁶⁴ Recitals 1 and 2. See <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (accessed 24 September 2018).

status of protection of biotechnological inventions,²⁶⁵ and the smooth operation in the internal EU market. Non-market goals include the application of patent rules to safeguard human dignity and integrity,²⁶⁶ the exclusion from patentability if commercial use would be a contravention of *ordre public* or morality,²⁶⁷ and the protection of fundamental rights.²⁶⁸

Article 3(1) of the Directive states that:

“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.”²⁶⁹

Article 3(2), continues to provide that when biological material is “isolated from its natural environment or produced by means of a technical process” this “may be the subject of an invention even if it previously occurred in nature”.²⁷⁰

The Directive emphasises the importance of utility. Recital 23 lays down the notion that DNA sequences without an indication of a function does not contain technical information and cannot be patentable. Recital 24 adds that where a full or partial sequence is used to produce a protein or part of a protein, it is necessary to meet the requirement of industrial application, to specify the protein produced or its function (the level of description required as to the specific utility may vary from case to case, depend on the knowledge available and vary as using genes for therapeutic and diagnostic purposes spreads).²⁷¹

Referring to genes, the Directive states that:

For the purposes of this Directive, the human body, at any stage of development and the discovery of its elements, for example a gene sequence, cannot constitute a patentable invention.²⁷²

²⁶⁵ Recitals 4 and 5. See <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (accessed 24 September 2018).

²⁶⁶ *Ibid.*

²⁶⁷ Recitals 36, 37 and 38. See <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (accessed 24 September 2018). A general principle of exclusion is established in Article 6(1) for inventions whose commercial exploitation would be contrary to *ordre public* or morality. Article 6(2) contains a list of exclusions from patentability and Recital 38 states that this list is not exhaustive and that any process whose application offends against human dignity should also be excluded from patentability. See *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* Report from the Commission to the European Parliament and the Council 2002 545.

²⁶⁸ Recital 43. See Faeh A *Judicial Activism, the Biotech Directive and its Institutional Implications: Is the Court Acting as a Legislator or a Court When Defining the "Human Embryo"?* European Law Review 2015 40(4) 613-627.

²⁶⁹ Directive 98/44/EC of the European Parliament and of the Council. For discussion on this see *The Ethics of Patenting DNA* a discussion paper Nuffield Council on Bioethics 2002 available at

[The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper](#) (accessed 26 September 2015). See also Jervis HH *Seduced by the Sequence: An Analysis of the U.S. Supreme Court's Opinion in Association of Molecular Pathology v Myriad Genetics, Inc.* Florida Coastal Law Review 2014 123.

²⁷⁰ Directive 98/44/EC of the European Parliament and of the Council.

²⁷¹ *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* Report from the Commission to the European Parliament and the Council 2002 545.

²⁷² Article 5 of the Directive 98/44/EC. For discussion on this see Schertenleib D *The Patentability and Protection of Living Organisms in the European Union* European Intellectual Property Review 2004 26(5) 203-213. See also Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 436. See also *Development and implications of Patent Law in the Field of Biotechnology and Genetic Engineering* Report from The Commission to The European Parliament and the Council 2002 545.

This rule is limited in Article 5(2), which provides:

“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.”²⁷³

Rule 29 of the EPC IRs corresponds with Article 5.²⁷⁴

In Europe DNA sequences once isolated, should meet the criteria of being novel, inventive and being capable of industrial application to be granted a patent. Each country that is part of the EU is obligated to ensure that their domestic legislation is in line with the standards that are set out for the union. France and Germany differ from the rest of the union as they do have restrictions on patenting human genes, but these restrictions apply only to patents obtained through their respective national routes.²⁷⁵

The German government failed to implement the Directive into their national legislation as they felt that the scope of protection provided by a product patent on genetic material was too broad but in 2005 the Directive was reluctantly implemented by them on a national level.²⁷⁶ A brief overview of the position on diagnostic gene patentability in Germany is discussed below.

6.3.5 German patent law

The German patent system is influenced by developments in the US and in turn, influenced legislation elsewhere.²⁷⁷ The Federal Republic of Germany is a democratic and social federal state comprising of 16 federal *Länder* (states).²⁷⁸ These states have part-sovereignty and can enact their own laws in certain fields of legislation. Each state has its own legislative, judicial and executive power which exist both on

²⁷³ Article 5(2) Directive 98/44/EC.

²⁷⁴ This is explained further in the EU Directive Recitals 20 and 21 to the Directive which state the following respectively: Recital 20 states that any inventions founded on an isolated element of the human body or created by a technical method and which has industrial use, is not exempt from patentability, despite it being structurally identical to its natural counterpart, provided that any rights conferred by the patent are limited to the human body and its natural elements. Recital 21 states that where an isolated element of the human body or elements produced is patentable as it is the production of a technical process that identified, purified and classified it so that it could be reproduced externally. These are human intravenous techniques. See Schrell A, Bauser H & Brunner H “*Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*” (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007. See Cook T *How Europe Has Learnt to Deal with Exclusions from Patentability* Journal of Intellectual Property Rights 2013 Vol 18 374.

²⁷⁵ Brinckerhoff CC *Dispelling the Myriad Gene Patent Harmonization Myth* 2013 available at <http://www.pharmapatentsblog.com/2013/04/30/dispelling-the-myriad-gene-patent-harmonization-myth/> (accessed 19 September 2015). See section 6.3.6.

²⁷⁶ Haag T & Kilger C *Myriad Ruling v Biotech Patent Eligibility in Europe* available at <http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (accessed 18 September 2015). See also Schrell A, Bauser H & Brunner H “*Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany*” (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

²⁷⁷ Including Argentina, Austria, Brazil, Denmark, Finland, Holland, Norway, Poland, Russia and Sweden. For more detail see Khan BZ *An Economic History of Patent Institutions* <https://eh.net/encyclopedia/an-economic-history-of-patent-institutions/> (accessed 18 September 2015). See also <http://www.law.indiana.edu/lawlibrary/research/guides/german/> (accessed 22 September 2015).

²⁷⁸ Basic law for the Federal Republic of Germany in the revised version published in the Federal Law Gazette Part III, classification number 100-1, as last amended by the Act of 11 July 2012 (Federal Law Gazette I p. 1478). (Translated by: Professor Tomuschat C and Professor Currie DP in cooperation with the Language Service of the German Bundestag).

the level of the federation and on the level of the states.²⁷⁹ On the federal level the *Bundestag* (national parliament) decides on new legislation with a simple majority. These laws would also have to be accepted by the *Bundesrat* (federal council) which is the representation of the states. Once accepted the *Bundespräsident* (President of Germany) will sign in the new law.²⁸⁰ Sources of German law include the German constitution and the *Bürgerliches Gesetzbuch* (the civil code).²⁸¹

The first controversial biotechnology related patent case was in the 1960s when a German pigeon breeder sought a patent for a method of breeding a dove with “a considerably larger” red plumage.²⁸² The Court explained that section 2(2) of the German Patent Act explicitly denied patent protection for plant or animal varieties, or essentially biological processes for producing plants or animals. The *Bundesgerichtshof* (the German Federal Supreme Court) refused to grant the patent and explained that breeding was biological, rather than technical as there was no guarantee of “reproducibility”.²⁸³ This position was again emphasised in 1975 when the court refused to grant patent protection for a new mutant of baker’s yeast which produced beneficial results in bakery products. Biotechnology innovations remained unpatentable in Europe during the 1970s and 1980s.²⁸⁴

6.3.5.1 The German Constitution

In 1948 the ministers-presidents of the West-German states formed a Parliamentary Council to begin drafting a constitution which the Council passed and which was approved by the occupiers in 1949. All the *Länder*²⁸⁵ approved the Constitution bringing it into law on May 24, 1949, creating the Federal Republic of Germany.²⁸⁶ The German Constitution, like the American, does not guarantee the right to health or reference morality.²⁸⁷ The German Constitution in Article 5(3) enshrines art and sciences research and teaching to be free.²⁸⁸ Article 5 generally translates to: Art, science, research and teaching are free. Freedom of teaching does not absolve from loyalty to the constitution.²⁸⁹

²⁷⁹ The states have the power of legislation, but for certain areas of legislation the Federation may have an additional or exclusive power of legislation.

²⁸⁰ http://www.internetratgeberrecht.de/frameset.htm?http://www.internetratgeberrecht.de/deutsches_recht/english/german_law.htm (22 September 2015).

²⁸¹ *Ibid.*

²⁸² *Rote Taube* IIC 01/1970 at 136, 137. See also Ragavan *S Patent Judicial Wisdom National Law School of India Review* 2008 167.

²⁸³ *Ibid.*

²⁸⁴ *Supra* note 281.

²⁸⁵ With the exception of Bavaria.

²⁸⁶ See <http://www.constitutionnet.org/country/constitutional-history-germany> (accessed 25 September 2018).

²⁸⁷ The Constitution can be accessed at http://www.servat.unibe.ch/icl/gm00000_.html (accessed 25 September 2018).

²⁸⁸ Basic law for the Federal Republic of Germany in the revised version published in the Federal Law Gazette Part III, classification number 100-1, as last amended by the Act of 11 July 2012 (Federal Law Gazette I p. 1478). (Translated by: Professor Tomuschat C and Professor Currie DP in cooperation with the Language Service of the German Bundestag).

²⁸⁹ Article 5: “Kunst und Wissenschaft, Forschung und Lehre sind frei. Die Freiheit der Lehre entbindet nicht von der Treue zur Verfassung.” The Constitution can be accessed at http://www.servat.unibe.ch/icl/gm00000_.html (accessed 25 September 2018).

Article 14 guarantees property but again, no direct reference is made to intellectual property so one can only assume property to include both tangible and intangible property.²⁹⁰

6.3.5.2 The German Patent Act

Requirements for patentability in Germany include novelty, inventive step and industrial applicability (the latter being in line with the US requirement of utility).²⁹¹ With respect to the inventive step, similarities exist between German and EPO practice. The decisive question in Germany is often whether the prior art can provide any motivation or incentive to add further features to an already-known solution of the prior art.²⁹²

Inventions in the field of microbiology and biotechnology are not generally excluded from patent protection. After the implantation of the EU Directive discussed above,²⁹³ long disputes, both in parliament and in public, were held in Germany. The country refused to impose the Directive's obligations and in 2004 was found in violation of its European obligations by the ECJ for its failure to transpose the Biotechnology Directive and enacting the necessary domestic legislation.²⁹⁴ Finally, in 2005 the Directive was implemented and the *Bundestag* introduced paragraph 1a section 4 to the German Patent Statute. The provision limits the scope of patent protection available for human gene sequences or parts thereof. It provides that if the subject of an invention is a human gene sequence, it requires disclosure of not only the sequence but also at least one application.²⁹⁵ When paragraph 1a section 4 came into effect on the 1st of March 2005, the *Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen* (law implementing the Directive on the Legal Protection of Biotechnology Inventions) satisfied all requirements of the EU Biotechnology Directive but only permitted the patenting of human gene sequences or parts thereof under conditions stricter than those laid down in the EPC.²⁹⁶

Section 1a ensures the human body including the simple discovery of one of the elements of the body such as a sequence or partial sequence of a gene, cannot constitute a patentable invention.²⁹⁷ Isolated elements and elements produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention but the industrial application of the sequence

²⁹⁰ Article 14: "Das Eigentum und das Erbrecht werden gewährt. Inhalt und Schranken werden durch die Gesetze bestimmt." Basic Law for the Federal Republic of Germany in the revised version published in the Federal Law Gazette Part III, classification number 100-1, as last amended by the Act of 11 July 2012 (Federal Law Gazette I p. 1478). (Translated by: Professor Tomuschat C and Professor Currie DP in cooperation with the Language Service of the German Bundestag). The Constitution can be accessed at http://www.servat.unibe.ch/icl/gm00000_.html (accessed 25 September 2018).

²⁹¹ Section 1(1) of the Patent Act (Patentgesetz). See

https://www.dpma.de/english/patents/patent_protection/protection_requirements/index.html (accessed 25 September 2018).

²⁹² Christoph A *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It* German Law Journal 2006 Vol 7(3) 279 - 292.

²⁹³ Article 5(2) of the Directive allowing for patents on gene sequences.

²⁹⁴ *Ibid.*

²⁹⁵ *Supra* note 291.

²⁹⁶ *Supra* note 291.

²⁹⁷ The German Patent Act states: section "1a(1) Der menschliche Körper in den einzelnen Phasen seiner Entstehung und Entwicklung, einschließlich der Keimzellen, sowie die bloße Entdeckung eines seiner Bestandteile, einschließlich der Sequenz oder Teilsequenz eines Gens, können keine patentierbaren Erfindungen sein. See Haag T & Kilger C *Myriad Ruling vs Biotech Patent Eligibility in Europe* available at <http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (accessed 18 September 2015).

or partial sequence of a gene will have to be specifically disclosed in the application and its function indicated.²⁹⁸

In line with the Biotechnology Directive, plant or animal varieties, methods for the surgical or therapeutic treatment of the human or animal body and diagnostic methods used on the human or animal body are not patentable. In addition, inventions whose commercial exploitation is contrary to public order or morality is also not patentable. The Act also excludes patents on processes for cloning human beings; for modifying the genetic identity of the germ line of human beings; uses of human embryos for industrial or commercial purposes; and processes for modifying the genetic identity of animals, which are likely to cause said animals suffering without any substantial medical benefit to man or said animal, nor will patents be granted for animals resulting from such processes.²⁹⁹

The German Patent Office (GPO) generally allows non-human gene sequence claims covering isolated DNA.³⁰⁰ To patent a sequence of a human gene in Germany it will not suffice to describe a general aim for an invention. The aim should be specific which is extensively stricter than the requirement of the Biotechnology Directive of 1998.³⁰¹ Subparagraph 4 of section 1a of the Act therefore exceeds the wording

²⁹⁸ The German Patent Act states: Section "1a(2) Ein isolierter Bestandteil des menschlichen Körpers oder ein auf andere Weise durch ein technisches Verfahren gewonnener Bestandteil, einschließlich der Sequenz oder Teilsequenz eines Gens, kann eine patentierbare Erfindung sein, selbst wenn der Aufbau dieses Bestandteils mit dem Aufbau eines natürlichen Bestandteils identisch ist. S 1a(3) Die gewerbliche Anwendbarkeit einer Sequenz oder Teilsequenz eines Gens muss in der Anmeldung konkret unter Angabe der von der Sequenz oder Teilsequenz erfüllten Funktion beschrieben werden. S 1a(4) Ist Gegenstand der Erfindung eine Sequenz oder Teilsequenz eines Gens, deren Aufbau mit dem Aufbau einer natürlichen Sequenz oder Teilsequenz eines menschlichen Gens übereinstimmt, so ist deren Verwendung, für die gewerbliche Anwendbarkeit nach Absatz 3 konkret beschrieben ist, in den Patentanspruch aufzunehmen".

²⁹⁹ Section 2a(1) "Patente werden nicht erteilt für:

1. Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren;
2. Verfahren zur chirurgischen oder therapeutischen Behandlung des menschlichen oder tierischen Körpers und Diagnostizierverfahren, die am menschlichen oder tierischen Körper vorgenommen werden. Dies gilt nicht für Erzeugnisse, insbesondere Stoffe oder Stoffgemische, zur Anwendung in einem der vorstehend genannten Verfahren.

(2) Patente können erteilt werden für Erfindungen,

1. deren Gegenstand Pflanzen oder Tiere sind, wenn die Ausführung der Erfindung technisch nicht auf eine bestimmte Pflanzensorte oder Tierrasse beschränkt ist;
2. die ein mikrobiologisches oder ein sonstiges technisches Verfahren oder ein durch ein solches Verfahren gewonnenes Erzeugnis zum Gegenstand haben, sofern es sich dabei nicht um eine Pflanzensorte oder Tierrasse handelt. § 1a Abs. 3 gilt entsprechend.

(3) Im Sinne dieses Gesetzes bedeuten:

1. "biologisches Material" ein Material, das genetische Informationen enthält und sich selbst reproduzieren oder in einem biologischen System reproduziert werden kann;
2. "mikrobiologisches Verfahren" ein Verfahren, bei dem mikrobiologisches Material verwendet, ein Eingriff in mikrobiologisches Material durchgeführt oder mikrobiologisches Material hervorgebracht wird;
3. "im Wesentlichen biologisches Verfahren" ein Verfahren zur Züchtung von Pflanzen oder Tieren, das vollständig auf natürlichen Phänomenen wie Kreuzung oder Selektion beruht;
4. "Pflanzensorte" eine Sorte im Sinne der Definition der Verordnung (EG) Nr. 2100/94 des Rates vom 27. Juli 1994 über den gemeinschaftlichen Sortenschutz (ABl. EG Nr. 227 S. 1) in der jeweils geltenden Fassung".

See also Haag T & Kilger C *Myriad Ruling Vs Biotech Patent Eligibility in Europe* available at

<http://www.law360.com/articles/451636/myriad-ruling-vs-biotech-patent-eligibility-in-europe> (accessed 18 September 2015).

³⁰⁰ Some examples include patents DE-B-19983297 (corresponds to US Patent No. 6,511,838), which covers naturally occurring gene sequences from a marine bacterium coding for a β -agarase. DE-B-10149715, covers polynucleotides from the bacterium *Rhodococcus ruber* and encoding an esterase; also covers short sequences. DE-B-102004386 (corresponds to US Patent No. 7,482,157) in having as its object the provision of genes related to the production of monacolin K (a naturally occurring statin also known as lovastatin) from the mold *Monascus*. The claims cover an isolated DNA molecule comprising a polynucleotide relating to monacolin K and encoding a polypeptide having an activity selected from β -ketoacyl synthase, acetyltransferase, dehydratase, methyltransferase, and ketoreductase.

³⁰¹ Promulgation January 21 2005 in force since 2005. See Schrell A, Bauser H & Brunner H "Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany" (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

of the Directive. This requirement solely applies for sequences of a gene where the structure of the gene is identical to the structure of the gene in its natural form.³⁰²

The reason for introducing paragraph 1a section 4 was because of the importance of research involving DNA sequences and the fear of granting such broad protection might hamper research into additional uses of genes and DNA sequences.³⁰³ The argument is that the patenting of DNA sequences based on the identification of one application will cause researchers to be less inclined to continue research on that particular sequence and therefore less likely to discover new applications of the sequence.³⁰⁴ In addition to this, filing an application through the German Patent Act could also result in investors being more likely to contribute to the study of DNA sequences as investors would know that if another scientist identifies a function for a sequence, that scientist will only gain protection for that application and future identification of new functions will still be available for protection.³⁰⁵ The limited protection encourages investment in DNA sequence research and it encourages scientists to continue their work, even if another discovers a possible application of a DNA sequence.³⁰⁶ Questions remain as to how these amendments will affect granted and pending German patents. There are also questions regarding the extent that a new (partial) gene sequence differs from a human gene in order to fall outside of the section 1a(4) PatG restriction.³⁰⁷

6.3.6 Acceptance of gene sequences as patentable subject matter

As mentioned previously in this chapter, biotechnology innovation remained unpatentable in the 1970's and 1980's.³⁰⁸ The *Relaxin* case³⁰⁹ in the mid-1990s was the first decision considered sufficiently significant to warrant publication in the official journal of the EPO. The case involved the H2-relaxin gene. The court held that the isolation of relaxin could not be dismissed as a mere discovery. The court also held that the granting of a patent for genetic sequences was not contrary to morality because the patenting of a single human gene did not amount to the patenting of human life.³¹⁰

The introduction of the Biotechnology Directive and its provision for the patentability of gene sequences introduced European Union countries to the notion of this type gene patent as the Directive has to be implemented in all Union countries.³¹¹

³⁰² Schrell A, Bauser H & Brunner H "Biotechnology Patenting Policy in the European Union – as Exemplified by the Development in Germany" (editor) Fiechter A & Sautter C *Green Gene Technology Research in an Area of Social Conflict* 2007.

³⁰³ Bryan E *Gene Protection: How Much is too Much? Comparing the Scope of Patent Protection for Gene Sequences Between the United States and Germany* Journal of High Technology 2009 Vol 69(9) 52.

³⁰⁴ *Ibid.*

³⁰⁵ *Supra* note 302.

³⁰⁶ *Supra* note 302.

³⁰⁷ Sreenivasulu NS & Raju CB *Biotechnology and Patent Law: Patenting Living Beings* 1st edition 2008 39.

³⁰⁸ See Rote Taube IIC 01/1970 at 136, 137.

³⁰⁹ *Howard Florey Institute's Application/Relaxin* (OJ EPO 1995, 388) (V 0008/94).

³¹⁰ *Ibid.*

³¹¹ Section 5(2) of the Biotechnology Directive.

In 2001 the European Court saw an application for the annulment of the Biotechnology Directive in the *Kingdom of the Netherlands v. Council of the European Union*.³¹² The court held that as member states are required to cover biotechnological inventions, including gene sequences, in their national patent laws, the Directive prevented damage to the unity of the internal market from the member states' deciding unilaterally to grant or refuse such protection. The Directive covers national patents issued in accordance with the procedures applicable from national laws. Gene sequences can only give rise to the grant of a patent if the application is accompanied by a description of the original method of sequencing that led to the invention and an explanation of the industrial application to which the work is to lead.

The *Monsanto*³¹³ case follows on this decision and held that Article 1(1)³¹⁴ of the Directive requires member states to protect biotechnological inventions under their national patent laws and to adjust these laws in accordance with the provisions of the Directive. Article 9 of the Directive refers to scope and should be regarded as exhaustive. Article 9 precludes national legislation from producing a different effect.³¹⁵

6.3.7 Effect of diagnostic gene patents in the EU – the BRCA case

In 1994 researchers from the University of Utah and Myriad Genetics reported the BRCA1 gene. The following year, after the grant of a patent in the US, Myriad Genetics, the University of Utah Research Foundation and the US Secretary of Health filed two patent applications jointly in Europe. The EPO granted both patents.³¹⁶ The patents confer rights over the gene sequence and it is various mutations, diagnostic tests and methods for screening tumours samples.³¹⁷ On 11 August 1995, Myriad Genetics and co-applicants filed another European patent application claiming rights to a mutant BRCA1 gene, a probe, a cloning vector and a method for identifying a mutant BRCA1 nucleotide sequence.³¹⁸

Prior to this, OncorMed and the University of Pennsylvania Genetics Diagnostics laboratory offered commercial genetics testing. Their method of testing differs to Myriad; instead of using protein truncation testing analysing variations in the length of a protein followed by localised DNA sequencing, they use conformation sensitive gel electrophoresis³¹⁹ detecting mutations by creating hybrids³²⁰ and runs them on

³¹² *Kingdom of the Netherlands v. Council of the European Union* (European Court, Case C-377/97) (2001).

³¹³ *Monsanto v Cefetra* case (C-428/08).

³¹⁴ Article 1(1) states that 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.

³¹⁵ Directive 98/44/EC

³¹⁶ For more information see *The Ethics of Patenting DNA a discussion paper* Nuffield Council on Bioethics 2002 <http://the%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper> (accessed 26 September 2015).

³¹⁷ In January 2001, Myriad Genetics was granted a European patent on the BRCA1 gene resulting in Myriad Genetics having temporary monopoly on diagnostic testing for BRCA1 in several European countries. See also Matthijs G, Huys I, Van Overwalle G et al *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines* Nature Biotechnology 2013 Vol 31(8) 708.

³¹⁸ Patent application EP705903. See Matthijs G, Huys I, Van Overwalle G et al *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines* Nature Biotechnology 2013 Vol 31(8) 708.

³¹⁹ Gel electrophoresis is a laboratory method used to separate mixtures of DNA, RNA, or proteins according to molecular size. In gel electrophoresis, the molecules to be separated are pushed by an electrical field through a gel that contains small pores. For more information on this see <https://www.nature.com/scitable/definition/gel-electrophoresis-286> (accessed 20 December 2018).

³²⁰ A strand of a known wild type sequence is paired with a single strand of test sequence which contains a mutation.

gel electrophoresis where mismatches in the DNA migration can be seen.³²¹ The British patent for the BRCA2 gene was awarded to a consortium of the Cancer Research Campaign Technology and Duke University and this consortium granted an exclusive licence for diagnostic services to the company OncorMed.³²² The latter had to meet certain strict conditions in exercising its licence.³²³ OncorMed and Myriad Genetics sued one another for patent violations resulting in Myriad Genetics obtaining exclusive rights to OncorMed's patents in exchange for undisclosed fees.³²⁴ This led to a discontinuation of OncorMed offering BRCA1 and BRCA2 genetic testing services. In addition, several European laboratories that had set up testing before the EPO granted Myriad's patent application for the BRCA1 gene suddenly faced an unexpected situation where the BRCA1 testing would either become impossible in the European laboratories, or significantly more expensive.³²⁵

The implication of the situation was a wave of opposition to the patenting of diagnostic genes across Europe.³²⁶ There was mounting opposition to the patents, including opposition from scientists and laboratories in countries such as France, Belgium, the United Kingdom, the Netherlands, Sweden, Spain and Germany. Institute Curie and the Institute Gustave-Roussy filed a formal opposition.³²⁷ Great concern was also generated when a team of scientists led by a Curie geneticist published a report in the *Journal of Medical Genetics* alleging a new mutation on the BRCA1 gene.³²⁸ The mutation was found on a patient diagnosed with breast cancer. The patient underwent Myriad's test, but the test failed to pick up this particular mutation on the gene as it cannot pick up large DNA deletions or rearrangements.³²⁹ The scientists claim that Myriad's test omits up to 20 per cent of expected BRCA1 mutations and as a result, the patent is too broad. It prohibits the distribution of alternate tests by Curie.³³⁰

The French Ministry of Health and the Ministry of Research expressed full support of the opposing action. The Institute's initiative aims to curtail the consequences of a monopoly in France and in Europe, which the Institute claims would jeopardise developing research, hinder access to testing and disrupt the national health system.³³¹ They state that: "it is clear that the Myriad test is not the gold standard. It only detects small mutations and deletions but not large rearrangements of the gene. There are various techniques

³²¹ Williams - Jones B *History of the Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 134 -135.

³²² *Ibid* 123.

³²³ Conditions include broad sublicensing of diagnostic tests to other companies, a requirement for pre - and post-test counselling for women tested, a ban on direct advertising to the public for screening tests and no charge for use of the techniques by the UK National Health Service.

³²⁴ For more information see *supra* note 321 at 123.

³²⁵ Patent application EP705902. *Supra* note 321 at 134 -135. For more discussion see also Matthijs G *The European Opposition Against the BRCA Gene Patents* Springer Familial Cancer 2006 5 97.

³²⁶ See *ibid*.

³²⁷ Benowitz S *French Challenge to BRCA1 Patent Underlies European Discontent* Journal of National Cancer Institute 2002 Vol 94(2) 80-81 available at <http://jnci.oxfordjournals.org/content/94/2/80.long> (accessed 18 September 2015).

³²⁸ The team was led by Dominique Stoppa-Lyonnet.

³²⁹ Matthijs G, Huys I, Van Overwalle G et al *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines* Nature Biotechnology 2013 Vol 31(8) 708.

³³⁰ *Ibid*.

³³¹ Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 25(1) 20-33.

that can be used".³³² In the same year three French organisations,³³³ and a coalition of the Belgian, Dutch, British, Danish and German genetic societies filed an opposition procedure against the Myriad Genetics' European patent on BRCA1.³³⁴

Oppositions were also filed concerning the BRCA2 patent which was granted to Myriad Genetics and the University of Pennsylvania, by several parties, including the French and Belgian led groups.³³⁵ In February 2002 an opposition against the third patent³³⁶ was filed by the original 'Belgian – Dutch' initiative and was further extended to include molecular and clinical geneticists, oncologists and cancer researchers from Austria, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Italy, the Netherlands, Switzerland and the United Kingdom.³³⁷

The parties claim that the patent held by Myriad Genetics is invalid as it suffers from a lack of novelty arising from the availability of several predisposition tests based on indirect methods. They also claim that granting monopoly rights seems legitimate when patents are based on human invention but as genetic tests patents are based on comparison to a known normal gene sequence, there are several different technologies that can be used and these are widespread and available to the "non-lay person".³³⁸

The opposing parties further argue that there is a lack of 'inventive step' because the patentees have benefited from prior research through a global consortium and that diagnostic methods on the human body are not patentable in accordance with Article 52(4) the EPC.³³⁹ They argue that "the patent application, as granted, has an excessively broad scope which does not correspond to the significance of Myriad's contribution to the public domain, at the date the patent was filed. At the time, the global public consortium had already located the BRCA1 gene and had already provided considerable information regarding the gene and its relevance for detecting breast and ovarian cancer. What remained to be achieved, was the final sequencing, a routine operation the results of which should at the most be protected by limited

³³² For more details see Brinckerhoff CC *Dispelling the Myriad Gene Patent Harmonization Myth* 2013 available at <http://www.pharmapatentsblog.com/2013/04/30/dispelling-the-myrriad-gene-patent-harmonization-myth/> (accessed 19 September 2015). See also Andrews LB *Patents: The Need for Bioethics Scrutiny and Legal Change* (with J Paradise) Yale Journal of Health Policy, Law and Ethics 2005 Vol 5 403.

³³³ These included the Curie Institute and the Institut Gustave-Roussy, the Assistance-Publique-Hôpitaux de Paris. See Lecrubier A *Patents and Public Health* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308311/> (accessed 22 September 2015).

³³⁴ Patent EP-B-699754. Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 Vol 10 783 – 784.

³³⁵ Patent EP785216. For more discussion see Fowler CA *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide* American University International Law Review 2010 Vol 25(5) 7 1074. See also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

³³⁶ Patent EP-B-705902. Minutes of the oral proceedings for patents EP0705902 and EP0705903 are available for download at the EPO's online public file inspection on <http://ofi.epoline.org/view/GetDossier>. For more discussion see Verbeure B, Matthijs G & Van Overwalle G *Analysing DNA Patents in Relation with Diagnostic Genetic Testing* European Journal of Human Genetics 2006 Vol 14 26–33. See also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

³³⁷ Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 Vol 10 783 – 784. See also Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 Vol 25(1) 20-33.

³³⁸ *Supra* note 330. See also Lecrubier A *Patents and Public Health* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308311/> (accessed 22 September 2015).

³³⁹ *Ibid.*

monopoly rights”.³⁴⁰ Michael Stratton, a Professor of Cancer Genetics at the Institute of Cancer Research commented as follows regarding inventive step:

“The identification of a gene such as BRCA1 and 2 is the culmination of several years of work requiring the input of activities and information from several groups. It is such as building a wall--the final brick in the wall is the identification of the gene. And awarding the patent, conversely the full rewards to those individuals, to that group that has put that last brick in the wall, is unfair because it does not recognise the contribution of others.”³⁴¹

Skolnick of Myriad argues that patents for BRCA1 and BRCA2 should be approved if the benefits from the research are to be realised. He claimed that, rather than letting lots of companies compete for a relatively small market, it would have been more effective if there had been one licensee, which would acquire enough money eventually to invest in developing a screening kit.³⁴²

Myriad claim that they had invested millions of dollars in a system which does fast and accurate testing and testing performed by mediocre labs could not detect mutations they should have detected.³⁴³ The Institute Curie argues that Myriad’s approach undermines the public health system in France and other European countries:

“Myriad's monopoly position has provided rise to a market for genetics in the US which tends to dissociate actual testing from genetic counselling and high-risk patient-care and follow-up. This approach goes much against the way we view public health care, in France and in most other European countries, where clinicians work within a model which integrates biological research, clinical investigation and patient-care, considering the medical and psychological aspects of diagnosis and the clinical history of high-risk patients and their families”.³⁴⁴

The court held that European patents on BRCA1 and BRCA2 held by Myriad are drastically reduced in scope. Infringing laboratories will have to be brought before a national court and it is uncertain whether the patents would be considered valid after a further exhaustive review in such courts.³⁴⁵ The proprietor and opponents both lodged appeals against the EPO’s decision. In May 2004, the EPO revoked one of Myriad’s patents on the basis that the product by-process claim did not meet the requirements of the

³⁴⁰ Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 25(1) 20-33. See also Lecrubier A *Patents and Public Health* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308311/> (accessed 22 September 2015).

³⁴¹ For more discussion see Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 Vol 10 783 – 784.

³⁴² Rimmer M *Myriad Genetics: Patent Law and Genetic Testing* European Intellectual Property Review 2003 25(1) 20-33. See also Lecrubier A *Patents and Public Health* available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1308311/> (accessed 22 September 2015).

³⁴³ *Ibid.*

³⁴⁴ For more discussion see Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 Vol 10 783 – 784.

³⁴⁵ Matthijs G, Huys I, Van Overwalle G et al *The European BRCA Patent Oppositions and Appeals: Coloring Inside the Lines* Nature Biotechnology 2013 Vol 31(8).

Article 123(2) EPC. It was not supported by the original application as filed.³⁴⁶ The patent was amended and reinstated during 2008, but excludes the actual gene from the patent.³⁴⁷ The European Parliament expressed concern that the granting of patents by the EPO could create a monopoly for Myriad Genetics, which could seriously impede the further use of existing genetic tests for breast cancer. It stresses that this development could have an unacceptable detrimental effect on the women concerned constituting a drain on public health funding and impeding research into new methods of diagnosis.³⁴⁸

6.3.8 EU trade agreements

Post TRIPS, much like the US,³⁴⁹ the EU also entered into TRIPS Plus agreements³⁵⁰ with developing countries.³⁵¹

Unlike the US, whose agreements are regulated under NAFTA, the EU has no 'model FTA' that forms the basis of negotiations.³⁵² Guidelines and strategies are however set out by the European Commission.³⁵³ The European Commission is an independent executive arm of the EU. It is responsible for drawing up proposals for new European legislation, and implementing decisions of the European Parliament and the Council of the EU.³⁵⁴ Historically, the EU approach to intellectual property has been to negotiate agreements containing the highest international standards of intellectual property.³⁵⁵ During 2006 the EU increased activities in relation to FTA's and started to adopt higher standards of intellectual property protection.³⁵⁶ The European Commission explicitly stated that its approach to intellectual property was to increase protection:

"[t]he EU should seek to strengthen IPR [Intellectual Property Right] provisions in future bilateral agreements and the enforcement of existing commitments"³⁵⁷

³⁴⁶ *Ibid.*

³⁴⁷ Andrews LB & Paradise J *Gene Patents: The Need for Bioethics Scrutiny and Legal Change* Yale Journal of Health Policy Law and Ethics 2005 Vol 5(1) 13. See also Williams-Jones B *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing* Health Law Journal 2002 Vol 10 139.

³⁴⁸ For more discussion, see Matthijs G & Halley D *European-Wide Opposition Against the Breast Cancer Gene Patents* European Journal of Human Genetics 2002 Vol 10 783 – 784.

³⁴⁹ See section 6.2.5

³⁵⁰ For a full discussion on TRIPS Plus agreements and how they operate see section 4.5.

³⁵¹ Andere CE *Bilateral Investment Treaties and the EU Legal Order: Implications of the Lisbon Treaty* Brooklyn Journal of International Law 2010 Vol 35(3).

³⁵² Woolcock S *European Union Policy Towards Free Trade Agreements* CIPE Working Paper 2014 available at <http://www.ecipe.org/app/uploads/2014/12/european-union-policy-towards-free-trade-agreements.pdf> (accessed 02 November 2018).

³⁵³ *Ibid.*

³⁵⁴ For more information on the European Commission's role see https://europa.eu/european-union/about-eu/institutions-bodies/european-commission_en#overview (accessed 02 November 2018).

³⁵⁵ The European approach to intellectual property in Europe partnership agreements with the African, Caribbean and Pacific group of countries - Discussion paper April 2007 available at http://www.ciel.org/Publications/EU_EPAs_Draft_18Apr07.pdf (accessed 02 November 2018).

³⁵⁶ *Ibid.*

³⁵⁷ European Commission *Global Europe: Competing in the World* EC Policy Review 2006 (available at http://ec.europa.eu/trade/issues/sectoral/competitiveness/global_europe_en.htm). See also Intellectual Property Quarterly update 2006 4th Quarter (available at https://www.ciel.org/wp-content/uploads/2015/03/IP_Update_4Q06.pdf (accessed 02 November 2018)).

This change in approach unifies with the US approach toward FTA's.³⁵⁸ 2015 brought a revision of the EU trade and investment policy to develop a comprehensive access to medicine policy. The revision aimed to ensure that future trade and investment agreements reinforced public health in developing countries.³⁵⁹ However, upon investigation Health Access International³⁶⁰ and Médecines Sans Frontières³⁶¹ have found the Commission's revisions to be "empty words and gestures" with TRIPS Plus agreements still being entered into in full force.³⁶²

In addition, similar to the USTR, the Commission uses other areas of its trade policy to pressure developing countries into refraining from utilising TRIPS flexibilities, including placing developing countries on a trade watch list.³⁶³ A 'priority country list' is produced by the Commission³⁶⁴ and contains country specific reports outlining perceived deficiencies in these countries' intellectual property frameworks.³⁶⁵ The Commission denounces the use of certain intellectual property measures provided by TRIPS including the use of compulsory licensing. Commission has also put certain countries, including Brazil and India, on its 'watch list' for using different and often stricter standards for granting pharmaceutical patents.³⁶⁶

The EU currently has FTA's with Mexico, Chile, South Africa, Tunisia, Morocco, Egypt, Turkey, India and Lebanon. Agreements with ECOWAS,³⁶⁷ SADC,³⁶⁸ CARIFORUM,³⁶⁹ CEMAC,³⁷⁰ Pacific,³⁷¹ Central America,³⁷² MERCOSUR,³⁷³ Andean Countries,³⁷⁴ Algeria, Cyprus, Israel, Jordan, Malta, Syria, Tunisia, Palestine and ASEAN³⁷⁵ are still under negotiation.³⁷⁶ The terms of these agreements are similar to those of the US.

³⁵⁸ Review of the European Union's Trade & Investment Policy *Empty Gestures: The EU's Commitments to Safeguard Access to Medicines* Health Action International 2015 available at <http://haiweb.org/publication/empty-gestures-the-eus-commitments-to-safeguard-access-to-medicines/> (accessed 02 November 2018).

³⁵⁹ *Ibid.*

³⁶⁰ For more information of Health Access International see <https://www.healthaccessinternational.com/> (accessed 02 November 2018).

³⁶¹ For more information on Médecines Sans Frontières see <https://www.msf.org/> (accessed 02 November 2018).

³⁶² Review of the European Union's Trade & Investment Policy *Empty Gestures: The EU's Commitments to Safeguard Access to Medicines* Health Action International 2015 available at <http://haiweb.org/publication/empty-gestures-the-eus-commitments-to-safeguard-access-to-medicines/> (accessed 02 November 2018).

³⁶³ *Ibid.*

³⁶⁴ The Commission's watch list can be found on their website at http://ec.europa.eu/trade/policy/countries-and-regions/index_en.htm (accessed 02 November 2018).

³⁶⁵ *Ibid.*

³⁶⁶ More discussion on Brazil and India's approach to pharmaceutical patents can be found in chapter 6. See also *supra* note 363.

³⁶⁷ Benin, Burkina Faso, Cape Verde, Côte d'Ivoire, The Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Sierra Leone, Senegal and Togo.

³⁶⁸ Angola, Botswana, Lesotho, Mozambique, Namibia, Swaziland and Tanzania.

³⁶⁹ Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St. Kitts & Nevis, St. Lucia, St. Vincent & the Grenadines, Suriname and Trinidad & Tobago.

³⁷⁰ Cameroon, Central African Republic, Chad, Democratic Republic of Congo, Congo, Equatorial Guinea, Gabon and São Tomé & Príncipe.

³⁷¹ Cook Islands, Fed. States of Micronesia, Fiji, Kiribati, Rep. of the Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu.

³⁷² Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica and Panama.

³⁷³ Argentina, Brazil, Paraguay and Uruguay.

³⁷⁴ Venezuela, Bolivia, Colombia, Ecuador and Peru.

³⁷⁵ Brunei, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam.

³⁷⁶ *Signing Away the Future: How Trade and Investment Agreements Between Rich and Poor Countries Undermine Development* Oxfam Briefing Study 2007. See also Nasu H *Public Law Challenges to the Regulation of Pharmaceutical Patents in the US Bilateral Free Trade Agreement* ANU College of Law Research study No 10-53 <http://ssrn.com/AuthorID=677218> (accessed 02 June 2015). See also Bartucci S & Dawson L *Use in conclusion maybe? Strong Medicine: Can Free Trade Agreements Cure Canada's Pharmaceutical Ills? Pills Patents & Profits III* 2013 Macdonald-Laurier Institute 14.

6.4 Conclusions

Most patents are filed in developed countries; most notably Japan, Europe and the US.³⁷⁷ The patent requirements in both the US and Europe are similar however, issues of priority, utility and added subject matter are of particular sensitivity in Europe. US courts progressed into accepting genes as patentable and has only recently ruled against the patenting of isolated DNA, while allowing synthesized and cDNA to be patented.³⁷⁸ As opposed to the US, in Europe there is no doubt in the last 15 years that isolated genomic DNA is not patentable, but cDNA is patentable as specified in the EU Biotechnology Directive.³⁷⁹ The Biotechnology Directive 98/44/EC clearly indicates that inventions founded isolated human elements or otherwise created through technical processes and have an industrial use, is not exempt from patentability, regardless of whether it is structurally identical to its natural counterpart.³⁸⁰ Isolated genes are not excluded from patentability as the legislator takes the view that an isolated gene contains technical information, in the sense that the aspect of “isolation” is considered to be the result of “technical processes used to identify, purify and classify it, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself”.³⁸¹

Comparing the US with European views in the *Myriad* case indicates the differences in law within these jurisdictions regarding the issue of diagnostic gene tests.³⁸² The US courts holding in *Myriad*³⁸³ that naturally occurring gene sequences are not patent-eligible merely because they have been isolated has no clear counterpart under either the European Patent Convention (EPC) or the national laws of Germany. Isolated gene sequences are patentable under the EPC. The national laws of Germany are more stringent; however, these laws are likely to remain untested for the foreseeable future as it is more pragmatic to file via the European Patent Office (EPO).

From the above discussion we find that both the US and EU, having strong biotechnology industries, thrive for high levels of intellectual property protection. Legislation is drafted with the aim to promote innovation and the judicial protection of such innovation.³⁸⁴ The EU does show more compassion toward rights effecting health care but still maintain strong levels of protection.³⁸⁵

³⁷⁷ Khan BZ *An Economic History of Patent Institutions* <https://eh.net/encyclopedia/an-economic-history-of-patent-institutions/> (accessed 18 September 2015).

³⁷⁸ *Association for Molecular Pathology v Myriad Genetics Inc.* 569 U.S. 576 (2013).

³⁷⁹ Article 5(2) of the Biotechnology Directive. For discussion see Cook T *How Europe Has Learnt to Deal with Exclusions from Patentability* Journal of Intellectual Property Rights 2013 Vol 18 377-381.

³⁸⁰ Rule 29(2) and Recital 20. For discussion see Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: Comparison Under Current European and US Patent Law* European Journal of Human Genetics 2011 Vol 19 1104–1107.

³⁸¹ Recital 21. For discussion see Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: A Comparison Under Current European and US Patent Law* European Journal of Human Genetics 2011 Vol 19 1104–1107.

³⁸² For discussion see Huys I, Matthijs G & Van Overwalle G *Gene and Genetic Diagnostic Method Patent Claims: A Comparison Under Current European and US Patent Law* European Journal of Human Genetics 2011 Vol 19 1104–1107.

³⁸³ *Association for Molecular Pathology v Myriad Genetics Inc.* 569 U.S. 576 (2013).

³⁸⁴ Proposed Restoring American Leadership in Innovation Act of 2018.

³⁸⁵ The Biotechnology Directive 1998.

When analysing the status of the right to health and property, the resistance applied by several EU countries against the patenting of genes and gene sequences it is safe to conclude that this property right is not of equal standing to the right to health within the EU. However, within the US, legislation and courts seem to favour the right to property and strive for strong intellectual property right

Chapter 7

Comparative study

7.1 Intrinsic Patenting of Diagnostic Genes in Developing Countries

This chapter aims to analyse the way that developing countries address biotechnology/pharmaceutical patents and whether intellectual property aims differ to the developed countries discussed in the previous chapter. Unlike developed countries, developing countries would generally promote weaker intellectual property rights or use tools such as compulsory licences in order to promote accessibility. Economic strain and diversity in research capacities¹ result in developing countries addressing the matter differently. This chapter analyses these jurisdictions in order to compare the patent regimes considering, historical context, research capacity and existence of a local based biotechnology industry. Patent requirements are not analysed in detail as it has already been established that genes (or rather certain types of genes)² are globally accepted as patentable and minimal or no biotechnology related case law within these jurisdictions. The focus within these jurisdictions is on accessibility to biotechnology/pharmaceuticals. The chapter also discusses steps taken, including legislative amendments and court decisions, by each jurisdiction to increase access to pharmaceuticals in order to evaluate the value/weight of the two rights within each jurisdiction. The legal position in these jurisdictions are subsequently examined to gain a reformist perspective.

7.2 The Brazilian Position

Brazil is a country that has faced tension within the intellectual property and health care regimes. Unaffordable pharmaceuticals and the increased need to access pharmaceuticals lead the Brazilian government to take the steps needed to ensure that most of its public could access essential pharmaceuticals. The discussion below aims to provide an understanding of the development of Brazilian intellectual property law and how current patent laws address biotechnology and pharmaceutical patents, including diagnostic genes, in order to provide both protection and accessibility despite facing pressure from developed countries to enforce stronger intellectual property.

¹ Brazil and India both have relatively well-developed biotechnology industries, while South Africa does not.

² Post *Myriad*, these are synthesised genes like cDNA.

7.2.1 History of Brazilian patent law

Being a country that underwent rapid and revolutionary economic growth, Brazil rapidly joined the ranks of other leading countries in the world of patents and intellectual property laws. Brazil was the fourth country to enact a patent law in 1809 and after gaining independence from Portugal in 1822, Brazil became one of the founding members of the Paris Convention for the Protection of Industrial Property in 1883.³ Brazil's Industrial Property law 5.648 of 1970 excludes both pharmaceutical product and process patents.⁴

During the 1980s negotiations within the WTO promoting a *New International Economic Order* agenda, Brazil faced harassing and threatening comments from the US for their weak enforcement of intellectual property rights.⁵ In 1987, Brazil had still not provided for the patenting of biotechnological/pharmaceutical products and processes and the US, tired of Brazil's failure to denounce the piracy of pharmaceutical products and process, imposed special section 301 actions against Brazil.⁶ The sanctions imposed a 100 per cent tariff on \$39 million worth of Brazilian imports to the US, justified as the "amount was equivalent to the market loss that the US pharmaceutical makers arising from Brazil's relative lack of patent protections for pharmaceuticals".⁷

In 1995 the country became a member of the WTO and a dramatic shift in pharmaceutical production policy followed.⁸ Subsequent to the TRIPS Agreement coming into force, Brazil had to look into granting patents for pharmaceuticals to become compliant with Article 27.⁹

In 1996 the Cardoso administration led the Brazilian Congress to amend the patent laws and Law no 9,279 was enacted to allow for the patentability of pharmaceutical product patents so that subject to procedural processes and certain restrictions, only patent-holders or their licensees would be permitted to market patented pharmaceuticals.¹⁰ TRIPS compliance affected the cost of pharmaceuticals as the possibility of generic production was eliminated.

³ Brazil adopted the French Civil Code enacted by Napoleon in 1804 as the foundation for intellectual property laws. See Deere C *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* 2009 35.

⁴ <http://www.wipo.int/wipolex/en/details.jsp?id=515> (accessed 02 June 2016).

⁵ Ryan MP *Patent Incentives, Technology Markets and Public-Private Bio-Medical Innovation Networks in Brazil* World Development 2010 Vol 38(8) 1082. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics 2009 Vol 42(1) 41-58.

⁶ Bass NA *Implications of the TRIPS Agreement for Developing Countries* George Washington International Law Review 2002 Vol 34 206.

⁷ Brazil's ambassador in Washington recalls that retaliations were imposed in the second half of 1988 on products from Brazil in two areas—pulp and study and electronic appliances. For more discussion see *supra* note 5.

⁸ *Supra* note 5.

⁹ For discussion see Guise Rosina MS, Wang D & De Campos TC "Access to Medicines: Pharmaceutical Patents and The Right to Health" (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project 2008 Yale Law School 182. See also Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics 2009 Vol 42(1) 41-58. See also Da Gama Camara E *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* 2013 IP Litigator 13.

¹⁰ *Ibid.*

7.2.2 Applicable legislation

7.2.2.1 The Brazilian Constitution

Brazil is a democratic country with both an executive and legislative branch. The latter constitutes the Federal Senate and the Chamber of Deputies, comprising the National Congress. Each state in Brazil is assigned a governor and an elected legislature.¹¹ The *Constituição da República Federativa do Brasil de 1988* (Brazilian Federal Constitution of 1988) Brazilian enshrines both the right to health and the right to property.¹² Article 196 affords individuals the right to health and it is the responsibility of the state to reduce the risk of illness and other hazards by means of social and economic policies and increasing access to services for health protection and the recovery of individuals.¹³

The right to health is qualified as a fundamental right, implementing it through the enactment of Law 8.080/90 and Law 8.142/90, established by the *Sistema Único de Saúde* (National Health System - SUS). This is the public health system providing health care coverage to all Brazilian citizens.¹⁴

Regarding the right to property, Article 5 item XXIX of the Constitution states that protection is provided for industrial creations and temporary privileges on using industrial inventions by their creators.¹⁵

To this effect Article 5, XXIX states:

“The law shall ensure the authors of industrial inventions of a temporary privilege for their use and protection of industrial creations, property of trademarks, names of companies and other distinctive signs, weighing the social interest against the country’s technological and economic development.”¹⁶

¹¹ <http://www.brazil.org.za/politics-intro.html> (accessed 20 November 2016.)

¹² The Constitution can be accessed at <http://english.tse.jus.br/arquivos/federal-constitution> (accessed 08 October 2018).

¹³ Brazilian Federal Constitution of 1988. For further discussion on the Brazilian Constitution provisions relating to health see Cristina de Campos T & Pogge T *Pharmaceutical Firms and the Right to Health* Journal of Law, Medicine & Ethics 2012 183. See also Guise Rosina MS, Wang D & De Campos TC “Access to Medicines: Pharmaceutical Patents and the Right to Health” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 167.

¹⁴ Even though the Constitution does not make explicit mention of access to medicines as part of the right to health, implementing legislation, Article 6(I)(d) of the Law 8.080/90, provides that SUS “must be responsible for promoting full medical assistance. Ordinance 3.916/98 created the National Policy on Medicines is also directed at guaranteeing access to medicines through affordable prices. See Guise Rosina MS, Wang D & De Campos TC “Access to Medicines: Pharmaceutical Patents and the Right to Health” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 167.

¹⁵ Yumy V & Kunisawa M “*The Brazilian Patent System: Challenges for the Future*” (editor) Shimanami R *The Future of the Patent System* 2012 283.

¹⁶ This clause is in line with TRIPS flexibilities which allow member states to decide on whether they would want to allow parallel importation or not. The latter could effectively increase access to essential drugs.

7.2.2.2 Industrial Property Law 9.279/1996

Law No 9279 was enacted in 1996 to regulate rights relating to industrial property.¹⁷ Brazil uses the “first-to-file” patent system similar to the jurisdictions mentioned above. An invention is required to be new; include an inventive step and be capable of being used in the industry.¹⁸

Concerning biotechnology patents, Brazilian patent law is restrictive. Chemical products can be patented provided they fulfil patent criteria: if DNA sequences are viewed as chemical products, they may be patentable; a court or the Brazilian Patent Office, depending on the type of DNA claimed, may conclude that DNA is not a large polymer and therefore a chemical product patent can be granted.¹⁹

Natural living beings and biological material found in nature or isolated from a natural living being, are not patentable according to Article 10, item IX.²⁰ Article 10 amongst others, excludes discoveries and rules of or diagnostic methods, for use on the human or animal body.²¹

Article 18 expressly prohibits inventions that are:

“... contrary to morals, good customs and public security, order and health” and “living beings, in whole or in part, except transgenic microorganisms meeting, the three patentability requirements - novelty, inventive activity and industrial application - provided for in Article 8 and which are not mere discoveries”.²²

Natural substances even if purified and isolated, are not patentable subject-matter but synthetic polynucleotides, polypeptides, antibodies, recombinant DNA structures and vectors are patentable subject-matters. The Act also excludes methods of surgical, therapeutic or diagnostic treatment,

¹⁷ Yumy V & Kunisawa M “*The Brazilian Patent System: Challenges for the Future*” (editor) Shimanami R *The Future of the Patent System* 2012 283.

¹⁸ These requirements are in line with those of the jurisdictions discussed in the previous chapter. The requirement of inventive step is a new requirement expressed for the first time by Law 9279. Article 8 Industrial Property Law 9.279/1996. See Da Gama Camara E *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* IP Litigator 2013 13.

¹⁹ This is dependent on how DNA is processed see *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* Report Information from ProQuest available at <http://search.proquest.com/docview/1355493717?accountid=8630> (accessed 20 April 2016). See also *supra* note 17. See also Guise Rosina MS, Wang D & De Campos TC “*Access to Medicines: Pharmaceutical Patents and the Right to Health*” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 169.

²⁰ The Act can be found at http://www.wipo.int/wipolex/en/text.jsp?file_id=125397 (accessed 31 May 2016). See also *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* Report Information from ProQuest available at <http://search.proquest.com/docview/1355493717?accountid=8630> (accessed 20 April 2016).

²¹ Also excluded are scientific theories and mathematical methods; purely abstract concepts; schemes, plans, principles or methods of a commercial, accounting, financial, educational, publishing, lottery or fiscal nature; literary, architectural, artistic and scientific works or any aesthetic creation; computer programmes; the presentation of information; Article 2 –8. Da Gama Camara E *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* IP Litigator 2013 14.

²² The Act can be found at http://www.wipo.int/wipolex/en/text.jsp?file_id=125397 (accessed 31 May 2016). These requirements are in line with those of the jurisdictions discussed in the previous chapter. The requirement of inventive step is a new requirement expressed for the first time by Law 9279. Article 8 Industrial Property Law 9.279/1996. See Da Gama Camara E *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* IP Litigator 2013 13.

applicable to the human body or to animals. Note that whilst products destined to put methods into practice, methods outside the body or non-therapeutic are patentable whilst first and second medical uses are patentable as a Swiss-type if inserted into the claim set, prior to the request for examination.²³

According to Article 229-C of the Act, after being examined by the INPI²⁴ any pharmaceutical patents should go to the Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency – ANVISA) for a technical examination.²⁵ Article 229-C states as follows: “The grant of patents to pharmaceutical products and processes will depend on the previous approval of the National Health Surveillance Agency”.²⁶

The 1996 Brazilian Industrial Property Act does provide for patent applications to be filed for previously non-patentable subject-matter with minimal administrative review in Articles 230 and 231. This is on the condition that the patent was previously granted in another country. This is known as a “pipeline” review and is a commonly used TRIPS Plus mechanism.²⁷

Article 230 (3) of the Industrial Property Act provides that:

“Once the provisions established in this Article have been satisfied and the granting of the patent in the country where the first application filed proved, the patent shall be granted in Brazil, just as it was granted in its country of origin.”²⁸

The Act also allows foreign manufactures to only obtain a Brazilian patent if part of the goods were produced in Brazil. This is known as the “local working” requirement. Should a manufacturer fail to satisfy this requirement, they may be subject to compulsory licences.²⁹

7.2.2.3 National Institute of Industrial Property and ANVISA

The INPI is the Brazilian Governmental authority responsible for examining and granting patents.³⁰ The INPI analyses polynucleotides, synthetic polynucleotides and proteins as chemical compounds for

²³ Galvão de Botton L *Patent Protection of Biotechnology Inventions in Brazil* AIPLA Webinar 2013.

²⁴ See section 7.2.2.3 for more on the INPI.

²⁵ For more discussion see Sampat BN & Shadlen KC *TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India* Studies in Comparative International Development 2015 50 228–257.

²⁶ This is discussed in detail in section 7.2.2.3 below. See Da Gama Camara E *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* IP Litigator 2013 13.

²⁷ Guise Rosina MS, Wang D & De Campos TC “Access to Medicines: Pharmaceutical Patents and the Right to Health” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 185.

²⁸ Industrial Property Law 9.279/1996. This is valid assuming the requirements of patentability was met as a patent was already granted elsewhere in the world. Certain medicines that would not usually qualify for a Brazilian patent may still gain one through the pipeline process. The Act can be found at http://www.wipo.int/wipolex/en/text.jsp?file_id=125397 (accessed 31 May 2016). See *supra* note 27.

²⁹ Industrial Property Law 9.279/1996.

³⁰ For more discussion on the INPI see Yumy V & Kunisawa M “The Brazilian Patent System: Challenges for the Future” (editor) Shimanami R *The Future of the Patent System* 2012 287.

patentability purposes. It also considers products expressed by cultures and transformed by expression vectors to be chemical compounds. Additionally, DNA sequences, vectors, plasmids are all treated as chemical compounds.³¹ According to the INPI any substance isolated from nature (even with an industrial application) cannot be patented as there is a lack of a novelty or an inventive step. The prohibition of article process patents is allowed.³²

As mentioned above,³³ the Act allows for the patenting of pharmaceuticals. The government established ANVISA, an institution equivalent to the FDA in the US and to the EMEA in Europe, stipulating that pharmaceutical patent applications require an approval from ANVISA.³⁴ The latter is an independent regulatory agency that manages the National Sanitary Surveillance System, monitors drugs and medical equipment prices, participate in regulating and inspecting producing generic medicines and works with INPI in the granting of pharmaceutical patents.³⁵

Ordinance no 1065 of 2012, requires pharmaceutical patent applications to first be sent to ANVISA for analysis. Only upon ANVISA's approval can the INPI examine the application on the merits.³⁶

According to the Ordinance, applications will follow these steps:

- Step 1: The first formal examination of the documentation of the patent application is completed by the INPI.
- Step 2: Once the application is approved, the INPI will identify the type of product and process and forward the application to ANVISA if related to pharmaceuticals.
- Step 3: ANVISA completes a technical examination and publishes their opinion in the Federal Official Gazette. This opinion will include their decision on granting prior consent of the application.
- Step 4: Once published, ANVISA will return the applications to the INPI.
- Step 5a: If the application is approved by ANVISA, the INPI will examine the technical application and publish the granting or rejection of the patent in the Brazilian Industrial Property Journal.
- Step 5b: If the application is not approved by ANVISA, the INPI will shelve the application and will publish such shelving in the Brazilian Industrial Property Journal.³⁷

³¹ For more discussion on the INPI see Yumy V & Kunisawa M "The Brazilian Patent System: Challenges for the Future" (editor) Shimanami R *The Future of the Patent System* 2012 287. See also Sampat BN & Shadlen KC *TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India* Studies in Comparative International Development 2015 50 228–257.

³² Resolution (RDC) No 45.

³³ In section 7.2.2.2

³⁴ *Supra* note 32. See also *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* Report Information from ProQuest available at <http://search.proquest.com/docview/1355493717?accountid=8630> (accessed 20 April 2016).

³⁵ ANVISA is the public entity that carries out a sanitary control of the production and commercialization of products and services in the health industry of Brazil. See Guise Rosina MS, Wang D & De Campos TC "Access to Medicines: Pharmaceutical Patents and the Right to Health" (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 185.

³⁶ *Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA* Report Information from ProQuest available at <http://search.proquest.com/docview/1355493717?accountid=8630> (accessed 20 April 2016).

³⁷ *Ibid.*

- Subsequently, in 2013, a new change was introduced to the procedure, stating that ANVISA will only examine cases involving subject-matter considered to be “contrary to public health”. For ANVISA to be involved, the application should relate to:
 - A pharmaceutical product or process that poses a health risk; a product, banned in Brazil, or a process producing such a product; or
 - A pharmaceutical product or process of interest to the policies or medicines or pharmaceutical assistance within the National Public Health System;
 - The product or process does not comply with the requirements of Brazilian intellectual property law.³⁸

7.2.3 Steps taken to increase access to pharmaceuticals

As mentioned previously, prior to 1996, Brazil did not offer patent protection for biotechnological/pharmaceutical products and processes, including diagnostic gene patents. Brazil aimed to copy branded pharmaceuticals and offer these at a lower cost. Until 1996, both branded and “similar” pharmaceuticals could be obtained in Brazil.³⁹ After the implication of the TRIPS Agreement, obtaining pharmaceutical patents became difficult and modifications were made to patent laws to facilitate government efforts to lower prices through compulsory licensing. The government enacted measures to encourage competition with generics.⁴⁰ This was achieved in accordance with the Ministry of Health’s obligations to provide access to medicines through the new national health care system.⁴¹

The Ministry of Health’s initiative to lower the cost of medicine through promoting generics led to three important modifications of Brazil’s new intellectual property system including: health authorities gaining importance in reviewing patent applications, flexibility of compulsory licensing provisions and introducing regulatory reforms to expedite post-patent generic entry.⁴² Law 9.279/96 provides for pharmaceutical patent applications to be approved by the INPI and sent to the Ministry of Health for review.⁴³ The patent is issued after intellectual property officials in the Ministry’s health surveillance agency, ANVISA issue prior consent.⁴⁴

³⁸ For more discussion see Gosain R & Advogados D *Brazil’s Pharma Saga* The Intellectual Property Magazine 2014 <http://www.intellectualpropertymagazine.com/patent/brazils-pharma-saga-99144.htm> (accessed 15 April 2016).

³⁹ Unlike similar drugs, generics are entirely interchangeable with reference drugs, the bioequivalence process being supervised by ANVISA. For more discussion see Guise Rosina MS, Wang D & De Campos TC “Access to Medicines: Pharmaceutical Patents and the Right to Health” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 199.

⁴⁰ As discussed in the section above.

⁴¹ Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics October 2009 Vol 42(1) 41-58.

⁴² *Ibid.*

⁴³ Guise Rosina MS, Wang D & De Campos TC “Access to Medicines: Pharmaceutical Patents and the Right to Health” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 195.

⁴⁴ *Ibid.*

In 1999, Law 9.787/99, known as the Generic Statute, a legal framework for Brazilian generic drug production was established. These new rules define generic production, assuring the population with high quality-low-cost pharmaceuticals. The law allows for what is known as a Bolar exception⁴⁵, allowing third parties to manufacture patented drugs in limited quantities without a licence.⁴⁶

Subsequently, the Ministry of Health prioritised generic medicines for national drug purchases.⁴⁷ Thus, within the national health system, prescription of generic medicines is mandatory. In addition, the *Programa Farmácia Popular do Brasil* (Popular Drugstore Programme) was established by Decree 5.090/04 to promote access to medicines. The programme works through public and private drugstores that choose to participate.⁴⁸ The Ministry of Health purchases the medicines, sold by participating drugstores for up to 90 per cent below market prices.⁴⁹ The government's determination to render medicines accessible, is also illustrated by the Brazilian guidelines on post-trial access to drugs. This also ensures that research sponsors provide post-trial drugs to patients who participated in trials and experiments.⁵⁰

The disadvantage result in Brazil's generic drug industry is that there is hardly any local production of new drugs and little investment in research and development. Research found that national investments in research and development, if present, focussed on the drug-making process and not on developing new medicines. This makes the industry heavily dependent on the importation of innovations from abroad. It was also reported that over 80 per cent of active pharmaceutical ingredients used in the local production of generic drugs are imported.⁵¹ Global trade is truly at the heart of the Brazilian public health system, placing the country in a dangerous position.

In 2000, the Brazilian government also capped medicine prices well below the rate of inflation.⁵² Major global pharmaceutical companies, grouped together as Pharmaceutical Research and Manufacturers of America (PHRMA), vigorously opposed the government's decision to cap pharmaceutical prices. PHRMA called for changes in Brazil's rules on compulsory licensing of patents, protection of clinical test data from use by competitors and local manufacturing of patented products.⁵³

⁴⁵ The Bolar exception allows third parties to manufacture patented drugs in limited quantities without a licence.

⁴⁶ Guise Rosina MS, Wang D & De Campos TC "Access to Medicines: Pharmaceutical Patents and the Right to Health" (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 195.

⁴⁷ *Ibid.*

⁴⁸ Shadlen KC *The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies* Comparative Politics October 2009 Vol 42(1) 41-58.

⁴⁹ *Ibid.*

⁵⁰ Cristina de Campos T & Pogge T *Pharmaceutical Firms and the Right to Health* Journal of Law, Medicine & Ethics 2012 183.

⁵¹ For more discussion see Guise Rosina MS & Shaver L *Why Are Generic Drugs Being Held Up in Transit? Intellectual Property Rights, International Trade and the Right to Health in Brazil and Beyond* Journal of Law, Medicine & Ethics 2012 200.

⁵² This was due to the HIV/AIDS epidemic and lack of access to other medicines. For discussion see *BRAZIL/UNITED STATES: Tensions Over HIV Drug Patent Report* Information from ProQuest <http://search.proquest.com/docview/192437137?accountid=8630> (accessed 20 April 2016).

⁵³ *Ibid.*

By 2001 the International Federation of Pharmaceutical Manufacturers' Associations threatened that their members would stop investing in Brazil if the country continued to question intellectual property rights on medicines, or authorise compulsory licences.⁵⁴ In the same year the US filed a complaint with the WTO, alleging that the Brazilian law violates Article 27 of TRIPS and unfairly discriminates against foreign manufacturers.⁵⁵ The actions of the US represented an intensification of the pressure on the country to moderate its policies on pharmaceutical prices and patenting in addition to sending a message to other developing countries that the US will take a tougher line on intellectual property protection.⁵⁶ AIDS activists and the international health community backed the Brazilian government as these laws afforded low-cost or no cost HIV drug treatment. Health activists, including non-governmental organisations, such as Oxfam and Médecins Sans Frontières/Doctors without Borders also shared their support.⁵⁷ After an HIV/AIDS conference held by the UN, the US withdrew its complaint against Brazil.⁵⁸

In 2003 the government established the *Fórum de Competitividade de Biotecnologia* (Biotechnology Competitiveness Forum) to unite researchers and industry to define industry specific policy goals and opportunities.⁵⁹ The *Política de Desenvolvimento da Biotecnologia* (Biotechnology Development Policy) of 2007, aim is producing affordable drugs and medicines, investing in DNA sequencing research and nano-biotechnology.⁶⁰ The policy reflects the notion that collaborative partnerships in scientific research and development can be beneficial for businesses and society.⁶¹ Examples of research undertaken within the policy include the *Genoa Biotecnologia*⁶² and *Recepta Biopharma* projects involving molecular biology, genetics and bioinformatics.⁶³

7.2.4 Trade agreements

Prior to the 1990s, South American countries were historically amongst the most reactive to the liberalization and protection of Foreign Direct Investment (FDI), strongly influenced by the so-called “Calvo Doctrine” indicating that foreigners receive the same treatment as domestic investors and are subject to national regulation and courts.⁶⁴ During the 1990s Brazil executed a wave of bilateral investment treaties

⁵⁴ BRAZIL/UNITED STATES: *Tensions Over HIV Drug Patent* Report Information from ProQuest <http://search.proquest.com/docview/192437137?accountid=8630> (accessed 20 April 2016).

⁵⁵ Bass NA *Implications of the TRIPS Agreement for Developing Countries* George Washington International Law Review 2002 34 208.

⁵⁶ *Supra* note 54.

⁵⁷ Cohen JC & Lybecker KM *AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health* The World Economy 2005 223.

⁵⁸ *Supra* note 54.

⁵⁹ The Biotechnology Competition Forum represents the interests of the business sector.

⁶⁰ Other aims include affordable vaccines, biodegradable plastic, development of more effective and less polluting industrial enzymes, nutritious food and cosmetics from our bio-diverse environment and techniques of environment recovery.

⁶¹ Octaviani A “*Biotechnology in Brazil: Promoting Open Innovation*” (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 132.

⁶² HIV/AIDS related research.

⁶³ Recepta Biopharma in Sao Paulo is developing new pharmaceutical therapies for ovarian and breast cancers as existing pharmaceutical therapies for these cancers are effective only in a small percentage of patients. Ryan MP *Patent Incentives, Technology Markets and Public-Private Bio-Medical Innovation Networks in Brazil* World Development 2010 Vol 38(8) 1089.

⁶⁴ Campello D & Lemos L *The Non-Ratification of Bilateral Investment Treaties in Brazil: A Story of Conflict in a Land of Cooperation* Review of International Political Economy 2015 Vol 22(5) 1055 – 1086.

(BITs).⁶⁵ The country's transition from military to democratic aimed at attracting and protecting investment. General pressure from the public also urged the government to move fast to attract investors, in response to the competition entailed by the transition to capitalism of former communist countries. In addition, Argentina already took steps in this direction and Brazil was eager to join the competition for foreign investment.⁶⁶ The investment treaties signed by Brazil in the 1990s, belong mainly to the traditional paradigms of the North-South without incorporating prominent innovations of the International Law of Investments.⁶⁷

Treaties were signed with Portugal, Chile, the United Kingdom, Ireland and Switzerland in 1994; Denmark, Finland, France, Germany, Italy and Venezuela in 1995; Cuba in 1997; the Netherlands in 1998; and Belgium in 1999.⁶⁸ Fourteen other treaties were also signed but never reached ratification due to lack of approval by the National Congress and were removed from consideration. In 2002 renegotiation on existing treaties became necessary, due to a shift in opinion regarding bilateral agreements.⁶⁹ These include considering sovereignty and the principle of equality of nation states in the new order of global economic relations. Brazil seeks to create a new world order to defend justice and equality in global relations and North-South bilateral investment treaties contain an implication of inequality at the starting point with the contracting parties on various levels of economic development and the same obligations.⁷⁰

Despite encouraging and protecting foreign investments against unilateral acts by the host country, BITs pose restrictions on the host country's powers to control and regulate the flow of foreign investments considering to public interests.⁷¹ The seated president⁷² was made to withdraw all BITs from the Brazilian Congress as the enactment of alternative legislation and constitutional provisions rather than ratifying BITs allowed Brazil to avoid foreign investors exiting the country.⁷³

Till present, Brazil is not party to BITs. Only large developing countries such as Brazil could refrain from signing liberal BITs in the context of liberalisation of foreign investments. With Brazil being a resource-intensive country, the intention in the negotiations of the BITs was always to create a favourable environment to attract foreign investment and to guarantee that their resources are allocated appropriately.⁷⁴

⁶⁵ For more discussion see Welsh NA, Schneider AK & Rimpfel K *Using the Theories of Exit, Voice, Loyalty and Procedural Justice to Reconceptualize Brazil's Rejection of Bilateral Investment Treaties* Washington University Journal of Law and Politics 2014 Vol 45 108.

⁶⁶ Argentina had 59 treaties signed between 1990 and 2011. 54 of the 59 treaties were ratified within 2.5 years.

⁶⁷ Wei D *Bilateral Investment Treaties: An Empirical Analysis of the Practices of Brazil and China* European Journal Law Economics 2012 Vol 33 675.

⁶⁸ *Supra* note 65 at 112.

⁶⁹ *Supra* note 67 at 669. See also Campello D & Lemos L *The Non-Ratification of Bilateral Investment Treaties in Brazil: A Story of Conflict in a Land of Cooperation* Review of International Political Economy 2015 Vol 22(5) 1076.

⁷⁰ *Supra* note 67 at 672.

⁷¹ *Supra* note 67 at 663 -690.

⁷² President Cardoso.

⁷³ Welsh NA, Schneider AK & Rimpfel K *Using the Theories of Exit, Voice, Loyalty and Procedural Justice to Reconceptualize Brazil's Rejection of Bilateral Investment Treaties* Washington University Journal of Law and Politics 2014 Vol 45 at 121.

⁷⁴ *Ibid.*

7.2.5 Summary

Diagnostic genes in Brazil, even though patentable, these patent applications must obtain dual approval making it more difficult to obtain than in other jurisdictions. Table 5 summarises relevant patentable subject matter in Brazil:

Table 5: Brazil gene patent law

Patentability of biotechnology inventions

Compound X isolated from nature (gene, protein, antibody etc.)	No
Modified DNA, RNA, gene, protein, antibody, vector, etc.	Yes
Vaccines, medicaments, formulations comprising natural compounds	Yes
Natural biological processes	No
Processes to isolate, modify and synthesise natural substances	Yes
Use of gene, protein or compound X isolated from nature (non-therapeutic)	Yes, with restrictions
Modified microorganisms/ microorganism cells	Yes
Surgical, therapeutic, diagnostic methods applications to the human body or animals	No
First and second medical use – Swiss-type claim	Yes

Genes that are isolated are not patentable in Brazil but genes are in certain instances patentable, the discussion shows that the Brazilian government has taken extensive steps in order to protect the constitutional right to health and to protect technological invention but also to promote access to such invention. The introduction of new policies designed to regulate pharmaceutical costs including instruments, such as compulsory licensing, the Bolar exception, the prior consent mechanism and the popular Drugstore Programme. The 1996 reforms also implemented two additional measures increasing the price of medicines even further, including pipeline patents and parallel import prohibition.

Author and academic, Monica Guise states that 2007 also brought a change in the pattern of court decisions regarding demands for medicines and medical treatments, as pressure was placed on public health budgets. Arguments included:

- Due to limited resources rationalisation of public spending needs to be sought to provide adequate health care;

- The right to health needs to be observed from a communal perspective and needs to be made a reality through public policies for equal and universal access;
- Decisions on funding allocation should be respected.⁷⁵

During the fight against HIV/AIDS, the government used the threat of compulsory licensing to negotiate discounts with global pharmaceutical companies and producing generic medicines, brought HIV/AIDS medicine prices down.⁷⁶ The Brazilian strategy has increased the probability of using compulsory licences to affect pricing strategies of multinational pharmaceutical firms, by providing the ability to threaten domestic production; the discounted prices granted to developing countries should drop to the level of domestic manufacture under compulsory licence.⁷⁷ The above, in addition to the reforms, such as the National Policy on Biotechnology Development, Brazil indicating the gap Brazil faced in research and development and innovation, puts Brazil on the front line on developing countries attempting to promote health and innovation.⁷⁸

7.3 The Indian Position

In India the tension between patent protection and affordability of pharmaceuticals is particularly evident.⁷⁹ The country, much like Brazil and South Africa, faces tension between providing adequate patent protection to promote scientific advancement and developing new pharmaceuticals, but also ensuring that pharmaceuticals remain affordable and accessible to the majority of the public.

The difference between India and its counterparts is that their generic pharmaceutical industry is significant, increasing their capacity to produce high quality, low-cost generics making them the third largest manufacturer of generic pharmaceuticals.⁸⁰ The discussion below addresses the development of intellectual property laws and steps taken by the government made in order to address the issue of accessibility in India.

⁷⁵ Guise Rosina MS, Wang D & De Campos TC "Access to Medicines: Pharmaceutical Patents and the Right to Health" (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* Information Society Project Yale Law School 2008 176.

⁷⁶ Prices were brought down from from \$10,000 to \$150 a year per patient Sell SK *Trips-Plus Free Trade Agreements and Access to Medicines* Liverpool Law Review 2007 Vol 28 41–75. For more discussion, see also *BRAZIL/ARGENTINA: Patents Disputes Return to the Fore* Report Information from ProQuest available at <http://search.proquest.com/docview/192443712?accountid=8630> (accessed 20 April 2016).

⁷⁷ An example of this is German manufacturer Boehringer Ingelheim who issued an official statement confirming that there will be no interference with the issuance of compulsory licences. The statement reads: "We agree with the Doha Declaration on the protection of public health and will not take any measures against countries which use the protective measures of the TRIPS Agreement or the Doha Declaration to protect their population (e.g.: compulsory licences) respectively implement them in their national laws". See Cohen JC & Lybecker KM *AIDS Policy and Pharmaceutical Patents: Brazil's Strategy to Safeguard Public Health* The World Economy 2005 225.

⁷⁸ Octaviani A "Biotechnology in Brazil: Promoting Open Innovation" (editor) Shaver L *Access to Knowledge in Brazil New Research on Intellectual Property, Innovation and Development* 2008 127.

⁷⁹ Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

⁸⁰ Eight per cent of the world's pharmaceuticals are manufactured in India. See Park C & Jayadev A "Access to Medicines in India: A review of recent concerns" 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

7.3.1 History of Indian patent law

The first Indian Patent Act was that of 1856 and was later consolidated into the Designs and Patents Act of 1911.⁸¹ Once India gained independence from the British in 1947, they inherited Britain's statutory and legal framework.⁸² This legal framework includes the Patents and Designs Act of 1911, allowing a broad range of inventions to be patented, including pharmaceuticals, which could be patented for sixteen years from the filing date.⁸³ Inaccessibility and unaffordability of essential pharmaceuticals, and concerns regarding foreign companies controlling the Indian economy, led to two committees being appointed by the government.⁸⁴ These included the Tek Chand Patents Enquiry Committee (1948-50) and the Ayyangar Enquiry Committee (1959). The second committee submitted a report known as the *Ayyangar Report* which recommended a revamp of the Indian patent system as the system "has failed in its main purpose, namely, to stimulate invention amongst Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country to secure the benefits thereof to the largest section of the public".⁸⁵

The Indian Patent Act was amended in 1970 and came into force in 1972. It is based on the recommendations of the report and is a copy of the English Patent Act of 1949 with the exception that it provides less patent protection.⁸⁶ The aim is to free India from foreign monopolies and establish strong domestic industries.⁸⁷ The Act abolishes product patents for food and for methods and processes leading to medicines being patented. Additionally, the patent protection term for pharmaceuticals is changed from fourteen years to seven years.⁸⁸ Additionally, compulsory licences are reinforced by the "licence of right" provision, an automatic compulsory licence of sorts. This allows any individual to freely practice invention without the fear of infringement as long as it was in the public's interest.⁸⁹

In 1972 after India adopted its patent law, product patented pharmaceutical manufacturing was prohibited and there was a fear that there would be a lack of access to pharmaceuticals as control over existing

⁸¹ Designs and Patents Act of 1911 available at <http://14.139.60.114:8080/jspui/bitstream/123456789/980/10/The%20Indian%20Patents%20and%20Designs%20Act%2C%201911%20%2874-111%29.pdf> (accessed 10 October 2018).

⁸² Barnes S *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa* Kentucky Law Journal 2002 Vol 91 919.

⁸³ Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

⁸⁴ Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 432.

⁸⁵ Named after the jurist Rajagopala Ayyangar who chaired the committee that drafted the report. For more details on the report. For more discussion see Park C & Jayadev A "Access to Medicines in India: A Review of Recent Concerns" 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

⁸⁶ The English Patent Act of 1949 is available at <https://www.legislation.gov.uk/ukpga/Geo6/12-13-14/87/contents> (accessed 11 October 2018). See also Barnes S *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa* Kentucky Law Journal 2002 Vol 91 919. See also Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 432.

⁸⁷ Barnes S *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa* Kentucky Law Journal 2002 Vol 91 921.

⁸⁸ See Chapter II of the Indian Patent of 1970 which is available at http://www.wipo.int/wipolex/en/text.jsp?file_id=128091 (accessed 11 October 2018). For discussion see Park C & Jayadev A "Access to Medicines in India: A Review of Recent Concerns" 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011. See at Drahos P *Developing Countries and International Intellectual Property Standard-Setting* Journal of Intellectual Property 2005 Vol 5(5) 768 available at <http://www.researchgate.net/publication/227994512> (accessed 18 April 2016).

⁸⁹ Chapter 16 of the Indian Patent of 1970 which is available at http://www.wipo.int/wipolex/en/text.jsp?file_id=128091 (accessed 11 October 2018). Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 September 432.

markets were lost. Despite this, India managed to preserve steady production of developed pharmaceuticals over the past three decades. This was partly due to the initial investment of government into laboratories enabling companies to develop technological expertise. As a result, most viable pharmaceuticals were successfully reverse engineered causing the growth of the generic pharmaceutical industry.⁹⁰ Between 1970 and 1995 the industry grew from 15 per cent to 18 per cent and the country became close to self-sufficient in the manufacturing of pharmaceuticals and active ingredients.⁹¹ The country successfully developed its generic pharmaceutical industry partly because it did not provide patent protection for the products of the pharmaceutical companies under patent elsewhere. If a developing country in Africa wanted to grant a compulsory licence to import a low-priced generic version of an antiretroviral medicine to treat HIV/AIDS, it could import from an Indian producer rather than an American company.⁹²

The establishment of WTO in 1995 signalled the end for the Indian patent regime that facilitated the generic pharmaceutical industry.⁹³ Under the terms of the TRIPS Agreement, India was mandated to make patents available for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁹⁴

Under the TRIPS Agreement, India would need to strengthen intellectual property laws and make both products and processes eligible for patent protection with an increase in the patent term to twenty years. After having become a signatory to the TRIPS Agreement, India opted for the 10-year transitional period to bring changes in its legislation.⁹⁵

7.3.2 Applicable legislation

7.3.2.1 The Indian Constitution

India, also known as *Bharat*, is a union of states and is a sovereign socialist secular democratic republic with a parliamentary system of government.⁹⁶ The country is governed under the Constitution of India, adopted by the Constituent Assembly in November 1949.⁹⁷ The latter came into force in January 1950 and

⁹⁰ Park C & Jayadev A "Access to Medicines in India: A review of recent concerns" 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

⁹¹ Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 September 433.

⁹² Abbott FM *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health* The American Journal of International Law 2005 Vol 99 319-320.

⁹³ *Ibid.*

⁹⁴ See chapter 4 for the full discussion on the relevant provisions of the TRIPS Agreement. See also Park C & Jayadev A "Access to Medicines in India: A review of recent concerns" 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

⁹⁵ For discussion see Khader FA *Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime* Journal of Intellectual Property Rights 2008 Vol 13 425.

⁹⁶ <https://india.gov.in/my-government/constitution-india> (accessed 21 June 2016). See also <http://indianexpress.com/article/explained/explained-india-that-is-bharat/> (accessed 20 June 2016).

⁹⁷ The Indian Constitution of 1950.

provides for a federal structured state with certain unitary features.⁹⁸ The Indian Constitution draws extensively from western legal traditions in its principles of liberal democracy and it follows a British parliamentary pattern with a lower and upper house. The Council of Parliament of the union comprises the President and two Houses known as the *Rajya Sabha* (Council of States) and the *Lok Sabha* (House of the People).⁹⁹

The Constitution of India is globally the lengthiest written constitution with 395 articles and eight schedules.¹⁰⁰ The Indian Constitution is also one of the most frequently amended constitutions globally with the first amendment being passed after a year of adopting the constitution. Since 1950 the Constitution was amended at a rate of almost two amendments per year. The current constitution is the Constitution (ninety-fourth amendment) Act of 2006.¹⁰¹

The Preamble to the Constitution emphasises certain of the core values and principles that guide the Constitution of India. Although not regarded as a part of the Constitution, the latter is interpreted in the light of the preamble and in majority of decisions, the Supreme Court of India held that the objectives of justice, liberty, equality and fraternity stated in the preamble constitute the basic structure of the Constitution. The Preamble directs the state to initiate measures to establish justice, equality and to ensure dignity, having a direct bearing on people's health.¹⁰²

The Constitution (ninety-fourth amendment) Act of 2006 lists its fundamental rights in part III.¹⁰³ Both the right to health and that to property are not listed here. In part IV Article 47 the right to health is mentioned for the first time.¹⁰⁴ The Article states as follows:

“The State shall regard the raising of the level of nutrition and the standard of living of its individuals and the improvement of public health as amongst its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption except for medicinal purposes of intoxicating drinks and of drugs which are injurious to health”.¹⁰⁵

⁹⁸ <https://india.gov.in/my-government/constitution-india> (accessed 21 June 2016). See also <http://indianexpress.com/article/explained/explained-india-that-is-bharat/> (accessed 20 June 2016).

⁹⁹ Article 79 of the Indian Constitution 1950 which is available at <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 11 October 2018).

¹⁰⁰ http://www.suramya.com/india/india_constitution.php (accessed 20 June 2016).

¹⁰¹ The Indian Constitution 1950 is available at <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 11 October 2018). See also http://www.suramya.com/india/india_constitution.php (accessed 20 June 2016).

¹⁰² *Ibid.*

¹⁰³ It embodies certain fundamental rights which are similar to the Bill of Rights declared by the US Constitution. It also borrows the concept of a Supreme Court from the US. See http://www.suramya.com/india/india_constitution.php (accessed 20 June 2016).

¹⁰⁴ The Indian Constitution 1950 as amended in 2006 is available at <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 11 October 2018). http://www.suramya.com/india/india_constitution.php (accessed 20 June 2016). See also <https://india.gov.in/my-government/constitution-india> (accessed 21 June 2016).

¹⁰⁵ The Indian Constitution 1950 as amended in 2006 is available at <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 11 October 2018). http://www.suramya.com/india/india_constitution.php (accessed 20 June 2016). See also <https://india.gov.in/my-government/constitution-india> (accessed 21 June 2016).

Also falling within the ambit of health, Article 38 imposes liability on the state to secure a social order for promoting welfare of the individuals. Article 41 imposes a duty on the state to provide public assistance for those who are sick and disabled and Article 42 makes provision to protect the health of infants and mothers by maternity benefit.¹⁰⁶ The first and only mention of the right to property in the Indian Constitution is in Article 300A, stating: “No person shall be deprived of his property save by authority of law”.¹⁰⁷ The Constitution does not refer explicitly to intellectual property or scientific advancement.¹⁰⁸

7.3.2.2 The Indian Patent Act of 1970

The Indian Patents Act experienced three major amendments from 1970 till present day.¹⁰⁹ Each of these amendments was significant to make India TRIPS compliant.¹¹⁰ The first amendment occurred in 1999 and introduced Exclusive Marketing Rights (EMR) with retrospective effect from 1995.¹¹¹ The 2002 amendment saw the following changes:

- Section 2(1)(j) amended the definition of invention as “a new product or process involving an inventive step and capable of industrial application”¹¹²
- Licence of right was deleted;
- Section 3(j) included microorganisms to be patentable; and
- Section 107 was inserted to include a research exemption.¹¹³ This enables pharmaceutical companies to perform further research and development over the patented product. This exemption is especially for generic manufacturers.¹¹⁴

The last amendment to the Indian Patent Act to bring it in line with TRIPS was that of 2005 which included the following:

- Section 2 (1)(ja) was amended to define inventive step as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious in to the person skilled in the art”.¹¹⁵

¹⁰⁶ *Ibid.*

¹⁰⁷ *Supra* note 105.

¹⁰⁸ *Supra* note 105.

¹⁰⁹ For more discussion on amendments see Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India* Journal of Intellectual Property Rights 2014 Vol 19 79.

¹¹⁰ *Ibid* at 79-88. Ragavan S *Patent Judicial Wisdom National Law School of India Review* 2008 165.

¹¹¹ The Patent Amendment Act of 1999. See Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 436 for more detail on qualifying criteria for EMR.

¹¹² *Ibid.* See also Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India* Journal of Intellectual Property Rights 2014 Vol 19 7-17.

¹¹³ As allowed by Article 30 of TRIPS which allows member nations to include exemptions to exclusive rights provided that they are consistent with the normal exploitation of patents and don't unreasonable prejudice the patent owners' interest, taking into the account the interests of third parties.

¹¹⁴ The Patent Amendment Act of 2002. For more discussion see Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 432-441.

¹¹⁵ *Ibid.*

- Section 92A was inserted to provide for compulsory licences for the export of patented pharmaceutical products.¹¹⁶ The section lists the circumstances that would allow for compulsory licences and section 84 lists conditions for the issuance of a compulsory licences.¹¹⁷
- Section 5 was amended to allow product patents in India. After the amendment, products and processes can be patented if they are new, involve an inventive step and are applicable in the industry.¹¹⁸
- The amendment broadens the pre-grant opposition and includes a post-grant opposition provision.¹¹⁹ The latter allows for “any person” to file an opposition before the patent was granted. The opposition should be on one of eleven specified grounds and will the other party will be granted a chance to request a hearing.¹²⁰
- The most controversial amendment was the section 3(d) inclusion which provided that the discovery of a known substance in a new form which did not enhance the known efficacy of the substance, is not considered new under the Act.¹²¹ Parliamentary debates clarify that the intention of the provision is to prevent “evergreening” and the impact of broad patent protection on access to medicines throughout the developing world is a concern.¹²²

Following all three amendments, the Act prescribed three requirements to be fulfilled under section 2(1)(j): the invention should satisfy the test of novelty, inventive step and industrial application.¹²³ Exceptions to patentability are listed in sections 3 and 4 and are the longest list of exceptions which include absolute¹²⁴ and limited¹²⁵ exceptions.¹²⁶ Section 3 lists classes as “not inventions within the meaning of this Act”. The following provisions are of relevance to pharmaceuticals:

¹¹⁶ Section 92A finds its origin in the Millennium Development Goals (MDG's) acknowledging special provisions will have to be made for combating HIV/AIDS, malaria and other diseases. For more information see also Nair GG & Fernandes A *Patent Policies and Provisions Relating to Pharmaceuticals in India* Journal of Intellectual Property Rights 2014 Vol 19 10.

¹¹⁷ The Patent Amendment Act of 2005. For more information see also Nair GG & Fernandes A *Patent Policies and Provisions Relating to Pharmaceuticals in India* Journal of Intellectual Property Rights 2014 Vol 19 7-17.

¹¹⁸ *Ibid.*

¹¹⁹ Section 25 of the Patent Amendment Act of 2005. A pre-grant opposition requirement changed from ‘any person interested’ to ‘any person’ allowing for civil society groups to become involved in the filing process of pre-grant oppositions against patent applications pending before the Indian Patent Office.

¹²⁰ Section 25(1). Section 25(1)(k). See Park C & Jayadev A *Access to Medicines in India: A Review of Recent Concerns* 78-108. See also Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

¹²¹ The Patent Amendment Act of 2005. *Ibid.*

¹²² Evergreening is a term that is used to describe the sequential accumulation of secondary patents on drugs, including alternative forms of active ingredients, new formulations, dosages and uses. As a result of secondary patents tending to be filed later in the life of a pharmaceutical than primary chemical compound patents, they can extend monopoly terms. For example, when a pharmaceutical company invents a new pharmaceutical, it is entitled to patent the product for a certain number of years, generally 14 years. Once this period ends, the patent expires. Other companies are then allowed to manufacture the generics of the pharmaceutical at a much lower price. An inventor would rather extend its patent with more than 14 years to prevent competition by obtaining a second patent however, secondary patents are less likely to satisfy traditional patentability criteria and are more legally vulnerable. For more discussion see Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India* Journal of Intellectual Property Rights 2014 Vol 19 79-88. See also Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 432-441.

¹²³ For discussion on each requirement see Khader FA *Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime* Journal of Intellectual Property Rights 2008 Vol 13 425.

¹²⁴ These are unqualified exceptions.

¹²⁵ These offer certain scope for exceptions to come within the purview of patentability subject to conditions.

¹²⁶ The Patent Amendment Act of 2005 can be found at <http://www.wipo.int/edocs/lexdocs/laws/en/in/in018en.pdf> (accessed 14 September 2016).

- (a) natural substances;
- (b) new uses of known substances;
- (c) new forms of known substances, unless the new forms exhibit an increase in efficacy; and
- (d) methods of treating humans and/or animals.¹²⁷

The most controversial of these being section 3(d) which reads as follows:

- (1) The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficiency of that substance; or
- (2) mere discovery of any new property or new use for a known substance; or
- (3) mere discovery of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.¹²⁸

The origins of section 3(d) lie in Article 10(2)(b) of the European Drug Regulatory Directive of 2004 where generic medicine is defined as “a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference medicinal product was demonstrated by appropriate bioavailability studies. The different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance will be the same active substance, unless they differ significantly in properties concerning safety and efficiency. In such cases, additional information providing proof of the safety and efficiency of the various salts, esters or derivatives of an authorised active substance should be supplied by the applicant”.¹²⁹

Section 3(c) provides that the discovery of a living or non-living substance that occurs in nature is not to be considered patentable. As an isolated gene or DNA fragment is an entity existing in nature, and is therefore not patentable.¹³⁰ The law establishes that simply isolating a gene from a living creature amounts to “discovery” and not “invention” and is therefore not patentable. Under the 1970 Act, a gene is only patentable after isolation and chemical modification, resulting in a sequence that is new, inventive with industrial application.¹³¹

Section 3(i) of the Act provides that any process for diagnostic or therapeutic treatment of human beings or animals is not to be considered an invention. Diagnostic method is defined in the manual of Patent

¹²⁷ The Patent Amendment Act of 2005.

¹²⁸ The explanation reads as follows: “For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, unless they differ significantly in properties concerning efficiency”. For discussion see *supra* note 123 at 426.

¹²⁹ Directive 2004/27/EC of the European Parliament and of the Council. For further discussion see also Nair GG & Fernandes A *Patent Policies and Provisions Relating to Pharmaceuticals in India* Journal of Intellectual Property Rights 2014 Vol 19 13.

¹³⁰ The Patent Act of 1970 (with all amendments). See http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf (accessed 11 October 2018). Rutt J *Where Can I Get a Diagnostic Patent?* Managing Intellectual Property 2012 available at <http://search.proquest.com/docview/1125360969?accountid=8630> (accessed 23 June 2016). See also Gupta M *Are Gene Patents a Hindrance to Innovation* Singh & Associates 21 2013 <http://www.lexology.com/library/detail.aspx?g=4a3197df-8ee7-4de9-a369-fcabb0cdb3ee> (accessed 22 February 2015).

¹³¹ *Ibid.*

Office Practice and Procedure as follows: “Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (for example a fitness test) is considered to be diagnostic”.¹³²

Any process performed on the human body to identify the nature of a medical illness is considered non-patentable, but any process performed outside the human body is acceptable. The definition of the diagnostic method as provided in the manual, clearly states that any methods performed on the living body or outside if they lead to diagnosis of a disorder, will be rendered non-patentable. Claims to a diagnostic method being performed outside the human body should be restricted to methods that do not lead to deduction of any disorder or ailment.¹³³ Section 3(i) also excludes plants or animals, or any part thereof as patentable¹³⁴

7.3.3 Steps taken to increase access to pharmaceuticals

The Calcutta High Court took the lead in *Dimminaco AG*¹³⁵ to protect biotechnology inventions by denying when a patent for the process of manufacturing a vaccine for infectious bursitis in poultry. *Dimminaco AG* appealed the decision of the Patent Office under section 116 of the Indian Patent Act of 1999.¹³⁶ On appeal, the Calcutta High Court held that the definition of “manufacture” in section 2 of the Act¹³⁷ did not pose a statutory bar to the patentability of a living organism. This was the first case in India to allow a biotechnology patent.¹³⁸ During this time India reserved the right to deny patent protection if the primary function of the invention is opposed to morality or is harmful to public health based on section 3.¹³⁹ Even though biotechnology patents are not explicitly excluded by the Act, they were never granted.

Another example where the courts acted to increase accessibility to pharmaceutical was the case of Novartis. Prior to India amending its legislation in 1999 to bring it in line with TRIPS, Novartis filed for a patent application¹⁴⁰ in the Chennai Patent Office for *Gleevec*, the beta crystalline salt form of the free base, *Imatinib* covered by an earlier pre-1995 patent.¹⁴¹

¹³² The manual can be found at http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_28_1_manual-of-patent-office-practice_and-procedure.pdf (accessed 28 October 2018).

¹³³ *Ibid.*

¹³⁴ The Patent Act of 1970 (with all amendments). See http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf (accessed 11 October 2018).

¹³⁵ *Dimminaco A.G. v Controller of Patents Designs* 2002 IPRL 255.

¹³⁶ For case discussion Ragavan S *Patent Judicial Wisdom National Law School of India Review* 2008 165.

¹³⁷ The Indian Patent Act of 1970 (as amended in 1999).

¹³⁸ *Supra* note 136.

¹³⁹ Section 3(b) of the Indian Patent Act of 1970.

¹⁴⁰ Application no 1602/MAS/1998.

¹⁴¹ The earlier patent was patent no 5,521,184A10 known as the “Zimmerman Patent”. See Park C & Jayadev A “Access to Medicines in India: A Review of Recent Concerns” 78-108 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011. See also Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India Journal of Intellectual Property Rights* 2014 Vol 19 79-88.

The company obtained EMRs¹⁴² for marketing *Gleevec*, an effective new cancer drug used for the treatment of chronic myeloid leukaemia (CML)¹⁴³ and gastrointestinal stromal tumours (GIST),¹⁴⁴ and obtained an injunction from the Madras High Court to restrain the generic of *Gleevec* being produced. This drastically increased the price of the drug.¹⁴⁵ This was the first instance of a patent such as granting of an EMR; it was also the first time an international multinational questioned the validity of a provision within the Indian Patent Act.¹⁴⁶ As a result, parallel proceedings saw the Bombay High Court reject the injunction application.¹⁴⁷

Since this occurred during India's TRIPS transitional period, the provision was not examined until 2005. After section 3(d) was introduced, various generic companies filed opposition proceedings against Novartis on the grounds of the invention lacking novelty and an inventive step. They alleged it to be a new form of a "known substance" as Novartis was already granted the Zimmerman patent in 1993. It was averred that different forms of *Imatinib Mesylate* did not offer different properties and was therefore the same substance.¹⁴⁸ In January 2006, the patent office denied Novartis's application and held that, the application did not meet the requirement of "efficacy" provided for in section 3(d).¹⁴⁹

Novartis appealed the decision of the patent controllers to reject their application with the Intellectual Property Appellate Board (IPAB).¹⁵⁰ Litigation ensued concerning the competence of a technical member of the IPAB, to hear the appeal. Although the case was meant to determine whether the rejection was appropriate, the broader issues of how the Indian Patent Office interprets and applies section 3(d) and the

¹⁴² Exclusive Marketing Rights can be obtained for that application if certain conditions as stated below are fulfilled:

1. Where an invention is made in India or outside India and before filing such a claim in India, application for the same invention claiming identical article or substance in a Convention Country (WTO) was filed on or after 1st January, 1995 and a patent was granted on or after the date of making a claim for article or substance in India and approval to sell or distribute was obtained in the said Convention Country based on the test achieved on or after 1st January, 1995.
2. Where an invention was made in India and before filing such a claim the applicant has made an application for patent on or after 1st January, 1995 for method or process of manufacturing the identical article or substance and patent was granted in India on or after the date of making of the product claim.
3. Marketing approval of the article or substance was obtained from the appropriate authority in India provided that the application for patent has not been rejected by the Controller based on the report of the Examiner that the invention is not an invention (section - 3) or the invention is an invention on which no patent can be granted (section - 4). The EMR will be valid for a period of five years or till the date of grant of the patent or date of rejection of the application for the grant of patent whichever is earlier. See <http://ipindia.nic.in/ipr/patent/emr.htm> (accessed 01 July 2016). for more information.

¹⁴³ CML is a disease in which the bone marrow makes too many white blood cells. CML accounts for 15-20% of all adult leukaemia. See <http://www.cancer.gov/cancertopics/pdq/treatment/CML/Patient/page1> (accessed 27 February 2015).

¹⁴⁴ GIST is a disease in which abnormal cells form in the tissues of the gastrointestinal tract. See <http://www.cancer.gov/cancertopics/pdq/treatment/gist/Patient/page1> (accessed 27 February 2015). Note that these are not gene based patents.

¹⁴⁵ The price increased from Rs 10 000 to Rs 1 20 00 per month.

¹⁴⁶ Khader FA *Transcending Differences: The Challenge for Pharmaceuticals in the Post-TRIPS Indian Patent Regime* Journal of Intellectual Property Rights 2008 Vol 13 429.

¹⁴⁷ *Novartis Ag and Anr v Mehar Pharma and Anr* 2005 (3) BomCR 191 2005 930 ptc 160 Bom. Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India* Journal of Intellectual Property Rights 2014 Vol 19 79-88.

¹⁴⁸ For more discussion see Nair GG, Fernandes A & Nair K *Landmark Pharma Patent Jurisprudence in India* Journal of Intellectual Property Rights 2014 Vol 19 79-88. See also Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry* Journal of Intellectual Property Rights 2008 Vol 13 432-441.

¹⁴⁹ The Patent Act of 1970 (with all amendments). See http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf (accessed 11 October 2018). See also Park C & Jayadev A *Access to Medicines in India: A Review of Recent Concerns* 78-108. See also Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

¹⁵⁰ IPAB Order Dated 26-Jun-2009 in *Novartis v. Union of India*. See <https://www.scribd.com/document/133340456/IPAB-Order-Dated-26-Jun-2009-in-Novartis-v-Union-of-India> (accessed 10 October 2018).

validity of the provision itself, were likely to be considered by the court, making the case for a referendum on section 3(d). Novartis emphasised that the drug has received patents in more than 40 other countries, implying that if even *Gleevec* cannot be patented in India, section 3(d) should be setting unreasonable standards.¹⁵¹ Eventually in 2009, the IPAB reversed the patent controller's decision and held that the beta crystalline form of *Imatinib Mesylate* was novel and involved an inventive step; it did not satisfy the section 3(d) test since there was no actual enhancement of known efficiency for the beta crystalline form of *Imatinib Mesylate*. No product patent was awarded based on not satisfying the section 3(d) requirement.¹⁵²

In response, Novartis filed for a written petition in the Madras High Court against the government of India, challenging both the patent controller's decision and the validity of section 3(d). The Court upheld the constitutional validity of section 3(d).¹⁵³ Novartis claims the provision is inconsistent with the TRIPS Agreement and violates the Indian Constitution.¹⁵⁴ CPAA,¹⁵⁵ also a party to the litigation, responded that the legislative intent of the provision was to allow for the fulfilment and protection of the right to life by the state under Article 21 of the Constitution and to enact measures preventing frivolous patents.¹⁵⁶ Generic companies Cipla and NGO also filed appeals against the IPAB's order regarding the invention having met the requirements of novelty and inventive step.¹⁵⁷

Novartis's challenge was dismissed on all grounds. The Court held firstly that there was no jurisdiction to declare inconsistency between national legislation and an international treaty; secondly that Novartis was not entitled to declaratory relief in the form of the court declaring inconsistency between section 3(d) and TRIPS and lastly that the provision was not unconstitutional. The Court stated:

"We have borne in mind the object of [section 3(d)], namely ... to provide easy access to the citizens of this country to life-saving drugs and to discharge the constitutional obligation of providing good health care to its citizens".¹⁵⁸

In upholding section 3(d), the court indicates a more restrictive definition of 'efficacy', such as the discovery of a known substance in a new form should be treated as an invention. The patent applicant should then display the substance to have a therapeutic effect. "Efficacy" is defined by Dorland's *Medical Dictionary* as the "ability of a drug to produce the desired therapeutic effect". "Efficiency" is independent of the

¹⁵¹ *Ibid.* See also Sampat BN, Kenneth CS & Amin TM *Challenges to India's Pharmaceutical Patent Laws Science* 2012 Vol 337(6093) 414-415.

¹⁵² *Ibid.*

¹⁵³ *Novartis AG v Union of India & Others* (2007) MLJ 1153. Park C & Jayadev A *Access to Medicines in India: A review of recent concerns* 81. See also Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

¹⁵⁴ Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry Journal of Intellectual Property Rights* 2008 Vol 13 432-441.

¹⁵⁵ Cancer Patients Aid Association.

¹⁵⁶ For more discussion see *supra* note 154.

¹⁵⁷ *Supra* note 154. For more discussion see also Nair GG *Impact of TRIPS on Indian Pharmaceutical Industry Journal of Intellectual Property Rights* 2008 Vol 13 432-441.

¹⁵⁸ *Novartis v Union of India* (2007) 4 MLJ 1153 para. 19. See Park C & Jayadev A "Access to Medicines in India: A review of recent concerns" 82 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

potency of the drug". By defining "efficacy" to mean "therapeutic" efficacy, the court indicated that benefits usually claimed by secondary patents, such as manufacturability, improved shelf life and better bioavailability, would fail to pass muster under section 3(d).¹⁵⁹

A similar case was that of *Roche v Cipla*.¹⁶⁰ Roche developed *Erlotinib*, a medicine used to treat lung cancer and Cipla, a generic manufacturing company, started producing a generic version of *Erlotinib* sold as *Erlocib*.¹⁶¹ There are two claims involving the patent granted on *Erlotinib*.

The first concerns a claim that Roche's patent was invalid as it was a derivative of a previously known product called *Quinazolin* and it did not involve an inventive step.¹⁶² The court found that a previous patent includes the mixture of polymorph A and B while Roche's patent includes only polymorph B. Cipla's claim is rejected and the court upheld the validity of the patent claiming that it was adequately dealt with by the patent office.¹⁶³

The second aspect concerns infringement proceedings on the grant of the patent.¹⁶⁴ Cipla argue that because the claim pertained to a life-saving drug, public interest needed to be taken into account. The court rejected the injunction that Roche requested to stop Cipla from marketing the drug.¹⁶⁵ The court claimed that it "cannot be unmindful of the right of the public to access life-saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in certain cases would be made impossible, if the injunction were granted. Such injuries to third parties cannot be compensated. Another way of viewing it is that if the injunction were to be granted, the court would in effect be stifling Article 21 as far as those would have or could have access to *Erlotinib* are concerned".¹⁶⁶ Roche's appeal failed.¹⁶⁷

¹⁵⁹ <https://www.dorlandsonline.com/dorland/home> (accessed 08 March 2018). *Novartis v Union of India* (2007) 4 MLJ 1153. See also *Novartis AG v Union of India & Others* Civil Appeal No. 2706-2716 of 2013 and Civil Appeal no.2728 of 2013 and Civil Appeal no 2717-2727 of 2013 Supreme Court of India 2012- see <http://juis.nic.in/supremecourt/imgs1.aspx?filename=40212>.

¹⁶⁰ *F. Hoffmann-La Roche Ltd. And Anr. v Cipla Limited* I.A. 642/2008 IN CS (OS) 89/2008,

¹⁶¹ Erlotinib is also known by its brand name, Tarceva and is a treatment for pancreatic cancer (that has spread) and non-small cell lung cancer (that has spread). For more information see <http://www.cancerresearchuk.org/about-cancer/cancers-in-general/treatment/cancer-drugs/erlotinib> (accessed 14 September 2016).

¹⁶² *F. Hoffmann-La Roche Ltd. And Anr. v Cipla Limited* I.A. 642/2008 IN CS (OS) 89/2008.

¹⁶³ *Ibid.*

¹⁶⁴ Patent no 196774.

¹⁶⁵ *F. Hoffmann-La Roche Ltd. and Anr. v Cipla Limited* I.A. 642/2008 IN CS (OS) 89/2008 See also Park C & Jayadev A "Access to Medicines in India: A review of recent concerns" 83 (editor) Subramanian R & Shaver L *Access to Knowledge in India New Research on Intellectual, Innovation & Development* 2011.

¹⁶⁶ *F. Hoffmann-La Roche Ltd. and Anr. v Cipla Limited* I.A. 642/2008 IN CS (OS) 89/2008 para 85. Article 21 of the Indian Constitution protects life and personal liberty. See the Indian Constitution 1950 at <https://www.india.gov.in/my-government/constitution-india/constitution-india-full-text> (accessed 11 October 2018).

¹⁶⁷ *Cipla Ltd. v F.Hoffmann-La Roche Ltd. & Anr.* RFA (OS) 92/2012.

7.3.4 Trade agreements

The government of India initiated BITs in the middle 1990s. The idea was to offer favourable conditions and treaty-based protection to the foreign investments. India signed its first BIT in 1994 with the United Kingdom and since then signed BITs with 75 states. Negotiations with a further 25 states are currently underway.¹⁶⁸

Each of India's BITs is unique although there are several common characters present. The basic premise is that the Indian government will not put the investors and their investments to risks which are either unreasonable or inappropriate.¹⁶⁹ One of the most noticeable features of the Indian BITs is that it does not provide other states a right to invest in India. All rights, under the BITs to which India is a party, can be exercised only after making investments in India.¹⁷⁰

The Indian government retains the freedom to determine which sectors are open to foreign investments and under which terms and conditions can those investments be made. Note that the investments made in India should be established or acquired in accordance with the national laws of India which as the discussion shows, aims to promote access to pharmaceuticals.¹⁷¹

In 2015, India adopted a new model BIT to replace the 2003 model. The model was provoked by foreign investors suing India under different BITs. The draft model was introduced in early 2015 and provides for the host state to expropriate investments indirectly.¹⁷² Expropriation of foreign investment is rarely accompanied by appropriation of the value of investment by the state. Consequently, this would have made it almost impossible for foreign investors to prove indirect expropriation even when there is total deprivation of their investment.¹⁷³ The final model removes the requirement of appropriation of value of investment and limits the test of indirect expropriation to substantial or permanent deprivation of foreign investment. The final model also contains an "enterprise" based definition of investment as indicated in the draft model. Only foreign enterprises legally constituted in India can bring a BIT claim. Assets held by the foreign enterprise are included in the definition of investment. The model provides that the issuance of compulsory licences will be outside the ambit of the treaty, only if such an issuance is consistent with the WTO treaty.¹⁷⁴ This indicates that the BIT tribunal will have the jurisdiction to examine whether the compulsory licence was issued in accordance with TRIPS. The tribunal will be less deferential to Indian

¹⁶⁸ Bagaria P & Desai V *India and its Tryst with BITs* Nishith Desai Associates available at: http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Bilateral_Investment_Treaties_and_India.pdf (accessed 09 March 2016).

¹⁶⁹ *Ibid.*

¹⁷⁰ *Supra* note 168.

¹⁷¹ *Supra* note 168.

¹⁷² *Supra* note 168.

¹⁷³ Bagaria P & Desai V *India and its Tryst with BITs* Nishith Desai Associates available at: http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Bilateral_Investment_Treaties_and_India.pdf (2016).

¹⁷⁴ Ranjan P T *India Seeks Protection with New Model Bilateral Investment Treaty* The Wire <http://thewire.in/22423/india-seeks-protection-with-new-model-bilateral-investment-treaty/> (accessed 28 June 2016).

courts since the issue would need to be resolved in compliance with global law and not Indian law. This will expose India's patent laws to global judicial scrutiny.¹⁷⁵

7.3.5 Summary

Facing a demand for access to pharmaceuticals and a need to increase patent protection, introducing pharmaceutical patents in India was particularly controversial. Indian producers have been suppliers of low-cost medicines for a long time both domestically and to other low - and middle-income countries.¹⁷⁶

In amending its patent law to meet global obligations, India attempted to use the flexibilities in TRIPS to enhance potentially negative effects that pharmaceutical patents might have on supplying pharmaceuticals. India, unlike Brazil, used its full transition period, waiting to introduce pharmaceutical product patents until 2005. At this point India has some of the highest patentability standards in the world. Gene sequences are patentable in India if isolated and modified, while also being novel and applicable in industry with regard to the status of the right to health and property, the Constitution enshrines both rights.¹⁷⁷

However, as the discussion shows drastic steps have been taken to ensure access to pharmaceuticals and stringent intellectual property requirements for biotechnology/pharmaceutical patents including the value of the right to health.

7.4 The South African Position

Similar to the two jurisdictions discussed above, South Africa also faces tension between patent protection and access to pharmaceuticals. However, unlike the jurisdictions discussed above, South Africa does not have the resources to manufacture generics locally or implement an additional agency equivalent to ANVISA. The South African pharmaceutical sector is still relatively small constituting 0.4% and 1% of the global market by value and volume respectively.¹⁷⁸ 65% of the national demand for pharmaceuticals is met by imports.¹⁷⁹ The discussion below aims to provide an understanding of the development of South African patent law and the reform of these laws to address pharmaceutical/biotechnology patents, in order to provide both protection and accessibility.

¹⁷⁵ *Supra* note 173.

¹⁷⁶ Sampat BN, Kenneth CS & Amin TM *Challenges to India's Pharmaceutical Patent Laws* Science 2012 Vol 337(6093) 414-415.

¹⁷⁷ The Indian Constitution of 1950.

¹⁷⁸ For more discussion see section 7 of the South African Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

¹⁷⁹ *Ibid.*

7.4.1 History of South African patent law

Patent law in South Africa was initially regulated by common law. It was thereafter codified in the Cape Patent Act of 1860.¹⁸⁰ The latter was based primarily on models of English law, and was limited to “a manner of new manufacture”. An invention is a manner of manufacture when it has an industrial application. Subsequently, the first Natal Patents Act 4 of 1870, came into operation. The Natal Patents Act also adopted the British concept of an invention indicating invention as being limited to “a manner of new manufacture”.¹⁸¹ In 1902, the Transvaal Patent Proclamation 22 came into being whereby the American and Canadian definitions of an invention were used. This widened the scope by including listing the species art, process, machine, manufacture or composition of matter.¹⁸² The patent statute promulgated in the Orange Free State gave no definition of an invention but qualified that an invention had to be in the industrial field and should be capable of being exploited as an object of trade or industry.¹⁸³

After the Union in 1910, all industrial property laws of the previously separate four colonies were consolidated and amended by the Patents, Designs, Trade Marks and Copyright Act 9 of 1916. The latter adopted the approach of the Transvaal Proclamation.¹⁸⁴ Subsequently, in December of 1947, South Africa acceded to the Paris Convention, resulting in intellectual property rights of any contracting state being accessible to the nationals of other states, party to the Convention. This was the first South African step toward modern intellectual property legislation.¹⁸⁵ Act 9 of 1916, was later repealed and replaced by the Patents Act 37 of 1952 that came into effect on 1 January 1953.

In 1978, the most recent Patent Act was promulgated, the Patent Act 57 of 1978. The Act regulates the enforcement of intellectual property and related laws, intellectual property regulatory body, patents (inventions) and plant variety protection. The Act underwent amendments in 1996 and is still in force today.¹⁸⁶

7.4.2 Applicable legislation

7.4.2.1 The South African Constitution

The Republic of South Africa is a representative democracy with a three-tier system of government and an independent judiciary, operating in a parliamentary system. Each of the nine provinces is governed by a unicameral legislature. The powers of the provincial government are limited to specific topics listed in

¹⁸⁰ Klopper HB & Van Der Spuy P De W *Law of Intellectual Property* 2012 220.

¹⁸¹ T Naidoo *Globalization and South African Patent Law* Point (Spoor & Fisher) 2010 2 May.

¹⁸² *Ibid.*

¹⁸³ *Supra* note 181.

¹⁸⁴ T Naidoo *Globalization and South African Patent Law* Point (Spoor & Fisher) 2010 2 May.

¹⁸⁵ *Ibid.*

¹⁸⁶ Klopper HB & Van Der Spuy P De W *Law of Intellectual Property* 2012 220.

the national constitution. On certain of these topics – for example, agriculture, education, health and public housing – the province's powers are shared with the national government, which can establish uniform standards and frameworks for the provincial governments to follow; on other topics the provincial government has exclusive power.

Both the right to have access to health care services and the right to property are enshrined in the South African Constitution. Chapter 2 of the Constitution contains what is termed the Bill of Rights, and is home to both the above-mentioned rights. The Constitution places two duties on the state when it comes to what is termed as “socio-economic rights”. The first duty placed on the state is to actively implement the rights¹⁸⁷ and the second is to enforce the rights.¹⁸⁸ Section 7(2) of the Constitution requires that: “[t]he state must respect, protect, promote and fulfil the rights in the Bill of Rights”.¹⁸⁹ It conveys the idea that the state should not only refrain from interfering with the enjoyment of rights, but should act to protect, enhance and realise their enjoyment. To elaborate:¹⁹⁰

- The *duty to respect* requires the state to abstain from interfering with the enjoyment of rights; it requires the state to protect existing enjoyment of rights and the capacity of individuals to enhance their enjoyment of rights or to gain access to the enjoyment of rights against third party interference.
- The *duty to promote* is to raise awareness of rights by promoting enforcement of rights and to promote the most effective use of existing access to rights.
- The *duty to fulfil* requires the state to “adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures” so that the rights can be accessed and enjoyed.

The Constitution protects the right to human dignity, life and freedom and security of the person.¹⁹¹ The Constitution also provides that courts should promote the values that underlie an open and democratic society based on human dignity, equality and freedom.¹⁹²

With regard to the right to have access to health care, section 27 guarantees everyone’s right to the accessibility of health care services:

“(1) Everyone has the right to access to

(a) health care services, including reproductive health care;

(b) sufficient food and water; and

(c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

¹⁸⁷ Section 2 requires the state to fulfil constitutional duties; section 7(2) requires the state to respect, protect, promote and fulfil rights.

¹⁸⁸ Brand D & Heyns C *Socio-Economic Rights in South Africa* Pretoria University Law Press 2005. See also Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* Lancet 2006 Vol 368 305–11.

¹⁸⁹ Section 7(2) of the Constitution of the Republic of South Africa 108 of 1996.

¹⁹⁰ *Intellectual Property Guide South Africa 2016* Intellectual Property Office 2016. See also Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 6.

¹⁹¹ These rights are enshrined in sections 10, 11 and 12 of the South African Constitution of 1996.

¹⁹² Section 39(1)(a) of the Constitution of South Africa 1996

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.”¹⁹³

To understand the significance of section 27 as a fundamental right concerning health, it is essential to take cognisance of the country’s historical circumstances and the transformation process under the new democratic dispensation, including the move towards substantive equality under the Constitution.¹⁹⁴ It does not merely require the state to abstain from interfering with the right of an individual to pursue health care services, but also imposes upon the state a positive duty to provide care according to need rather than the ability to pay for it.¹⁹⁵ This is made abundantly clear in section 27(2) above, which enjoins the state to take reasonable measures to realise of each of the rights in section 27(1).¹⁹⁶

Concerning the right to property, section 25(1) states that “no person may be deprived of property except concerning the law of general application and no law may permit arbitrary deprivation of property”.¹⁹⁷ Section 25(2) explains that concerning the law of general application, property can be seized for the interest of the public.¹⁹⁸ It is confirmed in section 25(4)(b) that “property is not limited to land”. The question that needs to be addressed is whether the term property includes intellectual property?

In 1996, the Constitutional Court handed down judgement that since the draft constitution did contain a property clause; it was primarily aimed at immovable property and dealt with expropriation.¹⁹⁹ The Court stated that the right to hold intellectual property could not be considered a universal right from a constitutional point of view since it is not expressly recognised in the constitutions of a large number of countries and is not recognised in various human rights treaties.

Subsequently, in the *First National Bank (FNB)* case²⁰⁰ the Court states that it was “practically impossible and judicially unwise” to attempt a definition of property.²⁰¹ It is pointed out by the court that the question of property involves both the object of the property rights and the rights themselves. Section 25(4)(b) seems to focus on the object of the property right.²⁰² The *FNB* case and subsequent major decisions only deal with tangible movables.²⁰³

¹⁹³ The Constitution of South Africa 1996.

¹⁹⁴ Ngwenya C, Cook R *Four / Rights Concerning Health* Pretoria University Law Press 2005 107-153. See also Hogerzeil HV, Samson M, Casanovas JV et al *Is access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?* Lancet 2006 Vol 368 305–11.

¹⁹⁵ *Intellectual Property Guide South Africa 2016* Intellectual Property Office 2016. See also Golay C & Cismas I *Legal Opinion: The Right to Property from a Human Rights Perspective* International Centre for Human Rights and Democratic Development 2010 6.

¹⁹⁶ The Constitution of South Africa 1996. See *supra* note 194.

¹⁹⁷ Section 25(1) of the Constitution of South Africa 1996.

¹⁹⁸ Section 25(2)(a) of the Constitution of South Africa 1996.

¹⁹⁹ *Ex parte Chairperson of the Constitutional Assembly: in re certification of the Constitution of the Republic of South Africa 1996* 1996 (4) SA 744 (CC) at 799E-800B. See also *Ex parte Chairperson of the Constitutional Assembly: in re Certification of the Amended Text of the Constitution of the Republic of South Africa, 1996* 1997 (2) SA 97 (CC).

²⁰⁰ *First National Bank of South Africa Limited t/a Wesbank v Minister of Finance 2002*(4) SA 768 (CC). See Van Der Walt A *Constitutional Property Law* (3rd Edition) 2011 112.

²⁰¹ *Ibid*.

²⁰² *Supra* note 200. See also Van der Walt AJ & Shay RM *Constitutional Analysis of Intellectual Property* Potchefstroom Electronic Law Journal 2014 17 1.

²⁰³ *Ex parte Chairperson of the Constitutional Assembly: in re certification of the Constitution of the Republic of South Africa*

However, intangible property is addressed in the *Laugh It Off* case²⁰⁴ where the Court states:

“[t]rade marks are property, albeit intangible or incorporeal. The fact that property is intangible does not make it of a lower order. Our law has always recognised incorporeals as a class of things in spite of theoretical objections thereto...”²⁰⁵

This *dictum* is not later challenged by the Constitutional Court indicating that intellectual property rights constitute property for the purposes of section 25 of the Constitution.²⁰⁶

In a paper by Du Bois he identifies a number of theories that may be used in order to justify the inclusion of intangible property interests under the section 25 of the Constitution.²⁰⁷ He proposes justificatory theories for intellectual property protection could be used to assess the relative value an intellectual property right has as compared to the relative value of a competing non-property right in order to obtain appropriate protection and balance.²⁰⁸

The Constitutional Court has however shown favour for non-property constitutional rights. In the *Laugh It Off* case,²⁰⁹ the Court weighed the constitutional right to free expression of the unauthorised use against the right to intellectual property of the trade mark owner and where appropriate the owner's freedoms of trade, occupation or profession.²¹⁰ The Court held that while there is unequivocal recognition of the right to hold intellectual property as a fundamental right having equal status to the right to freedom of expression, the latter cannot lightly be limited. The constitutional right to freedom of expression was in this case favoured.²¹¹

The Court has also shown favour to socio-economic rights in various cases.²¹² For example, in the case of *Soobramoney*²¹³ a public hospital failed to provide renal dialysis services to a terminally ill man who suffered from diabetes, ischemic heart disease, and cerebro-vascular disease. The hospital claimed that it prioritizes treatment for non-terminal patients because dialysis is a scarce resource. *Soobramoney* brought a suit claiming that the hospital's refusal to treat him violated his right to health care and to

1996 1996 (4) SA 744 (CC) at 799E-800B. See also *Ex parte Chairperson of the Constitutional Assembly: in re Certification of the Amended Text of the Constitution of the Republic of South Africa*, 1996 1997 (2) SA 97 (CC) at 113.

²⁰⁴ *Laugh it Off Promotions CC v The South African Breweries International (Finance) BV t/a Sabmark International (Freedom of Expression Institute as Amicus Curiae)* 2005 (2) SA 46(SCA)

²⁰⁵ *Ibid* at paras 10-11.

²⁰⁶ For more discussion see Dean O *Intellectual Property and the Constitution* 2015

<http://blogs.sun.ac.za/iplaw/2015/07/14/intellectual-property-and-the-constitution/> (accessed 24 December 2018).

²⁰⁷ Du Bois M *Justificatory Theories for Intellectual Property Viewed through the Constitutional Prism* Potchefstroom Electronic Law Journal 2018 Vol 21 4-5.

²⁰⁸ *Ibid*.

²⁰⁹ *Laugh It Off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International and Another* 2005 (8) BCLR 743 (CC).

²¹⁰ *Ibid*.

²¹¹ *Supra* note 209.

²¹² See cases below. For more discussion see Kende MS *The South African Constitutional Court's Embrace of Socio-Economic Rights: A Comparative Perspective* presented at the Chapman Law Review Symposium on Economic Liberties 2003.

²¹³ *Soobramoney v Minister of Health, KwaZulu-Natal* 1997 (12) BCLR 1696 (CC).

emergency medical treatment under section 27 of the Constitution.²¹⁴ The Court recited the Constitution's fundamental principles:

We live in a society in which there are great disparities in wealth. Millions of people are living in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services. These conditions already existed when the Constitution was adopted and a commitment to address them, and to transform our society into one in which there will be human dignity, freedom and equality, lies at the heart of our new constitutional order. For as long as these conditions continue to exist that aspiration will have a hollow ring.²¹⁵

In the case of *Treatment Action Campaign and Others v Minister of Health and Others*,²¹⁶ the Transvaal Provincial Division of the High Court found that the government failed to address the need to reduce the risk of HIV mother to baby transmission. The court found that the government had acted unreasonably in refusing to make the anti-retroviral drug *Nevirapine* available in the public health sector. On appeal, the Constitutional Court held that sections 27(1) and (2) of the Constitution required the government to use available resources to devise and implement a programme ensuring that pregnant women and their new born children can apply their right to have access health care services aimed at combating mother-to-child transmission of HIV.²¹⁷ The Constitutional Court held that the government would immediately remove the restrictions preventing the availability of *Nevirapine* for the purpose of reducing the risk of HIV mother-to-child transmission at all public hospitals and clinics; and to allow and facilitate using *Nevirapine* to reduce the risk of HIV mother-to-child transmission and to make it available for use in the judgement of the attending medical practitioner acting in consultation with the patient.²¹⁸

The cases above illustrate the Constitutional Court's inclination to promote access to healthcare in accordance with section 27 of the Constitution.²¹⁹ The *Laugh It Off* case also illustrates precedence of the Constitutional Court in the hesitance to limit other fundamental rights when weighed against an intellectual property right.²²⁰ If we were to implement these principles to diagnostic gene patents in the context of this thesis, could it be considered that the government would fail to comply with section 7(2) if they failed to take steps to ensure that diagnostic gene tests are made available to the public? Diagnostic tests are used to diagnose fatal genetic diseases, which in most cases could mean the difference between life and death. Genetic diseases diagnosed early (or at all) can be treated. As patents on gene tests result in it being

²¹⁴ The Constitution of South Africa 1996.

²¹⁵ *Soobramoney v Minister of Health, KwaZulu-Natal* 1997 (12) BCLR 1696 (CC) at 8.

²¹⁶ *Treatment Action Campaign and Others v Minister of Health and Others* 2002 (4) BCLR 356 (T). For further discussion of this case see Ngweni C, Cook R *Four / Rights Concerning Health* Pretoria University Law Press 2005 107-153. See also Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11.

²¹⁷ *Treatment Action Campaign and Others v Minister of Health and Others* 2002 (4) BCLR 1035 (T).

²¹⁸ *Ibid.*

²¹⁹ Hogerzeil HV, Samson M, Casanovas JV et al *Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable through the Courts?* Lancet 2006 Vol 368 305–11.

²²⁰ For more discussion see Dean O *Intellectual Property and the Constitution* 2015 <http://blogs.sun.ac.za/iplaw/2015/07/14/intellectual-property-and-the-constitution/> (accessed 24 December 2018).

inaccessible to majority of the public, it would be the duty of the government under section 7(2) to take steps to ensure access and to promote human dignity, freedom and equality.

7.4.2.2 The Patents Act 57 of 1978

The Patent Act is the primary legislation that regulates patents in South Africa and was last amended in 2005.²²¹ The Act, as in previously discussed jurisdictions, requires that for an invention to be patentable subject-matter the invention should be:²²²

- New;
- It should involve an inventive step; and
- It should have the capability of being used in trade, industry or agriculture.

If granted, the patentee would have the right to exclude other individuals from making, using, exercising, disposing or offering to dispose of, or importing the invention, in order to enjoy the whole profit and advantage accruing by reason of the invention for a period of 20 years from the date of filing.²²³

Section 25(2)-(4) of the Act deals with patentable subject matter. Section 25(2) excludes discoveries, scientific theories and mathematical theories amongst others.²²⁴ Section 25(4) excludes inventions that would generally be expected to encourage offensive or immoral behaviour and any variety of animal or plant or any biological process for producing animals or plants, that is not a process of micro-biology or the product of a process of microbiology.²²⁵ Section 25(11) states that a method of treatment of the human or animal body including surgery, therapy or diagnosis is not deemed to be capable of being used or applied in trade or industry or agriculture.²²⁶ Additionally, the Act excludes patentability for an invention, the publication of which would be immoral.²²⁷

Concerning diagnostic gene patents in SA, an inventor cannot obtain general patent protection for DNA sequences unless all patent requirements are met. Protection can only be obtained for the invention during filing the patent application, ensuring the patent is not artificially extended to protect aspects not indicated experimentally in the biotech patent application. DNA sequences for which no function is demonstrated are not considered patentable.²²⁸

²²¹ Patents Amendment Act 15 of 2005.

²²² Section 25(1) of the South African Patent Act 57 of 1978. See also Klopper HB & Van Der Spuy P De W *Law of Intellectual Property* 2012 225.

²²³ Section 45(1) of the South African Patent Act 57 of 1978.

²²⁴ Section 25(2) of the South African Patent Act 57 of 1978.

²²⁵ Section 25(4) of the South African Patent Act 57 of 1978. See also Gregory S *Intellectual Property Rights and South Africa's Innovation Future Trade Policy Report* No 23 2008. See also *Intellectual Property Guide South Africa 2016* Intellectual Property Office 2016.

²²⁶ Section 25(11) of the South African Patent Act 57 of 1978.

²²⁷ Section 25(4)(a) of the South African Patent Act 57 of 1978.

²²⁸ The South African Patent Act 57 of 1978.

7.4.3 Steps taken to increase access to pharmaceuticals

7.4.3.1 The Medicines and Related Substances Control Amendment Act

One option already utilised by the government to promote access to pharmaceuticals is compulsory licenses. In 1997, following the TRIPS Agreement, the South African government introduced the Medicines and Related Substances Control Amendment Act,²²⁹ which amends the Medicines and Related Substances Control Act²³⁰ in accordance with Article 8 of TRIPS which allows a member state to implement measures required to protect public health and nutrition, as long as these are consistent with the provisions of TRIPS.²³¹ Since medicine prices are generally exorbitant in South Africa,²³² the Act intended to provide cheaper medicines through a variety of ways including:

- parallel importation of medicines;
- Compulsory licensing;
- institution of price controls through establishing a pricing committee;
- promoting generic substitution;
- the prohibition of bonuses and rebates which drug manufacturers use to offer discounts to dispensers of medicines.

The amendment includes the insertion of section 15C “Measures ensuring supply of more affordable medicines” which reads:²³³

“The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances to protect the health of the public and in particular, may -

- a) Notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights concerning any medicine under a patent granted in the Republic will not extend to Acts in respect of such medicine put onto the market by the owner of the medicine, with his or her consent;
- b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by an individual other than the individual who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported; and
- c) prescribe the registration procedure for and using, the medicine referred to in Paragraph (b).²³⁴

²²⁹ Medicines and Related Substances Control Amendment Act 90 of 1997.

²³⁰ Medicines and Related Substances Control Act 101 of 1965.

²³¹ Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 17.

²³² Donald GM *Medicine Prices are Exorbitant in Africa* New York Times 17 June 2000 available at <http://www.nytimes.com/2000/06/17/world/prices-for-medicine-are-exorbitant-in-africa-study-says.html> (accessed 09 September 2014).

²³³ Section 15 of Medicines and Related Substances Control Act 101. For more discussion see Burrell TD *South African Patent and Design Law* (4th edition) 2016.

²³⁴ *Ibid.* See also *supra* note 231 at 18.

The section authorises the Minister of Health to prescribe conditions wherefore the facilitation of reasonably priced medicines is provided for in certain circumstances, to protect public health. The section also limits the rights of South African patent-holders in the pharmaceutical field. The insertion of section 15C quickly found the lime light causing various global reactions. In early 1998, the US Embassy approached both the Swiss and EU member embassies in South Africa to propose a joint effort to protest the provisions of section 15C since both American and European pharmaceutical companies could be adversely affected by the amendments. The European governments preferred to let the US government take the lead in the matter but the French, Swiss and German presidents raised the issue privately with then Deputy President Mbeki.²³⁵

Later that year, then assistant USTR for Africa Rosa Whitaker, travelled to South Africa rising concerns of the US Government with both the Minister of Health and the Minister of Trade and Industry.²³⁶ Following this South Africa was then placed on the “watch list” as one of several countries whose policies and practices deny adequate and effective protection of intellectual property rights or fair and equitable market access for individuals of the United States who rely on intellectual property protection.²³⁷ The Department of State, the USTR,²³⁸ and the Department of Commerce developed an administrative decision to also withhold preferential tariff treatment from certain South African exports. Four items for which South Africa had requested preferential tariff treatment under the Generalised System of Preferences (GSP) programme, would be held in abeyance pending adequate progress on intellectual property rights protection in South Africa.²³⁹

In 1999, the US Congress passed legislation in response to the Act. US Public Law 105-277 establishes that:

“... none of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate Committees of the Congress the steps being taken by the United States Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa’s Medicine and Related Substances Control Amendment Act 90 of 1997”.²⁴⁰

US pressure on South Africa intensified. In late April, then USTR Barshefsky²⁴¹ conducted an upgrade of the special 301 watch list and formally instituted a more serious “review”.²⁴² The US confirmed that the

²³⁵ Bond P *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians* International Journal of Health Services 1999 770.

²³⁶ *Ibid.*

²³⁷ Section 15 of Medicines and Related Substances Control Act 101. For more discussion see Burrell TD *South African Patent and Design Law* (4th edition) 2016.

²³⁸ The US Trade Representative.

²³⁹ *Supra* note 235 at 771.

²⁴⁰ US Public Law 105-277 155. For discussion see Ngwenya C, Cook R *Four / Rights Concerning Health* Pretoria University Law Press 2005 107-153.

²⁴¹ Ambassador Charlene Barshefsky served as the US Trade Representative—the chief trade negotiator and principal trade policymaker for the United States—from 1997 to 2001.

²⁴² *Special 301 Review* Washington DC April 30 1999. Note that this is similar to the Brazil incident cited in section 7.2.3.

government would be punishing South Africa for permitting its public health officials to speak out on trade and intellectual property issues at the WHO.²⁴³

The pharmaceutical industry was also less than impressed by these legislative changes. A PHRMA official stated that South Africa is mounting “a brazen assault on patent protection, the lifeblood of our industry”.²⁴⁴ The same article states that the amendment threatens developing medicines as the average drug costs \$300 million to \$500 million to develop. It also claims that one of the quickest ways to kill incentives for further research into a targeted disease was compulsory licensing for drugs that treat that disease,²⁴⁵ is compulsory licensing only benefit the fortunate commercial entity that is the beneficiary of the benefits offered by such licences and it is patients who will lack new treatments for serious diseases that suffer in the medium and long-term.²⁴⁶

Forty-one transnational pharmaceutical companies brought an action against the South African government in the High Court, challenging the validity of the provision.²⁴⁷ They argue that the changes were unconstitutional and not in compliance with TRIPS.²⁴⁸ The suit caused a global stir and with South Africa being home to the largest number of HIV/AIDS infected people, most individuals not having access to related pharmaceuticals, the suit caused major public outrage and was subsequently dropped.²⁴⁹

7.4.3.2 Promotion of access through courts

South African courts have not observed much action regarding gene patents. This is partly due to relatively low innovation levels with this industry. With South Africa lacking superior resources it is no surprise that its level of innovation is not on the same level as first world countries.²⁵⁰ Even though South African courts have not been exposed to any specific biotechnology cases, cases reflecting the stance of conducting pharmaceutical companies and access to medicines is discussed below.

²⁴³ Remarks by Ralph Nader. For discussion see Bond P *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians* International Journal of Health Services 1999 776.

²⁴⁴ This was a statement made by Jeff Truit in USA Today in May 1999.

²⁴⁵ This was stated by Harvey Bale the Director-General of the International Federation of Pharmaceutical Manufacturers Associations in Geneva.

²⁴⁶ Bond P *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians* International Journal of Health Services 1999 779.

²⁴⁷ *Pharmaceutical Manufacturers Association of South Africa & Another: In re Ex Parte President of the Republic of South Africa & Others* 1999 4 SA 788 (T).

²⁴⁸ For more discussion see Hein W & Moon S *Informal norms in Global governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013.

²⁴⁹ *Ibid.* The latest proposed amendments to the Medicines and Related Substances Act are in line with South Africa's recent intellectual property reform and is available at <http://www.samed.org.za/Filemanager/userfiles/Draft%20General%20Medicine%20Regulations%2027%20January%202017.pdf> (accessed 15 January 2019).

²⁵⁰ Jordaan AS & Jordaan DW *Reality Bites: Biotech Innovation in South Africa* Innovate University of Pretoria 2010 4. The number of PCT applications per year that have South African inventors were counted and the results were compared with similar searches in developing countries like Brazil. Results indicate that South Africa's PCT applications have dropped since 2006 and is half of that of Brazil.

The Competition Commission faced a pharmaceutical dispute when a complaint was lodged against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI).²⁵¹ Both of these companies held patents in South Africa on antiretroviral medicines used to treat HIV/AIDS.²⁵² GSK and BI refused to license their patents for the ARV's to generic manufacturers in return for a royalty fee. In 2003, the Competition Commission found that both GSK and BI had contravened the South African Competition Act and abused their dominant positions and that they:

- Denied a competitor using an essential facility;
- Engaged in excessive pricing; and
- Engaged in an exclusionary act.²⁵³

The Commissioner referred the matter to the Competition Tribunal for a decision; before the hearing occurred, the Competition Commission announced that it concluded settlement agreements with GSK and BI the terms of which included the issuing of voluntary licences to generic manufacturers of antiretroviral drugs. No fine or administrative penalty was imposed and GSK agreed to issue four licences while BI agreed to issue three licences.²⁵⁴

The *Taxotere* case illustrates the issue of public interest to be considered by courts when looking at the balance of convenience in granting an interim injunction. In *casu*, the Sanofi-Aventis group sought to enforce a patent for its oncology drug *Taxotere* against Cipla-Medpro (the local distributor of Cipla India's products in South Africa).²⁵⁵ Sanofi-Aventis initially brought preliminary interdict proceedings against Cipla-Medpro to prevent the launch of Cipla-Medpro's generic product, pending the outcome of a trial action. The interdict was refused by the court of first instance.²⁵⁶ Before appeal to the Supreme Court, the Treatment Action Campaign (TAC) unexpectedly sought to intervene as an *amicus curiae* and none of the parties objected to their intervention.²⁵⁷ TAC argues that the rights under the Patents Act should be observed through "the prism" of the Constitution. They illustrate that section 39(2) of the Constitution requires the courts to promote the spirit that is supportive of the object of the Bill of Rights when interpreting legislation. Section 27 of the Constitution provides that every individual has the right to have access to health care services, including the right to have access to medicines. The TAC further argue that, when weighing the balance of convenience in exercising its discretion whether to grant or refuse a preliminary interdict, the issue of public interest is relevant and is a factor that a court should take into consideration.

²⁵¹ Case Number 2002 September 226.

²⁵² GSK held South African patents on AZT (Retrovir), Lamivudine (3TC) and AZT/ Lamivudine (Combivir) whilst BI held South African patents on Nevirapine (Viramune). See Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 20.

²⁵³ The Competition Act 35 of 1999 applies to all economic activity within South Africa and can override the Patents Act. There are specific provisions for exemptions from applying the relevant chapter of the Competition Act to a practice that relates to the exercise of Intellectual Property Rights including rights granted under the Patents Act.

²⁵⁴ For more discussion see Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 17-20.

²⁵⁵ *Sanofi Aventis and Others v Cipla Medpro (Pty) Limited and Another* (2000/6386) [2009] ZACCP 2 (accessed 08 December 2009). See *ibid*.

²⁵⁶ *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (139/2012, 138/2012) [2012] ZASCA 108; 2013 (4) SA 579 (SCA) 2012.

²⁵⁷ The Treatment Action Campaign (TAC) is a South African HIV/AIDS activist organisation which was co-founded by the HIV-positive activist Zackie Achmat in 1998.

The Court was somewhat dismissive of the first argument but held that there was stronger ground when it submitted that the public's interest, as opposed to the interests of the litigating parties, should be placed in the scales when weighing the balance of convenience.²⁵⁸ The Court overturned the lower court decision by granting the preliminary interdict in favour of Sanofi-Aventis. The patented product is now supplied under two different brand names, *Taxotere* and a cheaper second brand called *Docetere*, owned by a Sanofi-Aventis affiliate.²⁵⁹ The former is supplied primarily to the public sector (under the award of a fixed term public tender) at a substantially lower price than the same product supplied in the private sector. The patented product would remain considerably more accessible to patients dependent on public health care, regardless of the availability of the Cipla product and, there was no question of prejudice at all to those patients, or to the state if the interdict were to be granted.²⁶⁰

The cases discussed above show a tendency SA courts leaning toward increased accessibility to pharmaceuticals over intellectual property rights. *Taxotere* case illustrates the stance of the Supreme Court favouring public interest over a private one.

7.4.3.3 South African Intellectual Property Policy

The draft National Intellectual Property Policy was published in September 2013²⁶¹ for comment and in May 2018 phase one of South African Intellectual Property Policy was released. The policy is part of the National Development Plan (NDP) calling for greater emphasis on innovation, improved productivity, the intensive pursuit of a knowledge economy and better exploitation of comparative and competitive advantages.²⁶² The objectives of the policy are to:

- Engender the ethos of the Constitution;
- Align the country's intellectual property regime to its NDP and broad industrial policy;
- Develop a co-ordinated inter-Ministerial approach to intellectual property;
- Strike a balance between the owners and users of intellectual property;
- Stimulate genuine innovation;
- Facilitate the development of key industries while striking a balance with the public interest;
- Foster investment and technology diffusion;
- Adopt a coordinated approach to intellectual property in sub-regional, regional and international forums;

²⁵⁸ *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (139/2012, 138/2012) [2012] ZASCA 108 [55]-[61]. For further case discussion see Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 20.

²⁵⁹ *Cipla Medpro (Pty) Ltd v Aventis Pharma SA, Aventis Pharma SA and Others v Cipla Life Sciences (Pty) Ltd and Others* (139/2012, 138/2012) [2012] ZASCA 108; 2013 (4) SA 579 (SCA) 2012.

²⁶⁰ *Supra* note 258.

²⁶¹ The draft Intellectual Property Bill can be found at http://www.dti.gov.za/gazettes/IP_Policy.pdf (accessed 14 October 2018). See Cochrane D *What's Behind the Drug Patent Future in South Africa* Managing Intellectual Property Spoor & Fisher 2014 available at <http://www.managingip.com/Article/3311377/Whats-behind-the-drug-patent-furore-in-South-Africa.html> (accessed 06 August 2016).

²⁶² The Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

- Promote public health; and
- Comply with international obligations, in particular those pertaining to human rights.²⁶³

The strategy employed in this comprehensive IP Policy includes:

- Advancing a balanced and coordinated approach to intellectual property that regulates IPRs in line with the South African Constitution
- Introducing key policy reforms that account for the development dynamics of South Africa
- Promoting innovation and a knowledge economy
- Leveraging competitive and comparative advantages to advance the transformation of the South African economy.²⁶⁴

The policy's overarching objective ensures that the intellectual property policy becomes a just, balanced, and integral part of the broader development strategy for South Africa by assisting in transforming the South African economy, and thereby leveraging human resources for the broader economic benefit, increasing local manufacturing, and generating more employment.²⁶⁵

The policy sets out the need for balance between access to pharmaceuticals and intellectual property protection. Section 7 establishes that phase one of the policy focuses toward promoting the right to health and increasing accessibility and affordability of pharmaceuticals.²⁶⁶

Section 7.1.6 confirms the status of section 15C of the Medicines Act in relation to parallel importing.²⁶⁷ The intellectual property policy recognises that section 69A of the South African Patents Act²⁶⁸ already has a Bolar-type provision for obtaining regulatory registration of a medicine in South Africa prior to the expiry of a patent, but excludes stockpiling.²⁶⁹ The policy therefore suggests maintaining the status quo on the entry of generic medicines on to the South African market. A number of tools discussed in chapter 3 are also enlisted within the policy as tools that may be used to increase accessibility.²⁷⁰

The policy has caught the attention of academics and the media and just as the 1997 amendments to the Medicines and Related Substances Control Act,²⁷¹ the policy in its draft form faces under major attack by

²⁶³ Section 4 of the Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

²⁶⁴ Section 5 of the Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

²⁶⁵ The Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

²⁶⁶ The South African Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

²⁶⁷ Medicines and Related Substances Control Amendment Act 90 of 1997. For more discussion on section 15C see section 7.4.3.1.

²⁶⁸ This was introduced by the 2002 amendment of the South African Patent Act 57.

²⁶⁹ This exception allows third parties to manufacture patented drugs in limited quantities without a licence.

²⁷⁰ The South African Intellectual Property Policy can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (access 29 October 2018).

²⁷¹ The Medicines and Related Substances Control Amendment Act 90 of 1997.

global pharmaceutical companies who complain that it favours local generic manufacturers who have put no research and development into developing the product.²⁷²

7.4.3.4 Introducing an examination office

Another step that has been proposed in order to increase access to medicines in South Africa, is the introduction of an examination system. From analysing other jurisdictions within this chapter, it is clear that there are two ways to promote access to pharmaceuticals. This includes stricter laws surrounding the grant of the patents,²⁷³ and the use of tools such as price caps and compulsory licenses. With regard to the former, South Africa is a non-examining patent country; any complete patent application that is filed and meets with the formal requirements listed above will therefore be granted.²⁷⁴ The practice of non-examination does in circumstances give rise to the potential of abuse, as patentees flaunt their rights, safe in the knowledge that the general public does not understand the concept of non-examination and that intellectual property litigation is both expensive and time consuming.²⁷⁵ The lack of examination also gives rise to a large number of pharmaceutical patents which in other circumstances may not have been granted. For example, the current system also allows pharmaceutical companies to obtain multiple patents for the same pharmaceutical, even for subject matter that does not fall under the country's definition of what is patentable allowing companies to extend the life of their patent monopolies and blocking competition.²⁷⁶

The non-examination practice may be viewed on the one hand as contrary to innovation and healthy competition policies; but, conversely, sufficient to suit the needs of the country as there are relatively few patent applications filed annually at the South African Patent Office.²⁷⁷

Recent developments in intellectual property opened the door for discussion of introducing an examination system in South Africa. Amongst the concerns raised are the following:²⁷⁸

- Due to the economy of the country, there may be staffing issues relating to trained examiners within different technical fields.

²⁷² For more details on comments on the initial draft see

https://libguides.wits.ac.za/Copyright_and_Related_Issues/SA_IP_Policy (accessed 29 October 2018). See also McLaughlin P *South Africa to Allow Avoidance of Medical Patents* 2014 <http://parlyreportsa.co.za/health/sa-allow-avoidance-medical-patents/> (accessed 16 April 2015). See also Baker B *US PhRMA Bares its Fangs – South Africa Patent Law Reform and Access to Medicine at Risk Yet Again* <http://infojustice.org/archives/31986> (accessed 13 April 2015). See Also Baleta A *Huge Pharma in the Dock Over Patent Law lot in South Africa* *The Lancet* Vol 383(9916) 499. See also *New IP Consultative Framework for SA: Three Years' Delay is Three Too Many* Fix Patent Laws 2016 <http://www.fixthepatentlaws.org/> (accessed 08 August 2016).

²⁷³ For example the dual approval system.

²⁷⁴ Gregory S *Intellectual Property Rights and South Africa's Innovation* Future Trade Policy Report No 23 2008 11.

²⁷⁵ *Ibid.*

²⁷⁶ Review of the European Union's Trade & Investment Policy *Empty Gestures: The EU's Commitments to Safeguard Access to Medicines* Health Action International 2015 available at <http://haiweb.org/publication/empty-gestures-the-eus-commitments-to-safeguard-access-to-medicines/>.

²⁷⁷ *Supra* note 274 .

²⁷⁸ Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* *The Licencing Journal* 2013 17.

- The current system permits an applicant to place a patent application on file and, provided that the formalities are met, the patent will be granted. This system is advantageous to a developing economy such as South Africa as the costs of obtaining patent protection are reduced.
- The argument is made that allowing invalid patents to remain on the register grants *prima facie* rights to a patentee to which the patentee is not entitled and the patent acts as an unjustified deterrent to competitors. The South African Patents Act allows a defendant to raise invalidity as a defence, or through a counterclaim in infringement proceedings and the courts invariably examine validity.
- Litigation costs are significantly higher than prosecuting a patent application to grant under an examining system.
- The current system places a heavy onus on patentees to amend their patent to take account of invalidity issues that arise, for example, as a result of prior art located during global prosecution. South African courts have often take the position that it is in the public's interest that the register be maintained by appropriate amendments to cure any invalidity and a culpable delay in doing so could lead to the amendment being refused.
- Introducing patent examination in South Africa to limit the grant of pharmaceutical patents would result in different technology areas being treated differently, possibly violating Article 27 of TRIPS.²⁷⁹

However, should an examination office be set up, it would be advantageous for the South African economy to encourage applications to be filed at the outset and only to consider the strength thereof before a court when the commercial value justifies this.²⁸⁰

The South African Intellectual Property Policy proposes substantive examinations be carried out in certain fields of technology, including pharmaceuticals, it remains to be observed whether and how the South African government will decide to adopt an examination system.²⁸¹

7.4.4 Trade agreements

As with the jurisdictions discussed above, after 1994, several BITs were signed between South Africa and mostly European countries that afforded investors various rights and privileges.²⁸² Many of these BITs include limitations on compulsory licences and access to test data, both of which are now standard fixtures of US and many EU FTAs and requires contracting countries to adopt high standards of patentability and longer patent durations.²⁸³

²⁷⁹ Article 27 requires that all technology areas be treated equally.

²⁸⁰ Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 17.

²⁸¹ For more discussion see section 7.1.2 of the Intellectual Property Policy which can be found at http://www.thedti.gov.za/news2018/IP_Policy2018-Phase_I.pdf (accessed 29 October 2018).

²⁸² South Africa's trade agreements can be found at https://www.thedti.gov.za/trade_investment/ited_trade_agreement.jsp (accessed 02 November 2018).

²⁸³ Collins-Chase CT *The Case Against Trips-Plus Protection In Developing Countries Facing Aids Epidemics* University of Pennsylvania Journal of International Law 2008 Vol 29 792-800.

In 2010 South Africa indicated that it intended to change its investment protection policy and undertook a review of existing BITs. The review came after South Africa's Black Economic Empowerment (BEE) policies were challenged by investors in global arbitration concerning existing BITs.²⁸⁴ The Department of Trade and Industry announced that it would strengthen investor protection by codifying the provisions of the various BITs South Africa have in place with other countries into a single piece of legislation as BITs posed unacceptably high risks to its legitimate and sovereign right to regulate in the public's interest.²⁸⁵

In 2013 South Africa proceeded to unilaterally terminate its BITs with certain European states and in November 2013, the South African Department of Trade and Industry published the draft Promotion and Protection of Investment Bill for comment.²⁸⁶ The Protection of Investment Act 22 of 2015 was approved in 2015²⁸⁷ and replaces the BITs concluded in the late 1990s with mostly European countries, which are expiring and not being renewed.²⁸⁸

Section 12 of the Act is entitled 'Right to Regulate' and provides for the government to take measures when in the public interest even where this may have a negative impact on investments.²⁸⁹ These measures include:²⁹⁰

- “(a) redressing historical, social and economic inequalities and injustices;
- (b) upholding the values and principles espoused in section 195 of the Constitution;
- (c) upholding the rights guaranteed in the Constitution;
- (d) promoting and preserving cultural heritage and practices, indigenous knowledge and biological resources related thereto, or national heritage;
- (e) fostering economic development, industrialisation and beneficiation;

²⁸⁴ An example of this was following the enactment of the Mineral and Petroleum Resources Development Act 28 of 2002 (MPRDA), foreign investors from Luxembourg and Italy came to regard the MPRDA and the black empowerment requirement for mining rights as a form of expropriation of their common law entitlement to exploit and mine minerals and initiated arbitration proceedings against South Africa alleging a breach of Article 5 of its BITs which prohibited expropriation. See Joubert N *New Protection of Investment Act – The Implications for Foreign Investors* Caveat Legal <http://www.caveatlegal.com/new-protection-of-investment-act-the-implications-for-foreign-investors/#sthash.aGnohuXx.dpuf> (accessed 03 August 2016). See also Feris J *Challenging The Status Quo – South Africa's Termination of its Bilateral Trade Agreements* International Arbitration Newsletter DLA Piper <https://www.dlapiper.com/en/uk/insights/publications/2014/12/international-arbitration-newsletter-q4-2014/challenging-the-status-quo/> (accessed 05 August 2016). See also Rogers A *ICSID Arbitration Filed Over South Africa's Black Empowerment Program* *Opinio Juris* <http://opiniojuris.org/2007/02/20/icsid-arbitration-filed-over-south-africas-black-empowerment-program/> (accessed 05 August 2016).

²⁸⁵ For more discussion see Joubert N *New Protection of Investment Act – The Implications for Foreign Investors* Caveat Legal <http://www.caveatlegal.com/new-protection-of-investment-act-the-implications-for-foreign-investors/#sthash.aGnohuXx.dpuf> (accessed 03 August 2016).

²⁸⁶ Specifically, Belgium, the Netherlands, Luxemburg, Germany, Spain and Switzerland. More discussion on the Bill see Dean O & Kleyn M *Promotion and Protection of Investment Bill, 2013 – A Review* <https://blogs.sun.ac.za/iplaw/2014/02/06/promotion-and-protection-of-investment-bill-2013-a-review/> (accessed 8 May 2015). Rugege U *Section 27 Comments on the Promotion and Protection of Investments Draft Bill* <http://www.section27.org.za/section27-comments-on-the-promotion-and-protection-of-investment-bill-2013/> (accessed 6 May 2015).

²⁸⁷ The Protection of Investment Act 22 of 2015 can be accessed at https://www.gov.za/sites/www.gov.za/files/39514_Act22of2015ProtectionOfInvestmentAct.pdf (accessed 06 November 2018).

²⁸⁸ For more discussion see Gazzini T *Rethinking the Promotion and Protection of Foreign Investments: The 2015 South Africa's Protection Investment Act 2017* available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2960567 (accessed 06 November 2018).

²⁸⁹ Boyce GM *An Examination of whether the Protection of Investment Act represents a successful alternative to Bilateral Investment Treaties* Master of Laws 2017 Graduate Department of Law University of Cape Town https://open.uct.ac.za/bitstream/item/28588/thesis_law_2017_boyce_gizelle_marie.pdf?sequence=1 (accessed 10 January 2020)

²⁹⁰ *Ibid.*

- (f) achieving the progressive realisation of socio-economic rights; or
- (g) protecting the environment and the conservation and sustainable use of natural resources.”²⁹¹

Under section 3, the Act stipulates that the legislation should be interpreted in a manner that is consistent with its purpose²⁹² and the Constitution.²⁹³

Despite the Act facing many criticisms in relation to lower level of protection offered to investors, for the purpose of limiting TRIPS Plus provisions and increasing accessibility to pharmaceuticals, the Act is a step in the direction of eliminating TRIPS Plus provisions which are detrimental to the access of biotechnology and pharmaceuticals.²⁹⁴

7.4.5 Summary

Transformation in the health sector has not been a smooth one in South Africa. Services in the public sector are inferior due to lack of supplies, equipment and extreme differences in income and living standards. In addition, the health sector also faces race discrimination concerning accessibility. Section 27 of the South African Constitution imposes duties, within the domestic framework to accommodate South Africa’s specific circumstance.²⁹⁵ Section 27 clearly and incontestably enshrines the right to health care services (which includes access to innovation such as diagnostic tests) and whilst the right to property is also enshrined, intellectual property is not explicitly mentioned.²⁹⁶

However, South Africa’s intellectual property reform is extensive and shows progression in intellectual property with minimum standards being implemented under the TRIPS agreement and legislative changes to increase accessibility.²⁹⁷ Even if the property clause would include patents, section 36 of the Constitution, better known as the limitation clause, sets out a test that any limitation should meet. The two central concepts are reasonableness and proportionality: any restriction on a right should be reasonable and proportional in that the impact or extent of the restriction should match the importance of the aim

²⁹¹ The Protection of Investment Act 22 of 2015.

²⁹² Section 4 of the Protection of Investment Act 22 of 2015 sets out the purpose of the Act.

²⁹³ The South African Constitution of 1996. Section 3 of the Protection of Investment Act 22 of 2015 which can be accessed at https://www.gov.za/sites/www.gov.za/files/39514_Act22of2015ProtectionOfInvestmentAct.pdf (accessed 06 November 2018).

²⁹⁴ For more discussion see Gazzini T *Rethinking the Promotion and Protection of Foreign Investments: The 2015 South Africa's Protection Investment Act 2017* available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2960567 (accessed 06 November 2018).

²⁹⁵ Bagnall R *Pharmaceutical Patents and Access to Medicine in South Africa—the Story So Far* The Licencing Journal 2013 17.

²⁹⁶ Note that the right to access to health care services and the right to health is used interchangeably within this study in reference to South African law.

served by the limitation of the right.²⁹⁸ Provided the history of the struggle of the right to health, the alarmingly high incidence of HIV/AIDS and other diseases such as tuberculosis, malaria, hepatitis, cancer, diabetes and heart disease and the economic circumstances of the majority of South Africans, would the right to property not be justifiably limited considering the right to health? The steps taken by the South African government through the South African Policy on Intellectual Property and its aim to introduce a health aspect into national intellectual property laws, together with the attitude of the courts in the cases discussed, allows it to for an inference that section 36 of the Constitution may well be used to limit section 25 considering the right to health.²⁹⁹

Considering the discussion within the previous section, we find that section 25 (2) and 25(11)³⁰⁰ of the Patent Act excludes diagnostic genes as patentable.³⁰¹ When applying the Patent Act in a technical sense and considering global patent requirements and case law, though questionable on moral grounds, it is highly possible that diagnostic gene patents do meet the requirements for patentability in South Africa.

7.5 Conclusions

There is a distinct difference in the area of focus between the jurisdictions discussed in the previous chapter and those discussed in this chapter. Table 6 below depicts a summary of the position on gene patentability; constitutional protection of the rights to health and property; and the approach to trade agreements in the field of biotechnology, within each of the jurisdictions discussed above.

²⁹⁸ Section 36 of the South African Constitution 105 of 1996.

²⁹⁹ The Constitution of the Republic of South Africa of 1996.

³⁰⁰ Section 25 (11) states: “An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnoses practised on the human or animal body will be deemed not to be capable of being used or applied in trade or industry or agriculture”.

³⁰¹ Nainkin J In “Gene” nious? 2013 Without Prejudice 2013 30.

Table 6: Summary of key jurisdictional differences

Jurisdiction	Are genes patentable within this jurisdiction?	Constitutional protection of relevant rights	Jurisdictional approach to relevant trade agreements
United States	Isolated genes are patentable (for the moment)	Only the right to property is protected (no specific reference to IPR)	Promotes high intellectual property protection standards in FTAs/BITs
Europe	Isolated genes are patentable	Only the right to property is protected in both supranational legislation and the German Constitution (no specific reference to IPR)	Promotes high intellectual property protection standards in FTAs/BITs
Brazil	Isolated and modified genes are patentable	Both the rights to health and property are protected (no specific reference to IPR)	Steps taken to restrict BITs in order to suit domestic needs including increased access to pharmaceuticals
India	Only the modified part of the gene is patentable	Both the rights to health and property are protected (no specific reference to IPR)	Restrictive BIT terms which aim to promote domestic needs including increased access to pharmaceuticals
South Africa	Patentable if a function is identified	Both the rights to health and property are protected (no specific reference to IPR)	BITs replaced by legislation in order to promote domestic needs including increased access to pharmaceuticals

In chapter 5 it is evident that developed countries with strong biotechnology industries place more importance on stronger intellectual property rights and protecting inventors while in this chapter it is evident that more importance is placed on increasing accessibility and observing the right to health.

The discussion reflects that each of the jurisdictions discussed within this chapter, unlike those discussed in the previous chapter, constitutionally protect the right to health. As such, the governments of these jurisdictions have made similar efforts to increase access to pharmaceuticals. Brazil and South Africa have made similar efforts to increase access to pharmaceuticals through the use of compulsory licenses.

According to the Organisation for Economic Co-operation and Development, there is a positive relationship between increased intellectual property protection and FDI.³⁰² Health activists, however, argue that a stronger intellectual property regime results in decreased access to pharmaceuticals, whilst pro-patent regimes claim that in countries with the strongest intellectual property laws, citizens enjoy greater access to pharmaceuticals.³⁰³

Developed countries, having sufficient infrastructure to develop biotechnology and pharmaceuticals, understand the importance of scientific research and the economic effects of patents but as observed with the BRCA case, access to pharmaceuticals is still a concern.³⁰⁴

³⁰² Urbach J *Intellectual Property Rights – Where to South Africa?* 2015 Government, Intellectual Property <http://www.freemarketfoundation.com/issues/intellectual-property-rights-where-to-south-africa> (accessed 04 August 2016).

³⁰³ *Ibid.* See also Thuo Gathii J *What History Teaches Us About International Protection of Intellectual Property Rights: The Case of Least Developed Countries* Georgia Journal of International and Comparative Law 2013 41.

³⁰⁴ Barnes S *Pharmaceutical Patents and TRIPS: A Comparison of India and South Africa* Kentucky Law Journal 2002 Vol 91 911-957.

Chapter 8

Conclusion and Recommendations

8.1 Conclusion

“The idea of a better ordered world is one which medical discoveries will be free of patents and there will be no profiteering from life and death”.¹

The scientific community has developed rapidly in the past 20 years. With all the significant technological advances, particularly in biotechnology, there has been a massive increase in biotechnology related patents, specifically diagnostic genes which have affected health care.² Despite patents providing a protective and incentive function with regard to diagnostic genes, they also portray negative effects as discussed above. The main effects being the cause of a rise in the cost of the diagnostic test and the hinderance on further research in the field. This has brought about a need to take a deeper look into the rights affected within this area.

The rights affected include the right to intellectual property and the right to health, both of which are given global status. However, should fundamental rights allow individuals to gain a property right over a subject-matter that is crucial to the health of the public, if such property right has the effect of making diagnostic tests less economically accessible for many? The discussion above broke down this main question into three sub-questions and each of these are addressed below.

8.1.1 Are diagnostic genes patentable subject matter?

As discussed in chapter 2, genes and their functions are scientific in nature as opposed to being technological in nature, in essence, being discoveries as opposed to inventions.³ The discussion in chapter 2 illustrates that genes meet the requirements of a patent in a strict technical sense.⁴ The only difference between a gene found in nature and genes “invented” is the removal of redundant codons. In essence the sequences and the information held by the sequences i.e. the protein code, is the same.⁵ Peter Drahos

¹ The above is a sentiment conveyed by Indira Gandhi at the World Health Assembly of 1982 obtained from Hestermeyer H *Rights and the WTO: The Case of Patents and Access to Medicines* (2007)15.

² The final report of the commission on intellectual property *Integrating Intellectual Property Rights and Development Policy, report prepared by the UK Commission on Intellectual Property Rights* (2002). See also Helfer LR & Austin GW *Mapping the Global Interface* 2011 19.

³ De Carvalho NP *The Problem of Gene Patents* <http://heinonline.org> (accessed 13 March 2013). See also Kane EM *Splitting the Gene: DNA Patents and the genetic code* Tennessee Law Review 2004 Vol 71

733. For more see *The Ethics of Patenting DNA* a discussion paper by Nuffield Council on Bioethics 2002 [The%20ethics%20of%20patenting%20DNA%20a%20discussion%20paper](#) (accessed 03 October 2015).

⁴ See chapter 2 sub section 2.2.1.

⁵ Drahos P *Biotechnology Patents, Markets and Morality* European Intellectual Property Review 1999.

indicates that this is basically the same as picking up a rock in the park and calling it an invention after it was washed and polished.⁶

In addition, the function of a diagnostic gene patent seems to be inconsistent with the overall function of the patent system. The patent system in general, is an intervention into the commercial free-market, designed to prevent market failure, foster innovation and provide a period of monopoly for inventors.⁷ As discussed in chapters 2 and 3, the intervention of a patent is a critical factor for driving innovation and in turn increasing public benefit.⁸ However, in the case of diagnostic gene patents, the discussion portrays a contradiction to these values of the patent system as it limits innovation and fails to achieve public benefit by limiting access to only a handful of the public.⁹

Notwithstanding the above, as observed from the discussion in this paper, genes sequences have been globally accepted as patentable subject matter albeit only specific types of genes sequences including synthesised sequences and cDNA.¹⁰

8.1.2 Are traditional patents appropriate in biotechnology?

The next question to address is whether patents are the most appropriate tool used within the area. When analysing alternatives to the traditional patent the aim is to obtain an appropriate balance between public and private interest as it applies to genomic material.¹¹ Patent balance assumes a particular significance in the pharmaceutical/biotechnological industry as it affects health care. As mentioned in chapter 3, in contrast with several other industries, the pharmaceutical/biotechnology industry relies heavily on the patent system to appropriate returns, and considerable innovation is based on the patent system.¹² However, limitations relating to conducting further research and high costs of end products require a tailoring of the system, in order for society to benefit from scientific innovation within these areas.

The current patent system is non-dimensional. Traditionally, patent law is applied across all fields of technology, despite a variance in the needs of each industry.¹³ Factors to be considered should include economic and social welfare.¹⁴ For example, the needs of the biotechnology industry, specifically in

⁶ *Ibid.*

⁷ Walpole IR, HJS Dawkins, Sinden PD et al *Human Gene Patents: The Possible Impacts on Genetic Services Health care* available at <http://www.mja.com.au/journal/2003/1794/human-gene-patents-possible-impacts-genetic-services-health-care> (accessed 30 March 2015).

⁸ For purposes of this paper, public benefit extends to the public as a whole being able to access technological developments in order to diagnose or treat specific and general conditions.

⁹ This being only those that can economically afford patented tests. This is illustrated by a number of cases including the Myriad case discussed in section 2.2.2. See also Holman CM *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation* Kansas City Law Review 2007 76(2) 295.

¹⁰ This is evidenced by the cases discussed in section 2.2.3, chapter 6 and 7.

¹¹ Pitcher AS *Contrary to First Impression, Genes are Patentable: Should There Be Limitations?* Journal of Health Care Law and Policy 2003 Vol 6(2) 7 300. For full discussion see chapter 3.

¹² Haracoglou I *Competition Law and Patents – A Follow on Innovation Perspective in the Biopharmaceutical Industry* 2008 25.

¹³ Van Overwalle G *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches* UC Irvine Law Review 2011 Vol 1(2) 492-512.

¹⁴ *Supra* note 11.

relation to diagnostic gene patents, can be met by tailoring diagnostic gene patents in one or more of the following ways:

- A reduction of the scope of these patents
- A reduction of the period of the patent
- An inherit research exemption
- Patent pools
- Semi- exclusive or exclusive licences

If patents are tailored for the biotechnology industry in one or more of the ways mentioned above, the needs of innovators would be met. Incentive for further research would exist and the initial innovator would still have some control. This still leaves the issue regarding high costs and inaccessibility by the public. If prize schemes or ex-officio licenses are tailored into the patent system then the needs of innovators are not met.

Even if the system could be tailored in a way that balances the needs of both innovators and the public, difficult as it may be, tailoring the patents system to suit the needs of a particular industry may be seen as contrary to Article 27 of the TRIPS Agreement. Article 27 provides for non-discrimination in fields of technology.¹⁵ As TRIPS is binding for all WTO members and noncompliance could result in sanctions.

In addition to the issues named above, it is identified throughout this paper that the economic and social needs of various jurisdictions differ. Developed countries are suited to stronger intellectual property laws inclusive of biotechnological and pharmaceutical patents, whereas developing countries are not. In fact, when developed countries were in the developing stages, they lacked patent systems. France, Germany, Italy, Sweden and Switzerland, comprising some of the most innovative pharmaceutical companies, did not provide pharmaceutical products with patents until their industries reached a certain development level.¹⁶

It suits the economic needs of the EU and the US to tailor diagnostic gene patents in a way that allows for further research (thereby opening the door to more patents) yet this will be unsuitable for developing countries. The issues mentioned above indicate that tailoring the patent system to suit the needs of the biotechnology industry is not suitable.

8.1.3 The status and relationship between fundamental rights and property rights

With diagnostic genes accepted as patentable subject matter, and no viable alternative to patents in the field of biotechnology found, the focus shifts to the status and relationship between the rights involved

¹⁵ Article 27 of TRIPS provides that ".....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".

¹⁶ Oddi S *The International Patent System and Third World Development: Reality or Myth?* Duke Law Journal Vol 1987 837.

when these genes are patented in order to assess the limitation of one right over the other. These rights include the right to health and the right to property, assuming that intellectual property falls under the ambit of property.

There is no question regarding the fundamental status of the right to health as it is accepted globally as a fundamental right and is mentioned in various human rights instruments including the UDHR.¹⁷ Accepting intellectual property rights as fundamental, despite not being expressly incorporated into various human rights instruments, is more problematic because of the nature of the right. Reasons to exclude patents as fundamental in nature range from it being a private right as opposed to a communal right, to the fact that intellectual property rights need to be registered and hold time constraints, as opposed to being automatic and absolute.

As discussed in section 5.8, in order for property rights, including intellectual property rights, to be considered as a fundamental right, it would need to be without distinction. Just as the right to health needs to be of equal status to each individual, intellectual property rights would need to benefit both the creator and the consumer of the technology.¹⁸ Additionally, from the discussion in chapter 4 regarding international intellectual property instruments, and the comparative study in chapters 6 and 7, it is clear that the intellectual property needs of jurisdictions differ depending on individual economies and infrastructure. Certain jurisdictions require stronger levels of intellectual property protection while others require a lower level of protection. However, when analysing a fundamental right like the right to health, no such differences exist. Individuals in all jurisdictions, regardless of the national economy and infrastructure, require the same level of protection with regard to health care. Fundamental rights in a sense, are a one size fits all species of rights while, as reflected in this study, intellectual property is not. Put simply, when intellectual property rights, specifically patents, and fundamental rights are compared it comes down to an individual who has had their work copied being compared to an individual being deprived of a survival substance.¹⁹

Despite the conflict in the nature of these rights, they are also compatible in certain ways. Fundamental aspects are found within intellectual property. Fundamental concepts such as morality and dignity are explicitly mentioned in intellectual property instruments.²⁰ As a result of the ethical implications of biotechnology and diagnostic genes in particular,²¹ it is important to integrate fundamental rights law into the patent law regime, particularly in the context of human genetics.²² Concepts such as morality also play a role in the interpretive process involved in judicial decision-making on patent law.

¹⁷ For a deeper analysis of these international instruments see chapter 5.

¹⁸ For discussion see Hein W & Moon S *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines* 2013 507.

¹⁹ For more see Drahos P *Intellectual Property and Human Rights* Intellectual Property Quarterly 1999 348. See also Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 15.

²⁰ For example, many jurisdictions exclude inventions that are contrary to morality from patentability.

²¹ The ethical implications being that diagnosis could mean the difference between death and obtaining treatment.

²² Grosheide W *Intellectual Property and Human Rights. A Paradox* 2010 245-247.

The author thus conforms to the compatible theory observing that the two areas of law as compatible but in need of balancing. Both intellectual property and fundamental rights serve to enhance public welfare and benefit society, and both regimes need to equally attempt to define the appropriate scope of private rights, whilst safe guarding public interest in the area of biotechnology.²³

8.1.4 Balancing of the rights

With the two rights in issue having a somewhat equal status, they must be weighted in value against each other in order to justifiably limit one in favour of the other.

Du Bois's justificatory theory for intellectual property protection is one that can be applied here in order to access the relative value of a particular intellectual property right as compared to the relative value of the competing non-property right, in order to find a constitutionally acceptable level of protection for each right.

The right to health has been the centre of attention both nationally²⁴ and globally²⁵ for several years. Several global instruments, such as TRIPS, the UDHR and the ICESCR, all encourage members to adopt methods to protect and promote public health.²⁶ More importantly, the right is communal, benefitting the public as opposed to an individual and is listed an absolute right.²⁷ The right to intellectual property, on the other hand, is also provided for in several global instruments but is a private right benefiting an individual or a corporation and is periodical.

As mentioned in chapter 4, key provisions in international instruments dictate that a limitation must be provided by law; serve a legitimate interest; and a proportionality between the ends and means.²⁸ If applied within the South African context, the limitation is provided for by section 36 of the Constitution,²⁹ the legitimate aim serves to increase public access to biotechnology essential to health care, specifically diagnostic gene tests. The proposed means to obtain this end is a change in the interpretative perspective of intellectual property. The suggested change requires the right to health care be promoted without completely retracting or voiding the intellectual property right but rather by applying fundamental right values during interpretation of intellectual property laws in order to balance these rights in a way that increases access to health care technology. Sections 10, 11, 12(2) and 29(1)(a) of the Constitution are

²³ *Ibid* at 237. See also General Comment 17 E/C.12/GC/17 which confirms the theory and is available at <http://tb.ohchr.org/default.aspx?Symbol=E/C.12/GC/17> (accessed 23 January 2015). See also Human Rights Commission, Report of the High Commissioner *Impact of the Agreement on Trade-Related of Intellectual Property Rights on Human Rights* U.N.Doc. E/CN.4/Sub.2/2001/13 – 27 June 2001 https://www.ohchr.org/en/issues/globalization/pages/reports_hc.aspx (accessed 19 September 2017).

²⁴ Article 2 of the Universal Declaration of Human Rights.

²⁵ See chapters 6 and 7.

²⁶ See chapter 5.

²⁷ TRIPS Article 8, ICESCR Article 12, UDHR Article 25. Refer to chapters 4 and 5.

²⁸ Absolute rights are those rights which can be neither restricted nor restrained under any condition.

²⁹ Article 29 (2) of the UDHR.

³⁰ The South African Constitution of 1996.

being promoted by awarding the right to health care a higher status.³⁰ As the proposed lesser valued right, being the right to property, is not completely retracted or voided in favour of the stronger one, the suggested means to the end is proportionate. This is in sync with the national justification analysis carried out in chapter 7 in relation to the provisions of the Protection of Investment Act of 2015.³¹

The justification analysis illustrates the massive public health benefit in contrast to the private economic benefit. The public would benefit in terms of access as well as further development in biotechnology without completely voiding an intellectual property right. By applying fundamental right values during the interpretation of intellectual property laws pertaining to biotechnology such as diagnostic gene tests, a balance can be established between private interest and public interest, fundamental rights law and intellectual property law, individual rights and community-based rights, and, an inventor's right to property and a patient's right to health care.

8.2 Recommendations

Intellectual property laws are only one factor amongst several that foster innovation and development. Successful implementation of intellectual property rights depend on complementary factors such as the quality of legal institutions, markets and infrastructure. The efficacy of intellectual property reform is ultimately subject to the environment where intellectual property rights operate. National prosperity is achieved when countries implement a policy paradigm, of which intellectual property rights are an important component and suit the needs of that country.

Considering that the South African Constitution is underlined with the values of human dignity, equality and freedom, it is only rational for it to be required that property rights be balanced with the public's interest. This is not only a national requirement, but from a communal perspective, a global one.

The balancing of the right to health/health care and intellectual property requires fundamental values such as human dignity³² and equality³³ be incorporated into any legal regime that is related to health care including that of intellectual property. All states should monitor intellectual property legislation, ensuring that the fundamental right standards are met.³⁴ Intellectual property as a constituent of the fundamental rights regime, requires the level of protection be raised to promote scientific progress in a manner that will broadly benefit members of society individually and collectively.³⁵ A higher standard for evaluating patent applications needs to be established to ensure proposed inventions are consistent with the inherent dignity

³⁰ The South African Constitution of 1996.

³¹ See section 7.4.4.

³² For more discussion on human dignity see section 5.7.

³³ Equality is defined in section 5.4 note 74.

³⁴ Human Rights Commission - Report of the High commissioner *Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights* U.N.Doc.E/CN.4/Sub.2/2001/13 -June 27201 [https://www.ohchr.org/en/issues/globalization/pages/reportshc.aspx_\(accessed 19 September 2017\)](https://www.ohchr.org/en/issues/globalization/pages/reportshc.aspx_(accessed 19 September 2017)).

³⁵ Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

of a human being and with fundamental rights norms.³⁶ Finally, as a result of fundamental rights being a universal entitlement, its application should be measured by the degree to which it benefits the public.

As economic and social needs differ depending on a country's stage of development, it is recommended that an interpretive perspective on intellectual property within this sector be applied universally. The first step to accomplishing this could be global instruments offering guidance on such an interpretive perspective within the remit of biotechnology patents such as diagnostic genes. Steps could also be taken to incorporate such interpretive perspectives into future international agreements requiring member states to such agreements adhere to and/or incorporate such interpretive perspectives into their national legislation. This would allow different jurisdictions to employ intellectual property rights that are suited to domestic economic and social needs, while still keeping to a universal objective to increase access to health care technology.

A universal objective to interpret intellectual property legislation regarding diagnostic gene patents, with the aim to balance the rights to access to health care and to property, will also resolve international inconsistencies in diagnostic gene patentability. Resolving these inconsistencies will create legal certainty within this area of the law and equal access to genetic testing for patients.³⁷

It is recommended that a universal objective to interpret intellectual property legislation regarding diagnostic gene patents, with the aim to balance the rights to access to health care and to property guides the interplay between intellectual property and health. This allows the economic and rewarding function of the patent to be served while allowing for the certainty that tools such as compulsory licences and research exemptions are inherent when technology pertains to health care. More specifically, this will increase access to diagnostic tests; decrease prices of these diagnostics tests and a step will be taken towards reaching a balance between innovation and public benefit in health.

³⁶ Coombe RJ *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity* Indiana Journal of Global Legal 1998 Vol 6(1) 3 64.

³⁷ Jamison M *Patent Harmonization in Biotechnology: Towards International Reconciliation of the Gene Patent Debate* Chicago Journal of International Law 2015 688.

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The Economic and Social Council 08/11/2000 (Article 12 of the International Covenant on Economic, Social and Cultural Rights) E/C.12/2000/4

The European Patent Convention

The International covenant on economic, social and cultural rights (ICESCR)

The Paris Convention for Industrial Property

The Universal Declaration of Human Rights

United Nations General Comment 14: The Right to the Highest Attainable Standard of Health
E/C.12/2000/4 *WIPO Intellectual Property Handbook* International Treaties and Conventions on
Intellectual Property WT/MIN(01)/DEC/W/2