A SOUTH AFRICAN PERSPECTIVE ON THE (NON)PATENTABILITY OF HUMAN GENETIC MATERIAL

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SUMMARY

South Africa has yet substantively and comprehensively to engage with whether human genetic material would be (or rather should be) considered a patentable subject matter. This thesis seeks to address the patentability of human genetic material from both a legal and an ethical perspective, with particular reference to genetic patents utilised in genetic diagnostics and testing. The aim of the study is to present a South African perspective on the validity of gene patents through an evaluation of applicable legislation, constitutional interpretation and constitutional conflict, international agreements, moral and philosophical considerations, as well as ethical concerns that flow from the consequences associated with the recognition of human genetic material as intellectual property. It is argued that a South African approach to genetic patents should not readily accept the patentability of genes in an attempt to stay relevant and competitive in the biotechnology industry, as doing so will disregard the unique nature of human genetic material, as well as undermine uniquely South African values and contemplations.

Keywords: Gene patents, Intellectual property rights, Biological material patents, Patentability, South African patents, Bioethics, Technology and morality, Ethics, Values

DEDICATION:

“My mother’s gifts of courage to me were both large and small. The latter are woven so subtly into the fabric of psyche that I can hardly distinguish where she stops and I begin.”

- Maya Angelou

I am unequivocally the product of my mother’s unwavering love.

This thesis is as much hers, as it is mine.

Table of Contents

List of Abbreviations

ASSAf	Academy of Science of South Africa
AU	African Union
DNA	Deoxyribonucleic acid
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Office
HFE	Haemochromatosis
HGM	Human genetic material
HGP	Human Genome Project
HIV	Human immunodeficiency virus
IPRs	Intellectual property rights
LQTS	Long QT Syndrome
NIH	National Health Institute
OECD	Organisation for Economic Co-operation and Development
R&D	Research and development
RNA	Ribonucleic acid
TAC	Treatment Action Campaign
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UNESCO	United Nations Educational, Scientific and Cultural Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

1 CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 Introduction

We live in a time where one fifth of our genes are owned privately by commercial entities, universities, research institutes and hospitals, to name a few.[1] For most of us the initial reaction on hearing this is that it is unacceptable and wrong and that it even may be unethical as we have learned our genes make us who we are.[2] Some may wonder why only a few corporations, institutions or even individuals should benefit from what forms all living matter. Should what may be gained from those genes not benefit humankind in general as common property, and should genetic material be capable of becoming private property in the first place?

The thesis examines the legality and ethical acceptability of patenting human genetic material (HGM). The discussion, therefore, addresses the law governing patents, as well as its ethical regulation, since these fields encompass important and relevant concerns, uncertainties and difficulties. South African perspectives on and approaches to granting such patents are highlighted.

The consequence of granting patents relating to HGM, however, is the real topic in need of attention. It is argued that patents would restrict access to diagnostic testing, hinder research and development (R&D) in the biotechnological and medical fields and result in the potential and actual violation of individual rights.[3] The examination, therefore, includes an analysis of whether genetic material complies with the requirements for the granting of a patent in the first place by taking into consideration the law as it stands. Thereafter, consideration is given as to whether there are any ethical and moral considerations beyond the purely legal to support the claim that such patents should not be granted. As said above, these issues will be evaluated from a uniquely South African perspective.

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1 Koepsell *Who owns you? The corporate gold rush to patent your genes* (2009) 4.

2 *Idem* 13.

3 Andrews 'The gene patents dilemma: balancing commercial incentives with health needs' 2002 *Hous. J. Health L. & Pol'y* 65-106.

1.2 Background

South African patent law was regulated by common law until the first Patent Act came into effect in 1860.[4] The 1860 Act almost mirrored English patent legislation from 1853, but it differed by allowing only the patenting of "inventions", and not "any new manufacture" as prescribed by English law.[5] In 1978 the current Patents Act was promulgated in South Africa, following a definition of a patent similar to that in Europe.[6] This Act complies with the Trade-Related Aspects of Intellectual Property Rights (TRIPs) treaty of 1994, binding South Africa to the World Trade Organisation (WTO) which regulates international trade. The basis for the right to patent an invention in South African law is that it is to the advantage of society and in the interest of the public that technology be improved.[7] What it does is grant the inventor an exclusive monopoly in respect of the invention for a limited period (20 years) after which an invention becomes part of the public domain.[8] This restricted monopoly granted to the patent holder both encourages individuals to present their inventions and sees to it that the benefits of invention are accessible to the public.[9]

The Courts established as a general principle that patents regarding natural products are not to be granted,[10] but in 1912 the United States Circuit Court condoned a patent on adrenaline in the *Parke-Davis & Co v HK Mulford & Co* decision.[11] Although adrenaline is a natural hormone, the application succeeded as the hormone was identified, isolated and purified by the applicant. Since this exact form of the hormone as isolated and purified could not be found in nature and as it was valued in the medical field for treatment purposes, the granting of a patent over the said isolated and purified hormone was permitted.[12]

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4 Van der Merwe *et al Law of intellectual property in South Africa* (2016) 360.
5 Klopper & Van der Spuy *Law of intellectual property* (2012) 220.
6 Patent Act 57 of 1978.
7 Klopper & Van der Spuy 221.
8 *Ibid*.
9 *Idem* 221.
10 *Funk Brothers Seeds Co v Kalo Inoculant Co* 76 USPQ 280 (1948).
11 196 F. 496-97 (2d Cir. 1912).
12 Andrews 71.

In the famous 1980 case of *Diamond v Chakrabarty*,[13] the US Supreme Court decided that a genetically-engineered living bacterium was patentable.[14] Prior to this decision the patenting of life forms was opposed by US Courts.[15] In this case, an organism was produced which existed only as a result of the inventor's intervention and this bacterium cannot be found in nature.[16] The Court declared that "anything under the sun that is made by man" may essentially be patented, as long as it is not a product of nature and if the invention complies with the three patent requirements.[17] The court decided by a five to four majority ruling that Chakrabarty was entitled to a patent, on the basis that awarding the patent was not in terms of whether the invention was dead or alive but rather whether or not the invention was a product of nature. They concluded that since the bacterium was Chakrabarty's own invention and not a product of nature it was patentable.[18] Critics argue that this decision left little or no obstacle to the patenting of higher and more complex forms of life.[19]

Two years later, in 1982, the first human gene patent was issued.[20] Patents were allowed in the US for genes of which the functions were known.[21] One such gene was the gene for insulin, since it was patented in a form that was derived from DNA which had been manipulated, and therefore it was argued that it was not in its natural form.[22] Genes in the form of cDNA (complementary DNA) therefore were patentable as technically they are not products of nature.[23] By 2008 it was estimated that there were between 3 000 and 5 000 US patents on human genes and about 47 000 patents on inventions that encompass genetic material.[24]

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13 447 US 303, 100 S. Ct. 2202, 65 L.Ed.2d 144 (1980).

14 Andrews 70.

15 Kevles & Berkowits 'The gene patenting controversy: a convergence of law, economic interests, and ethics' 2001 *Brook. L. Rev*. 234.

16 Ebermann *Patents as protection of traditional medical knowledge* (2012) 79.

17 *The Diamond* decision at 309.

18 Kevles & Berkowits 234.

19 *Ibid*.

20 Caulfield 'Human gene patents: proof of problems?' 2010 *Chi.-Kent L. Rev*. 133; US Patent No. 4.322.499.

21 Kevles & Berkowits 235.

22 *Ibid*.

23 *Ibid*.

24 Cook-Deegan 'Gene Patents' in *From birth to death and bench to clinic: the Hastings Center bioethics briefing book for journalists, policymakers, and campaigns* (2008) 69.

In 2013 the US Supreme Court ruled in the *Myriad Genetics* case,[25] that "genes and the information they encode are not patent eligible … simply because they have been isolated from the surrounding genetic material".[26] However, the Court did conclude that cDNA still is eligible for patentability[27] as cDNA is considered to be a novel synthetic creation even though effectively it contains the same genetic information as DNA.[28] Naturally-occurring genomic DNA contains regions known as introns, which do not code proteins, as well as exons, which are genes that code proteins. cDNA is synthesized from messenger-RNA (mRNA), meaning that it contains only exons (the protein-coding regions) without introns.[29] Therefore, cDNA is considered to be novel and 'inventable' even though fundamentally it contains the same proteins and genes as normal DNA (which now is not patent eligible, according to the US Supreme Court).[30]

1.3 Significance of study

Given the rate of scientific development, the law not only needs to develop in parallel to scientific breakthroughs but to predict future issues that might arise as well, however difficult and burdensome this task might be. The reason is if the law fails to envision or even consider future implications and consequences of scientific advances, then the law will not properly and adequately protect those who require protection when science fiction becomes reality. If the legislature wishes to encourage innovation through statutes such as the Patent Act, it also should foresee the consequences of such potential contributions to society and regulate scientific breakthroughs in a precautionary manner that considers an array of societal needs.

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25 *Association for Molecular Pathology, et al. v Myriad Genetics, Inc., et al* 133 S. Ct. 2107 (2013).

26 *Ibid.* The case dealt with the issue of the BRCA1 and BRCA2 gene being patented. These genes – if mutated- result in five to ten percent chance of breast cancer cases in women, as well as an increased risk for other cancers, such as ovarian cancer; Sideri *Bioproperty, biomedicine and deliberate governance: patent as discourse on life* (2014) 59.

27 Hurter 'No one 'owns' the Genome: The United States Supreme Court rules that human DNA cannot be patented' 2013 *SAJBL* 53.

28 *Ibid*.

29 http://www.differencebetween.com/difference-between-dna-and-vs-cdna/ (accessed 23 July 2017).

30 Hurter 53.

Genetic patents sought by and granted to inventors in “First World” countries impact the availability of resources in countries in which genetic patent applications are scarce or even absent. The situation in developing countries is affected by genetic patents granted to First World applicants. There is a domino effect to granting patents and developing countries draw the short straw in terms of benefits. The discussion at hand is important in a South African context when the vast disparity between the supply and demand in the public health care system is taken into consideration.

In law mostly issues of interpretation arise as a result of too narrow an interpretation of the law. In this thesis I argue, in some instances, having too broad an interpretation of legal requirements also may result in an unfavourable outcome. This is the case where the public is impacted adversely by a broad interpretation or if constitutional rights are negated by an interpretation of this kind.

Ethical issues cannot be ignored in a discussion of a procedurally and requirement-driven topic such as patents. At the end of the day ethical principles should influence the law. Ethics and morality mirror what is judged right and wrong in a specific society, and in turn this judgment dictates the laws that society imposes. If the law does not appear to truly advance justice (be it in economics or in a social setting) we need to get to the bottom of what has influenced the law such as the ethical foundation upon which the statutes is built. If the law does not accomplish the aims it sets out to achieve, ethical principles and morals must show the path forward. Ethics and morals also need be considered contextually. The study aims to evaluate the conflicts between the economic value of genetic patents in the global North against the societal and public interest of the global South.

1.4 Reasons for comparative study

To investigate the effectiveness and scope of South African intellectual property law in relation to the issue at hand[31] one must compare the law to the circumstances governing the biggest role players in gene patents. South Africa is yet to deal with the controversial issue of patenting genes, so there is no legal precedent to speak of. In order to establish what the South African approach pertaining to the topic would (and should) be it is reasonable for the courts to refer to foreign law as a basis for comparison when inevitably they are faced with the same dilemma which in other jurisdictions have led to established principles.

Chapter four of the thesis presents a comparative study of South African and European patent law, as South African patent law is very similar to that found in Europe, and is modelled on the European Patent Convention (EPC).[32] The European Patent Office (EPO) is the authority for examining the patentability of subject matter for European patent protection.[33] Even though the extensive and thorough principles and guidelines implemented by the EPO to assess European patent applications do not have direct influence on the South African patent law, these guidelines aid in the judicial interpretation of matters in South African courts where the courts have yet to adjudicate on such matters.[34] It is for the abovementioned reasons that a comparative analysis is appropriate to the discussion. The comparison is useful in determining whether South Africa follows an approach similar to that of the EPO or whether South African values require a different approach to genetic patents after consideration of the European approach.

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31 "Intellectual property" is defined as a "generic term used to refer collectively to a variety of diverse intangible products such as inventions and patents, trade marks and brand names, industrial designs, copyright, plant breeders' rights, performances, trade secrets and know-how, etc."; Adams & Adams *Practitioner's guide to intellectual property law* (2011) 1.

32 Van der Merwe *et al* 360.

33 *Idem* 361.

34 *Ibid*.

1.5 Chapter outline

Chapter two of this thesis deals with the science behind genetic patents and unpacks what genes are and what exactly is patented. This chapter considers the practical application of such patents and illustrates the significant impact of such patents. Chapter three discusses the legal framework of patents, specifically genetic diagnostic patents. This chapter looks at the validity requirements of a patent in terms of South African legislation, as well as constitutional rights that may be affected adversely or violated by granting patents. Chapter four draws a comparison between South African law and that of Europe to emphasise the difference in moral considerations in these jurisdictions. Chapter five deals with the ethical issues surrounding genetic diagnostic patents. In this chapter Utilitarianism is discussed as an ethical theory in terms of which the ethical compliance of genetic patents is considered. I address specific dilemmas and concerns related to genetic diagnostic patents that should be considered in the evaluation of the legitimacy of genetic patents. The final chapter concludes the thesis and discusses a recommended approach to be followed, internationally and domestically with reference to genetic patents.

1.6 Methodology

With the acceleration of genetic technological advances over the past few decades, genetic patents become increasingly relevant. Numerous debates about the validity of such patents abound in law and ethics and produce a plethora of literature on the topic.

For the most part a desk-top research method is followed based on the literature available and observations made by authors on this topic. Therefore, the research methodology is a literature study consisting of the following:

I. Books and articles on human genetic patents, including ethical and legal arguments for and against.
II. Books and articles on ethics, referencing theories appropriate to the study at hand.
III. South African legislation, case law and the Constitution, 1996 in relation to patents.
IV. European Union patent law as regulated by the European Patent Convention and Biotechnology Directive.

V. Web-pages and sites related to bioethics, patent law and genetics, as well as overlapping web sites.

VI. Comparative study methods to assist in analysing the South African approach by comparison to a state that not only is a key player in biotechnological advances and patents but has a system upon which we built our law.

VII. International treaties related to patent law to which South Africa is bound as a member, such as the Trade-Related Aspects of Intellectual Property Rights Agreement.

1.7 Research questions

To study the legal and ethical validity of HGM, patents and the issues presented by the granting of patents, requires that the following questions are addressed:

1. Does genetic material comply with the patent requirements of being an invention (and not a discovery) as well as displaying novelty, inventiveness and utility?
2. What is the influence of patents on scientific research and access to diagnostic care?
3. Do the intellectual property rights of the patent holder infringe the rights of the individual?
4. What approach should and would South Africa follow to granting human genetic patents?

1.8 Limitations of study

1.8.1 Diagnostics

There are many uses of patented HGM to discuss, however the area focused on in this study is that of diagnostic patents as related to HGM. The reason for this focus is that discussing other areas of human genetic patent uses results in a discussion that is too broad for the aim in this thesis. Other uses of genetic patents are not necessarily as controversial as the topic of diagnostics, nor is there nearly as much written on the other uses as there is on diagnostics.

1.8.2 Lack of sources

Another limitation faced in addressing the topic is that not a lot is written on HGM being patented in a South African context. A recent newsletter briefly addresses the patentability of living things in a South African context merely to state that South African law is "likely" to regard genetic sequences as patentable "if they are not slavish copies of naturally occurring nucleotide sequences".[35] Therefore, in addressing patents in a South African perspective, I do so based largely on my own analysis and investigation of the law and interpretation of the works of authors. The South African approach to the study is based on an interpretation of the law and the Constitution in general, and then related to the validity of gene patents.

1.8.3 Lack of empirical data

Another obstacle is a lack and the unavailability of empirical data which reflect whether these patents truly limit or reduce R&D in the field. The contrary also is true, empirical data which reflect that patents encourage R&D and serve as an incentive is rare and scarce.

1.9 Delimitations

1.9.1 Exclusion of United States patent system as a comparative system of patent law

In the study some topics or areas will be excluded to ensure that the study is not too broad or is arbitrary in its definition. The first exclusion is US patent law. US patent law is referred to for examples of biological patents or to illustrate the impact and effects of gene patents. American authors are referred to to the extent that their writings are relevant to the topic in general, and are not US specific. It must be noted that it is not possible to discuss genetic patents without referring to precedence, rendering the reference to decisions

[35] https://www.internationallawoffice.com/Newsletters/Intellectual-Property/South-Africa/KISCH-IP/Patentability-of-living-things-a-South-African-approach (accessed 4 October 2019).

handed down by United States courts unavoidable. This study will reference United States precedence as examples of decisions handed down in the field of genetic patents in general. Nevertheless, the patent requirements and the eligibility of genetic material in terms of the US patent system are excluded from the comparative evaluation. The US patent system differs vastly from that found in South African patent law, and as the aim of the study is to establish the most likely and appropriate approach to gene patents in a South African context the US approach is omitted. Differences in our system and that in the US mean a comparison arbitrarily prolongs the discussion. To find answers related to granting gene patents the obvious choice is to inquire into an intellectual property system similar to ours. The discussion therefore focuses on the European law.

1.9.2 Diagnostics

A discussion centred on the practical application of gene patents in terms of gene therapy is excluded, placing the focus on genetic diagnostics. The reason for this exclusion is rooted in the availability of sources discussing application; the application of genetic patents related to gene therapies is still in its infancy. Its application is yet to be properly regulated or decided even in jurisdictions considered to be pioneers in the field. Furthermore, gene therapy raises many ethical controversies unique and particular to the specific field. The limitation of the study as a result of the exclusion of genetic patents applied to the science of gene therapy inevitably allows for a more focused discussion.

1.9.3 Universities as patent holders

A further exclusion relates to gene patents of which universities are the patent holders. If universities were included in the discussion as patent holders, then the state technically is a patent holder as universities in South Africa are state institutions. To include the state as patent holder in terms of genetic patents requires an in-depth discussion of the state's obligations to the public in terms of public health responsibilities as well as its rights as a property holder in terms of incorporeal property. Inevitably, this discussion is too broad in relation to the set research questions. By extension the exclusion of human genetic patents held by publicly-financed institutions further excludes a discussion of the Act on Intellectual Property Rights from Publicly Financed Research and Development 51 of

2008 from the scope of the study. In terms of legislation (as discussed in chapter three of this study) the focus primarily is on the Patents Act 57 of 1978.

1.9.4 Competition law

The final exclusion takes into account a competition law perspective on whether HGM should be patentable. A discussion based on competition law is too broad for the purpose of this study. The relevant area of intellectual property law in establishing whether HGM should be patentable in a South African context is patent law. Extending the study to other areas of intellectual property law (albeit relevant in terms of the pricing of drugs related to genetic patents) is irrelevant to the aim of the current study.

1.10 Definitions

Definitions and concepts are discussed in the different chapters as necessary and as the concepts presented become relevant to the discussion. However, the concept of ethics to some extent features in each chapter and it is fitting and necessary briefly to elaborate on the understanding of this concept prior to any substantive engagement with the topic.

This study adopts an approach-rooted philosophical ethics as opposed to formal ethics, applied ethics or practical ethics.[36] Ethics is a branch of philosophy that involves the study of morality and stems from seemingly simple questions that have complicated answers and present themselves naturally throughout our lives.[37] Ethics therefore deals with the evaluation of what is the right thing to do when presented with situations and questions throughout the course of one's life.[38] Ethics considers how we ought to conduct ourselves and behave in life and in our decision-making that unavoidably affects those around us. As a branch of philosophy it further can be divided into different ethical theories which serve as different lenses or perspectives through which questions pertaining to morality are assessed or evaluated.[39] In Western studies of philosophy ethics refers to

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36 Emmerich 'What is bioethics?' 2015 *Med Health Care and Philo* 437.
37 Deigh, *An introduction to ethics* (2010) 1 & 7.
38 *Idem* 7.
39 *Idem* 8.

what is considered to be proper conduct,[40] and justifies or questions the moral rules we follow and entails the investigation into what we believe.[41]

Advances in biotechnology too are encouraged and motivated by ethics and in turn it is moulded by the technology available.[42] Scientific breakthroughs, developments and advances therefore impact ethics, which in turn influences the law. Ethics serves a dual purpose, on one hand it points out flaws in a scenario or a system and questions or critiques the scenario considering it bad or wrong. On the other hand, ethics sheds light on why something is good and is to be celebrated or striven towards.[43]

In discussing something as progressive and controversial as genetics, ethical issues and considerations are unavoidable. The ethicality of genetic patents becomes of even greater contention when considering the consequences of the commodification of commonly-held genetic information and the public good. Chapter four considers an African approach to morality, as the Patents Act 57 of 1978 prohibits the patenting of inventions that encourage offensive or immoral behaviour. Chapter five examines the impact of such patents on downstream research and development, as well as how they affect health care. The theory of Utilitarianism is applied to determine whether the award of such patents is considered ethical based on the effects.

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40 Rosenstand, *The moral of the story: An introduction to ethics* (2013, 7th Ed) 6.

41 *Ibid*.

42 O'Mathúna 'Bioethics and biotechnology' 2007 *Cytotechnology* 113.

43 *Idem* 114.

2 CHAPTER TWO: THE SCIENCE BEHIND GENE PATENTS

2.1 Introduction

Before embarking on a discussion of whether human genetic material (HGM) should be patentable, it is important to have a good understanding of what genes are, how they work, and precisely what is being patented and how such patents apply in practice. This chapter deals with the "science" part of the discussion. The controversial nature and complexity of patents and the discussion surrounding gene patents can be considered and understood only if one has an understanding of the subject matter.

2.2 Genes

The study of genes is the basis for one of the most dynamic and evolutionary fields of science in the twenty-first century – the field of genetics. Genetics is concerned with the study of variation in populations caused by inheritance and specifically with the "origin, transmission and expression of genetic information".[1] In its most basic form genes are "[t]he fundamental physical unit of heredity".[2] Genes are the building blocks not only of body parts but also of the processes and functions involved in the human body.[3] Genes are what differentiates one species from another, as well as being the cause of diversity in a species.[4] All living things, except for some viruses, are built though the interaction of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) not only within a cell but through interactions with the environment as well.[5] Our double helix DNA is what allows us to reproduce and what determines the genetic make-up of offspring as the existing DNA helixes of two individuals are split and recombined into a new unique double helix which forms a new unique individual or organism.[6]

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1 Klug, Cummings, Spencer & Palladino *Concepts of genetics: Ninth edition* (2009), A-7.
2 *Ibid*.
3 https://www.medicalnewstoday.com/articles/120574.php (accessed 12 June 2018).
4 *Ibid;* Klug *et al* 764.
5 Klug *et al* 19.
6 Koepsel 49.

The human DNA sequence is three-billion base pairs long and is composed of only four single units which repeat over and over again.[7] These repetitive units are linked together and are known as nucleotides.[8] Nucleotides are the basic structural unit of DNA and are known as the building blocks of DNA.[9] Nucleotides are comprised of a sugar, a phosphate group and one of the four nitrogenous bases, being G (guanine), A (adenine), C (cytosine) and T (thymine).[10] The structure of a single strand of DNA (which forms one half of the double helix DNA structure within a cell) therefore is a long chain in which these four nucleotides are repeated in different and varied combinations and sequences.

The nucleotides in one strand of DNA form base pairs with the nucleotides in the other strand of DNA to create the wound-up structure we know as the double helix.[11] These are called base pairs as nucleotides on one strand of DNA on the double helix (be it G, A, C or T) will form a pair and bind with a certain nucleotide on the other DNA strand through hydrogen bonds to then form complementary DNA strands.[12] These complementary base pairs that form the double helix structure of DNA are A-T and G-C.[13] Stated differently, an adenine nucleotide on one strand of DNA normally will pair only with a thymine nucleotide on the complementary strand of DNA, while a guanine nucleotide normally pairs only with cytosine on the complementary strand.[14] This means that where an A is on one strand a T must complement the A on the other strand, and the same is true for the pairing of G and C.

This double helix DNA goes through intricate and crucial processes of transcription and translation within a cell.[15] Transcription refers to the process within the nucleus of a cell where DNA is used as a template to create mRNA.[16] mRNA is a copy of one of the strands of DNA found in a cell, and by the same reasoning, is complementary to the other

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7 Venter *et al* 'The sequence of the human genome' 2001 *SCIENCE* 1306.
8 Klug *et al* 5.
9 https://www.genome.gov/about-genomics/fact-sheets/Deoxyribonucleic-Acid-Fact-Sheet (accessed 20 March 2019).
10 Pierce *Genetics: A conceptual approach, sixth edition* (2017) 296.
11 *Idem* 299.
12 *Idem* 300.
13 Klug *et al* 5.
14 Pierce 300.
15 Klug *et al* 363.
16 DNA transcription and translation, as published by McGraw-Hill Animations on 3 June 2017, https://www.youtube.com/watch?v=2BwWavExcFI (accessed on 13 July 2019).

strand of DNA found in a cell. This strand of mRNA, however, does not contain thymine, but uracil.[17] This means that if a DNA template sequence reads '…GATTACA…' the process of transcription results in the production of a complementary strand of mRNA with a sequence that reads '…CUAAUGU…'. This mRNA strand is comprised of regions referred to as introns and exons.[18] Exons contain the genetic information that encodes proteins, whereas introns are the non-coding sections of the genetic sequence.[19] The mRNA transcript then goes through a process referred to as intron splicing by means of which the non-coding introns are removed from the mRNA strand.[20] This mature mRNA strand, which now consists only of exons, is exported to the cytoplasm of a cell and then goes through the process of translation.[21]

Translation refers to the process by which the information contained in the mRNA (the product of transcription) is used to assemble proteins.[22] During the process of translation the mRNA strand is organised into a variety of triplets called codons.[23] The genetic code contains 64 different combinations of three (codons) out of the four possible nucleotides (A, G, C, and U) in the mRNA sequence,[24] and 61 of these codons found in the genome code for twenty specific amino acids.[25] It means that the amino acids to be produced in order for protein synthesis to take place are determined by the sequence of the gene being transcribed and translated. Different combinations of amino acids in turn produce different known proteins, which creates different organisms and functions and products that comprise a functioning organism or species.[26] Stated differently, genes are sequences or portions of DNA that comprise nucleotides that encode proteins. Any organism's complete set of genetic instructions as to its composition and functions is known as its genome.[27]

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17 Pierce 297.
18 *Idem* 402.
19 *Ibid*.
20 Klug *et al* 369.
21 Pierce 407.
22 Pierce Glossary C21.
23 *Idem* 404.
24 *Idem* 438.
25 *Ibid*.
26 *Idem* 433.
27 Pierce 4.

Different organisms and species have a characteristic number of chromosomes in each cell.[28] These chromosomes are "structures consisting of DNA and associated proteins that carries and transmits genetic information".[29] For humans, each cell houses 46 chromosomes which are structured into 23 homologous chromosome pairs (or sets of chromosomes).[30] Two sets of chromosomes is the result of sexual reproduction; each set is inherited from the male and female parent, respectively.[31] Human beings therefore inherit 23 chromosomes from each of their parents, which accounts for the 46 chromosomes in a human cell.[32] On these different chromosomes genetic information for specific traits can be found at specific positions on a chromosome (referred to as a locus),[33] which contain variants of genes inherited from each of the parents (referred to as an allele).[34] The forms (being dominant or recessive in nature) and the combinations of such specific gene variants (alleles) inherited from each parent then determine the expression of genes in offspring. By these means similar and differing genetic traits and characteristics are transferred from a parent to offspring through reproduction.[35] To simplify, a gene is "an ordered sequence of nucleotides [within a fragment of DNA] located at a particular position on a particular chromosome that encodes a specific functional product".[36]

The human genome consists of 25 000 different genes and although all humans share much of the same genome, there are differences in each genome responsible for the uniqueness of each individual.[37] Being able to identify the genes present in an individual can lead to the prediction of potential disease development and even the prevention of diseases occurring in the first place.[38]

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28 *Idem* 20.
29 *Idem*, Glossary C3.
30 *Idem* 21.
31 *Ibid*.
32 *Ibid*.
33 Klug *et al* 22-23.
34 Pierce 21.
35 *Ibid*.
36 Carvalho 'The problem with gene patents' 2004 *Washington University Global Studies Law Review* 701-753, 701 at footnote 3.
37 Koepsel 49.
38 *Idem* 14.

Advancing in leaps and bounds, genetics continues to dominate biological research.[39] The usefulness of genetics and the value of genetic information in biotechnology are of great importance in an array of other fields and industries.[40] Now it is possible to perform diagnostics on individuals for diseases or the predisposition for a disease that is not visible to the human eye and otherwise cannot be diagnosed by classical methods of clinical diagnostics.[41] This possibility allows for early intervention in patient health care. We now can produce drugs of therapeutic proteins based on the patient's needs and unique condition which allow for patient-specific designer treatments.[42] We can control the expression of traits and conditions by regulating the activation and deactivation of genes in cells or body tissue. Apart from the mentioned medical uses for genes, non-medical uses associated with genetics entice other fields to utilise genes to assist for their own ends. We are now able to account for the diversity within nations,[43] to trace the ancestry of an individual,[44] and unpack evolutionary mysteries through the DNA analysis of ancient bones.[45] Modern genetic techniques enable us to identify genes that are of great significance in the determination of "agriculturally important characteristics", such as cattle size, chicken domestication, horse speed and crop resistance (to pests, drought, heat and diseases) to name a few examples.[46]

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39 Pierce 11.
40 Klug *et al* 9-10.
41 *Idem* 10.
42 Hellermann & Mohapatra 'Genetic therapy: on the brink of a new future' 2003 *Genetic Vaccines and Therapy* 1.
43 Pierce 11. Geneticists have obtained the entire genome for over 2006 Icelanders, revealing in detail the genetic diversity for the people of Iceland.
44 Sideri 59.
45 Pierce 11.
46 *Ibid*.

2.3 Genes and patents

Human gene patents entail the cloning as well as the description of a genetic sequence, where the function of that particular genetic sequence (therefore the gene itself) and the role that sequence plays in the greater scheme of things is understood to some degree by those skilled in the field.[47] As previously mentioned, a sequence of A, T, C and G's form codons and the codon encodes specific amino acids and then code specific proteins which have a specific function in the human body and can express a certain trait. A gene patent therefore grants the patent holder exclusive rights over the DNA sequence, that is, a specific sequence of A's, T's, C's and G's associated with a specific trait and function.[48]

Genes or gene fragments have been considered patentable by Patent Offices, but the patent is not over the gene as found in an individual, but rather an isolated or purified form of the gene.[49] The moment a patent is granted to someone who has discovered the gene function associated with a specific DNA sequence, the holder of that exclusive right over the sequence dictates all uses of the relevant gene. Such use of the gene includes both commercial and non-commercial uses of the gene.[50]

Broadly speaking, three separate types of "inventions" deal with gene patents: the composition of matter, functional uses and diagnostics.[51] Genetic inventions relating to the composition of matter include the isolated and purified gene, known as cDNA, and its derivative products.[52] This type of genetic patent uses covers a vast variety of technologies as well as chemicals.[53] These patents of human genetic composition of matter enable the patent holders to dictate and monopolise the use and disposal of the

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47 Merz & Cho "What Are Gene Patents and Why are People Worried About Them?" 2005 *Community Genet*. 203-208, 204.

48 Andrews 70.

49 *Idem* 71.

50 U.S. National Library of Medicine & National Health Institute (NIH) 'Help Me Understand Genetics: Genetic Testing' Published July 16, 2019 at https://ghr.nlm.nih.gov/primer/testing/genepatents (accessed on 19 July 2019). Commercial uses of the gene would include clinical genetic testing, and non-commercial uses would include research.

51 Merz & Cho 204.

52 *Idem* 206. Derivative products as related to genes used in inventions in the context of compositions of matter would include viral vectors and gene transfer therapies, recombinant proteins or drugs, transfected cells, cell lines and higher order animal models in which the patented gene has been inserted or knocked out.

53 *Ibid*.

products resulting from processes which relate to genetics and the composition of matter, and are afforded protection by the granted patents.[54] The next broad type of gene patents relate to the functional use of genes. Such patents are based on a discovery which establishes the role that specific genes play in bodily pathways, functions and diseases.[55] However, it is more accurate to say that these gene patents strictly speaking are not related to the products of genes but rather are drugs used in the down- or upregulation of the specific gene and the types of chemicals that affect the function.[56]

The focus of the current discussion is on the last type of so-called inventions related to genetic patents, that is, genes used in diagnostics, which relates to the discovery of the functional use of the gene.[57] This final broad type of "inventions related to gene patents" covers the testing for genetic differences.[58] The results of genetic testing allows an individual to confirm whether they have a genetic condition or determine what their chances are of developing a genetic disorder and/or passing on a genetic disorder to their offspring.[59] Genetic testing therefore enables medical practitioners to identify the potential for a genetic condition early on, enabling patients to make an informed decision or allowing early intervention.[60] Currently, there are more than a thousand genetic tests in use and many more are being developed.[61] Methods of genetic testing include molecular, chromosomal and biochemical genetic testing.[62] Diagnostic testing is used to confirm a diagnosis where there is a suspicion of a particular disease or disorder based on physical

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54 *Ibid*.
55 *Ibid*.
56 *Ibid*.
57 *Idem* 204.
58 *Ibid*.
59 U.S. National Library of Medicine & NIH 4, https://ghr.nlm.nih.gov/primer/testing/genetictesting (accessed on 20 February 2018).
60 Pierce 158.
61 U.S. National Library of Medicine & NIH 4.
62 *Ibid* Molecular genetic testing involves the study of single genes to identify whether the gene of an individual contains a variation or mutation that results in a genetic disorder. Chromosomal genetic testing involves the analysis of an entire chromosome to identify large genetic changes (like an extra copy of a chromosome for example) that result in a genetic disorder. Biochemical genetic testing involves the study of protein quantities and activities which may potentially result in DNA changes and genetic disorders.

symptoms or familial history.[63] Genetic diagnostic testing can be performed during a person's life or before they are born.[64]

These patents entail the protection of monopoly rights over the characterisation of a person's genetic makeup at a locus which is associated with a specific disease.[65] The patents associated with a specific disease linked to a specific gene as identified by the patent holder usually include all diagnostic methods or testing that result in diagnosis of the associated diseased-gene.[66] It means that the gene patent in diagnostic use covers the statistical observation of a genetic difference which usually expresses itself through phenotypical (or physical/observable) differences in the individual.[67] Consequentially, *any* diagnostic method of identifying the genetic difference is covered by the patent related to that gene.[68] This allowance results in the statistical observation of the genetic difference through testing methods such as polymerase chain reaction (PCR), hybridisation, DNA chips and Southern analysis being covered by the patent related to the specific gene in question.[69]

Patents not only extend over individual genes but cover mutations of those genes associated with a specific trait or condition in the human body and the tests that identify those mutations as well.[70] Thus, institutions other than the patent holder can use those markers to perform diagnostic tests or to research the specific gene only if they pay royalties to the patent holder.[71] Or a company can isolate a gene that has a therapeutic value and patent it, after which they can clone that gene on a large scale and be the sole supplier of a therapeutic drug developed from that isolated gene.[72] Evidently, we are entering the age of "pharmacogenetics", where the dream is to have treatment personalised to the needs of the individual based on their genetic sequence.[73]

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63 *Idem* 5.
64 Pierce 158.
65 Merz & Cho 204.
66 *Ibid*.
67 *Ibid*.
68 *Ibid*.
69 *Ibid*.
70 Andrews 88.
71 Campo-Engelstein & Chan 4.
72 Cook-Deegan & Heaney 'Patents in genomics and human genetics' 2010 *National Institute of Health Public Access* 12.
73 Sideri 171.

A specific gene associated with a disease may be covered by many patents in terms of the diagnosis of that disease in that different polymorphisms (or variations) in the gene may result in the expression of the genetically-linked disease[74] so that each of the different mutations of a gene can be covered by individual patents.[75] Furthermore, a specific disease that is being phenotypically expressed can also be caused by a combination of different genes resulting in several patents coming into play. Diagnostic gene patents can result in patent thickets, which is when the same diagnostic method of testing or screening for specific alleles results in the diagnosis of different diseases or conditions.[76]

Ultimately, the patents are granted over gene function and the identification in a specific individual. Classically, gene function was established by geneticists performing a genetic analysis in the form of collecting many individuals that display the mutations of the disease in question.[77] Thereafter, it has to be determined whether the phenotype (or disease) in question is the result of one or more genes, and exactly *which* gene(s) are responsible for the disease in question. Today geneticists run genetic analysis through reverse genetics[78] by cloning a gene of which the function is unknown, after which they synthetically create a mutation in the cloned gene and place the mutated cloned gene in a model organism. The expression of the mutated cloned gene in the model organism will reveal the function and the physical expression of the gene.[79] Organisms might not have the same genotype or genetic make-up, since different genotypes make up different species, but all organisms have similar genetic systems in how they work, which means that studying the genes of one organism will reveal the functions and principles of the genes of another organism.[80] Model organisms (flies and mice, for example) allow us to

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74 Merz & Cho 205.

75 *Ibid.*

76 *Ibid*. The example used by Merz and Cho to illustrate these genetic patent thickets is that of the Apo-E test. In this test it is determined how many E2, E3 and E4 alleles the patient is carrying. This one test can be used to perform many patented uses, ranging from the determination for the risk of developing early onset Alzheimer's Disease to the risks associated with the development of prostate cancer.

77 Klug *et al* 606.

78 Phenotype refers to the "appearance or manifestation of a characteristic" (Pierce Glossary C14).

79 Klug *et al* 606.

80 Pierce 4.

investigate genetic sequences and gene functions with a high turn-over rate, as well as addressing ethical concerns related to the synthetic creation of mutation and diseases in humans.[81]

Applicants for genetic patents contend that they have created something novel as the non-coding regions of the genes have not been reproduced although the product still performs the same function of the gene as it would in nature.[82] Essentially, they argue that they discovered the function of a specific DNA sequence in the human body by using well-established techniques in genetic analysis such as reverse genetics and using well-known methods of identification such as PCR and Southern Blotting, which they claim to produce something innovative and novel when merely they remove the parts of the sequence that serve no function and retain the sequence they associate with the discovered function.[83]

The patent holder can require anyone wishing to do research relating to the patented gene or to perform the test related to a specific gene in the determination of genetic differences to pay the patent holder a licence fee for any use of that particular gene.[84] All commercial applications of a gene require the approval of the patent holder of the gene if a patent is issued for a particular gene.[85] Diagnostics or gene therapies that result from the research done in the field of genetics cause the patent holder to demand royalties and fees for tests and treatments with the result they are unaffordable to many patients.[86]

The monopolisation of something intimate, universal and natural as human DNA is considered and evaluated in different ways in this thesis. Firstly, the patent system granting monopoly rights must be considered to determine whether it should permit extending property rights over human DNA in terms of it being subject matter for patentability from a doctrinal perspective. Such a discussion will consider South African legislation as well as the South African Constitution, and is followed by a discussion regarding the ethicality and morality of such patents.

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81 Klug *et al* 606.

82 Andrews & Paradise "Gene patents: The need for bioethics scrutiny and legal change" 2005 *Yale Journal of Health Policy, Law, and Ethics* (YJHPLE) 403-412, 405.

83 Andrews 71-72.

84 Klug *et al* 660.

85 Carvalho 705.

86 Klug *et al* 660.

3 CHAPTER THREE: THE LEGAL FRAMEWORK OF GENE PATENTS IN SOUTH AFRICA

3.1 Introduction

Addressing the question of whether human genes should be patentable requires an examination of the law as well as of ethics. In this study it is argued that there are many arguments why human genes should not be patentable as a consequence of the proper interpretation of the legal requirements and exclusions found in law.

Patents as a species of intangible property exclusively regulated by legislation, therefore is considered a creature of statute in terms of South African law.[1] Intellectual property differs from conventional property in that it comes into existence and is afforded legal recognition and protection only if the said intangible material complies with the relevant legal criteria set out in the applicable statute.[2] Different species of intellectual property law therefore have to meet the prescribed requirements set out in the applicable legislation to enjoy protection.[3] The discussion focuses on patents as a species of intellectual property, regulated by and afforded protection through the Patents Act 57 of 1978.[4]

In dealing with a creature of statute, intellectual property rights (IPRs) in the form of patents are not awarded in terms of the common law, the sources that should be considered in the evaluation of the validity of gene patents are legislation establishing and protecting patent rights as well as the constitutional right that protects patent rights.

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1 Du Bois & Shay 'Regulation at the edge of the property concept: Judicial treatment of intangible interests' in Muller, Brits, Slade & van Wyk (eds) *Transformative Property Law* (2018) 419.

2 Adams & Adams 2.

3 This means that different species of intellectual property will have to comply with different requirements or fall within the parameters of a specific species, as prescribed by different intellectual property statutes and laws. It however should be noted that not all species of intellectual property law are regulated by statute, as confidential information, trade secrets, know-how, etc. are regulated by common law principles; *ibid*.

4 The Patents Act 57 of 1978 replaced the Patents Act 37 of 1952. Prior to the 1952 Act, the relevant statute was the Patents, Designs, Trade Marks and Copyright Act 9 of 1916. The 1978 Act is based on the European Patent Convention, while the 1916 and 1952 Acts were based on UK law. The 1978 Act applies to all patents within South Africa (including patents granted prior to the commencement of the Act), and both the 1916 and 1952 Acts no longer are relevant; *idem* 63.

Therefore, it is argued, based on the principle of subsidiarity,[5] that one should first assess the validity of gene patents in terms of the applicable legislation (the Patents Act 57 of 1978) and only thereafter, if it were to be decided that despite the arguments against the award of patent rights over genetic sequences based on the statutory requirements that patents *are* to be awarded according to the relevant statute and requirements, that such IPRs in the form of patents should not be awarded as property rights in this case conflict with other constitutional rights. This is the case as the principle of subsidiarity applies to defendants and respondents in an action dealing with a constitutional dispute.[6] Stated differently, the approach a litigant takes to seek protection for their property rights (based on the principle of subsidiarity) serves as the basis why human genetic material (HGM) should not be patentable.

In this chapter the discussion deals first with the validity of genetic patents based on the legal requirements applicable in South Africa. This evaluation entails an assessment of whether HGM should be patentable according to South African legislation to be followed, as well as by the evaluation of constitutional conflicts between the property-clause in the Constitution and other fundamental rights entrenched in the Bill of Rights. Thereafter, this chapter briefly discusses international treaties that regulate IPRs to which

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5 The principle of subsidiarity is divided into two main principles. First, it requires that a person who claims that a right of theirs is protected by the Constitution and that such a right has been infringed must rely on the statute which was specifically enacted to protect their constitutional right. The constitutional right may not be relied on in the first instance if such a statute has been enacted to protect the relevant right. The proviso of this first subsidiarity principle is that the claimant may rely directly on the Constitution only when there is a statute protecting their constitutional right if the claimant is attacking the constitutionality or the adequacy of the legislation enacted to protect the said constitutional right. The second subsidiarity principle requires that if a constitutionally protected right has been infringed, the holder of that right would not be able to rely directly on the common law to protect their constitutional right, obliging the holder to find refuge in the statute specifically enacted to protect that right. The proviso to this second subsidiary principle submits that the person alleging the infringement of a constitutional right may rely on the common law instead of the statute that was enacted to protect the relevant right only to the extent that the applicable statute was not intended to deal with that certain aspect of the common law and to the extent that the common law is not in conflict with the relevant constitutional right or with the scheme established by the statute or "can be developed by the interpretation to that effect". Since "patents" is a creature of statue and not granted or protected through the common law, the second principle of subsidiarity is not relevant to the discussion. (Van der Walt *Property and Constitution* (2012) 36).

6 Du Bois & Shay 419.

South Africa is a signatory in order to put into perspective that intellectual property laws specific to South Africa are structured to be in harmony with those of other jurisdictions (some of which have recognised HGM to be a patentable subject matter).

3.2 Legislation

3.2.1 Patents Act 57 of 1978

The South African Patents Act 57 of 1978 describes a patent as a "certificate in the prescribed form to the effect that a patent for an invention has been granted in the Republic".[7] Such a patent is granted only for an invention that is **new**, that involves an **inventive step** and which is **capable of being used or applied in trade or industry or agriculture**.[8] However, this definition in the Act does not explain what a patent encompasses. A patent is a limited monopoly over an invention granted by the government to the inventor[9] which entitles the holder of the patent a right to exclude others from the use, production, sale, importation or offer it for sale for a fixed period.[10] Compliance with the requirements of the applicable legislation therefore grants the patent holder the binding legal protection to ensure that the inventor has the legal right to exclude others from the unauthorised use of the invention to the impairment of the true owner.[11]

The duration of a patent is 20 years from the date of application and is subject to the continued payment of the required renewal fees associated with the patent.[12] This limited monopoly is granted to the patent holder and in exchange the patent holder reveals information regarding the invention to the public in the patent application that enables the reproduction of the said invention.[13] Patents therefore are granted on a *quid pro quo* basis, they serve as an incentive granted by the government to encourage inventors to present their inventions by affording them legal protection and commercial advantage and

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7 S 2 of the Act.
8 Ss 25(1) of the Act.
9 Kuney & Looper *Mastering intellectual property* (2009) 28.
10 *Ibid*.
11 Legal protection not only is extended to the inventor but to the successors in title as well; Adams & Adams 1.
12 Ss 46(1).
13 Kuney & Looper 28.

in return the public benefits from their disclosure.[14] Granting an inventor a patent over his invention gives the patent holder the right to do with his invention as he pleases for a period of 20 years after which the right to the invention ceases and the product will become part of the public domain.[15] This restricted monopoly granted to the patent holder encourages individuals to come forward with their inventions and sees to it that inventions are accessible to the public.[16]

The benefit that accrues to the public is the publication of the information associated with the invention, which can then be used (upon the expiry of the patent) in the development and promotion of scientific and technological advance.[17] An inventor seeking patent protection for his/her invention will have to file a patent application with the Patent Office, which filing includes the specifications describing the invention.[18] Unlike territories such as the US and Europe, there is no examination of the substantive content of the patent or the merits on which the patent application is based in South Africa.[19] A patent is granted if the Registrar is satisfied that the patent application complies with the formal requirements as set out in the Patents Act.[20]

As mentioned, the South African Patent Act states that a patent will be granted in South Africa for any **new** invention which involves an **inventive** step, which is capable of being **used or applied** in trade, industry or agriculture.[21] Prior to an examination of these requirements for a patent, the subject matter in question must first be regarded as in invention. This definition of what subject matter a patent will be granted for and the requirements with which an invention has to comply pose a challenge for patents relating to HGM as it can be argued that human genes do not meet these requirements rendering genes as a non-patentable subject matter.

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14 Adams & Adams 3.
15 *John Waddington v Arthur E Harris* 1968 1 SA 611 (A).
16 Klopper & Van der Spuy 221.
17 Adams & Adams 3.
18 Dean & Dyer *Introduction to intellectual property law (*2014) 253.
19 *Idem* 258.
20 Van der Merwe *et al* 389.
21 S 25bis(1).

3.2.1.1 Invention

Before investigating compliance with these requirements, it must be established whether the subject matter in question is an invention in the first place or whether it is not better defined as a discovery. The distinction between invention and discovery is an essential one as inventions are patentable whereas discoveries specifically are excluded from the scope of patentable subject matter.[22]

A so-called "invention" involves new knowledge obtained through an intellectual contribution.[23] "Invention", therefore, implies the creation of something new, as it is the implementation of knowledge in order to fill a gap or opening in society. It is generally acknowledged that intellectual property is "the product of the creative and the innovative effort of the human mind".[24] This means that the subject matter of the invention does not exist in nature prior to the innovative contribution or come into existence as a product of the forces of nature, and according to section 25(1) of the Patents Act 57 of 1978 a patent may be granted in terms only of an invention.[25] The definition in the Act as to what an invention entails is minimalist and vague. An invention is defined in the Act as "an invention for which a patent may be granted under section 25" of the Act.[26] This definition of a patentable invention fails to elaborate as to what an invention itself entails or consists of and deliberately is defined in broad terms in order to ensure a flexible definition as to what is considered to be a patentable invention and to allow the Act to find application and relevance to continuous development and progress in the technological field. [27]

Instead, the Act lists things that will not be regarded as an invention.[28] It can be assumed that anything that does not fall within the scope of these listed exclusions is considered to be an invention for the purposes of granting a patent as prescribed by the Act.[29] Furthermore, an invention can be either a process or a product or both.[30] An

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22 Ss 25(2)(a) of the Act.
23 Van der Merwe *et al* 363.
24 Adams & Adams 2.
25 *Ibid*.
26 S 2.
27 Adams & Adams 66.
28 Ss 25(2), (11), (12) and 36.
29 Dean & Dyer 241.
30 Art 27 (1) of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS agreement).

invention in product form entails something like a piece of apparatus, a system or a chemical compound.[31] On the other hand, an invention in the form of a process consists of steps to be followed which do not necessarily produce a product.[32] An invention in terms of intellectual property law also has to involve something of a technical nature in order to be patentable and contribute to technological progress.[33]

One of the above-mentioned exclusions found under section 25(2)(a) of the Patents Act is that of a discovery. A discovery cannot be regarded as an invention in terms of the Act which renders anything considered to be a discovery unpatentable.[34] A discovery is deemed to be something that is already in existence, before it came to light and before it fell into the realm of human knowledge.[35] Prior to the discovery the information or phenomenon applicable to the discovery was unknown even though it already existed in its entirety. A discovery therefore is an uncovering or unveiling of unknown, pre-existing information.[36] The difference between invention and discovery was discussed in *Reynolds v Herbert Smith & Co*[37] where the judge articulated the following:

> Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention necessarily also adds to human knowledge, but not merely by disclosing something. Invention necessarily also involves the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result.

A new method of application of a discovery therefore qualifies as an invention.[38] In other words, a discovery of a new method utilising an already existing invention may be

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31 Van der Merwe *et al* 363.
32 *Ibid*.
33 *Idem* 359.
34 Ss 25(2)(a).
35 Dean & Dyer 241.
36 Ebermann 77.
37 1903 20 RPC 123.
38 Klopper & Van der Spuy 223.

patentable.[39] It often is immensely challenging to distinguish between discoveries which are non-patentable and patentable inventions.[40]

In terms of South African case law the courts have been adamant that a mere discovery will not be patentable. In the matter of *Veasey v Denver Rock Drill and Machinery Co Ltd* it was confirmed that if someone were to discover that an existing machine already known produces results which previously were unknown and does no more, then such a discovery (however useful and brilliant such a discovery may be) is not a patentable invention.[41] In *Drummond-Hay v Fram & Co (Pty) Ltd* the court held that the "mere discovery or appreciation of a new or different result or benefit to be gained from a prior patented invention is not in itself patentable".[42]

These opinions raise the question whether human genes and the link to specific traits and characteristics expressed in people are to be regarded as a discovery or as an invention. The answer to this question is crucial to the discussion, if the association of a gene with an expression of a specific (disease) trait in humans is regarded as a discovery, then clearly at the first step in the statutory requirement inquiry of patentability, genes will not be regarded as eligible subject matter for patent protection. The United States, Europe and Japan as frontrunners in the field of biological and biotechnological patents historically have elected either to include discoveries as patentable material or to interpret them in such a manner that allows for the patentability of discoveries if joined to technical human intervention.[43] [44] It is argued in this thesis that genetic material in the first place should not be regarded as an invention since it is a discovery, excluding such material from patentability in terms of section 2(2)(a) of the Act even before the three technical statutory requirements for a valid patent are considered. In the context of human gene patents and the analysis of gene function to be used in diagnostics (and any breakthrough associated with gene function) we are dealing with an "existing machine" which is used to "produce results which was previously unknown". More to the point: the discovery of

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39 *Ibid.*

40 *Veasey v Denver Rock Drill and Machinery Co Ltd* 1930 AD 243 at 270.

41 *Idem* at 247. This principle was also applied in *Marine Construction and Design Co v Hansen's Marine Equipment (Pty) Ltd* 1972 (2) SA 181 (A) at 196.

42 1963 (3) SA 490 (A) at 508.

43 *US Patent Act* of 1952 s 100 (a).

44 Ebermann 80.

gene function is nothing more than the "disclosure of something which before had been unseen or dimly seen", and therefore is rendered non-patentable by section 25(2)(a).

In the context of patentability what has been discovered about genes is a pre-existing natural phenomenon.[45] Linking a specific gene to a particular disease or condition or phenotypic irregularity is nothing more than an observation of that gene and the phenotypic or its genetic expression, accompanied by a mental step that involves the understanding of the information observed and the value of that information.[46] As previously mentioned, the purified and isolated forms of genes in fact are the subject matter that is being patented, but there are patents over segments of genetic sequence just as they feature in the human body.[47] Furthermore, genes have properties such as the codification of a particular protein and the binding to complementary DNA during diagnostics which are inherent to genes and which are not a man-made invention, but nonetheless are patentable.[48] The value of genes and the importance of genetic-related breakthroughs are to be found in the natural properties of the genes and the information accompanying such products of nature. Natural genetic discoveries therefore are being rebranded to be inventions to allow for their monopolisation.

In considering HGM in relation to disease diagnostics, we are dealing with existing technologies and methods of associating or linking a specific gene or the interaction between a number of specific genes to a particular disease or abnormal physiological expression that produce results but now these results are submitted for patent protection. Even though the knowledge gained from the application of existing technologies and methods previously was unknown, the knowledge which is gained is the unveiling or discovery of a previously unknown natural phenomenon.[49] Those who favour genetic patents contend that the discovery of information already existing in nature is capable of private ownership despite the reality that the only invention involved in the process is the

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45 Merz & Cho "Disease genes are not patentable: A rebuttal of McGee" 1998 *Cambridge Quarterly of Healthcare Ethics* 425-429, 426.

46 *Ibid*.

47 Andrews & Paradise 405.

48 Andrews 71.

49 See the discussion under para 3.3.1.3.

already patented technologies and computer programmes that bring associations between genes and their expression to light.

These patents essentially extend over gene function and the expression of genes in their control over phenotype. Science textbooks which explain the methods of determining gene function and associating genes to a specific phenotype or physical expression speak of them as ways to "discover genes and dissect genetic processes that regulate biological function".[50] If those skilled in the field, whose life work is to make the mentioned associations between genotype and phenotype, regard such breakthroughs as discoveries[51] it seems confusing and somewhat arbitrary to regard them as an invention if monopoly commercial interests are involved and the law of inventions requires a change in the terminology in order to award the associated rights. A change in terminology seems trivial, but considering the effects of such changes in the law of inventions means the difference between deeming genetic material patentable or non-patentable, and no change undoubtedly will result in the exclusion of such patents in terms of section 25(2)(a) of the Act. Such "minor" changes in terminology are even more problematic when the health of the public and scientific progress and accuracy are the price to be paid by granting monopoly rights.

As mentioned, the three criteria for patent eligibility are novelty, inventiveness and utility, and human genes have been interpreted to comply with these requirements and therefore to be patentable. They are considered novel as the relevant gene was unknown before the patent and because the isolated and purified forms of these products do not exist naturally in nature. Genes fulfil the inventiveness (or inventive step) requirement as the isolation of a genetic sequence is considered to be an art. Finally, it has been interpreted that genetic material meets the utility requirement of a patent as the DNA sequence can be used in diagnostics, therapeutic procedures and drug development.[52] In the chapter to follow it is argued that compliance with each of these requirements is problematic when it comes to human genes and that human genes, therefore, should not

50 Klug *et al* 606.
51 *Ibid*.
52 Andrews 70-71; Sideri 59.

be patentable. There is an argument to be made for their non-compliance with the statutory requirements of a patent.[53]

3.2.1.2 Novelty

Even if the above argument that the linking of a phenotypic expression of genes to a specific trait is a discovery is to be rejected (and rather regard such a discovery as an invention), the other requirements for awarding patent protection for an invention raise other issues and controversies in terms of genes as the subject matter. Section 25(2)(1) of Act 57 of 1978 states that an invention should be new in order for a patent to be granted. The Act further states that an invention is considered novel if it does not fall within the scope of the prior state of the art at the time of the priority date of that invention.[54] Section 25(6)-(8) of the Act elaborates on what exactly is meant by the state of the art of which the invention in question should not form part in order for it to be regarded as new.[55] The priority date mentioned in relation to the novelty of a patent (the date before which an invention should be deemed to be novel for the purposes of being granted patent protection in terms of the Act) is the filing date of the very first application in terms of which the invention in question is disclosed, submitted anywhere – in South Africa or elsewhere.[56] Stated differently, to justify the monopoly awarded by the state to the inventor or applicant through the granting of a patent, the invention must not be old at the time the first patent application for the invention was filed.[57] If an invention is not

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53 Andrews 70.

54 Ss 25(5).

55 Ss 25(6)-(8) reads as follows:
(6) The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.
(7) The state of the art shall also comprise matter contained in an application, open to public inspection, for a patent, notwithstanding that the application was lodged at the patent office and became open to public inspection on or after the priority date of the relevant invention, if –
(*a*) that matter was contained in that application both as lodged and as open to public inspection; and
(*b*) the priority date of that matter is earlier than that of the invention.
(8) An invention used secretly and on a commercial scale within the Republic shall also be deemed to form part of the state of the art for the purposes of subsection (5).

56 Dean & Dyer 245; Adams & Adams 70.

57 Van der Merwe *et al* 372.

considered to be novel, then awarding the monopoly rights cannot be justified which disqualifies an invention from patent protection.[58] This is known as the so-called "absolute novelty" requirement that needs to be complied with in order to qualify for the award of a patent.[59]

South Africa does not examine the merits of a patent prior to its granting. [60] It means that a patent application is permitted to proceed if the required documents are submitted and the application formalities complied with.[61] The patent office will not examine whether a patent is truly novel or inventive when awarding the patent. When the validity of a patent is questioned on the allegation that an invention is not novel, a three-step test is applied.[62] First, the patent claims must be construed, after which the prior art must be construed.[63] Lastly, the construed claims must be compared to the construed prior art.[64]

Those seeking patent protection over HGM assert that they are entitled to patent protection as they (as the inventor or applicant) successfully isolated and purified the gene(s) in question, meaning they successfully removed the non-coding regions of the gene (the introns of the gene).[65] The patent applicant or inventor alleges novelty for a natural substance because they are able to do away with the useless parts of the gene (which encodes no genetic information), even though the exons/coding regions of the genes (which they contend to be novel) contain the same genetic information they did in its natural form (which included the non-coding introns).[66] It is difficult to understand how something such as a gene that exists in nature and subsequently was removed or isolated from an individual is deemed sufficiently novel to meet the novelty requirement associated with patentability.[67] It is clear that what is being patented is a specific arrangement of nucleotides (As, Ts, Cs and Gs), that gives us a certain genetic function and the

58 Dean & Dyer 245.
59 Adams & Adams 70.
60 Dean & Dyer 258.
61 *Ibid*.
62 This test was set out in *Gentiruco A.G. v Firestone South Africa (Pty) Ltd* 1971 BP 58 (A) at 149.
63 *Ibid*.
64 *Ibid*.
65 Andrews 71.
66 *Ibid*.
67 *Ibid*.

identification of such an arrangement of nucleotides exists in nature prior to such unveiling of the function. Carvalho notes the uncommon reasoning followed in Europe to accommodate gene patents relates to the "methods and processes of isolation, not in the isolated or purified genes themselves, because the genetic composition remains the same as in their natural environment".[68] Despite this blatant irregularity in the interpretation of *what* is novel (being the method of isolation and not the genes) patents are enforced over the genes themselves.[69]

The human genome has been sequenced and is accessible to the public, exactly for the purpose of encouraging universal research and development. Genetic information should not be interpreted to meet the novelty requirement of patentability as the material (and the function and information associated with the gene) rather is to be understood to be a product of nature and thereby to be excluded from patentability.[70] It is even harder to justify compliance of the novelty requirement of genetic material when one considers that inventors and applicants seek exclusive rights to all uses of the gene they contend to have "invented", including the natural properties of the genes.[71]

3.2.1.3 Inventive step

Section 25(1) of the Patents Act 57 of 1978 explicitly states that a patent is to be granted only if an invention involves an inventive step. This inventive step requirement is known in patent law alternatively as the inventiveness or non-obviousness requirement.[72] The Act states that an invention is considered: [73]

> …to involve an inventive step if it is not obvious to a person skilled in art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art…

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68 Carvalho 719.
69 *Ibid*.
70 Andrews 68 & 71.
71 Such natural properties of the genes refer to the abilities of the genes to code for proteins and to bind to markers in diagnostics (Andrews 72).
72 Dean & Dyer 249.
73 Ss 25(10) of the Patents Act 57 of 1978.

In terms of inventiveness the state of the art differs from that assessed in the novelty requirement. Only section 25(6) is considered in the assessment of inventiveness, disregarding sections 25(7) and (8). Inventiveness therefore requires an assessment that sets out to determine whether an invention is not obvious to a person reasonably skilled in the relevant art. If it is established that the invention is obvious (taking into consideration all matter published and available to the public worldwide), then the invention lacks an inventive step and thus is not regarded as matter eligible for patent protection. The inventive step therefore is a step forward involving some creativity and human ingenuity and therefore should not be obvious.[74] As noted by Wessels JA:[75]

> [O]n the one hand inventors are to be encouraged; on the other hand the public is not to be hampered by patents which show no real inventive skill… A patent must do something more; he must make some addition not only to knowledge but to previously known inventions, and must so use his knowledge and ingenuity as to produce either a new and useful thing or result, or a new and useful method of producing an old thing or result.

These remarks beg the question whether the discovery of gene function merely adds to knowledge and nothing more.

Botha JA emphasised that the lack of inventiveness could negate patentability,[76] despite the commercial success of an invention for which a patent was granted referring to the observation of Lord Herschell in *Morgan & Co. v Windover & Co*.:[77]

> [T]he mere adaptation to a new purpose of a known material or appliance, if that purpose be analogous [to a purpose to which it has already been applied, and if the mode of application be also analogous] so that no inventive faculty is required and no invention is displayed in the manner in which it is applied, is not the subject-matter for a patent.

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74 Van der Merwe *et al* 377.
75 *Veasey v Denver Rock Drill and Machinery* at 269-270.
76 *Marine Construction and Design Co v Hansen's Marine Equipment (Pty) Ltd* 1972 (2) SA 181 (A) at 198.
77 7 R.P.C. 131 at p.137.

Gene discovery might qualify as 'the mere adaptation to a new purpose of a known material' in that we are dealing with an already published genetic sequence for which function (purpose) is discovered through well-established scientific techniques.

The South African courts further have pointed out that it would not be enough for an invention to involve an inventive step merely by bringing about a substantial improvement or by being a step forward in order for it to be a patentable subject matter as inventive ingenuity is essential to an inventive step.[78] An invention therefore can be considered to be obvious and to lack an inventive step even if the invention is a substantial and important improvement on what comprised the prior art. It further was established by the courts that if a person skilled in the art naturally would try or pursue the claimed subject matter themselves, then such matter is not patentable.[79] It means that if it is probable that a person skilled in the art (in our case, geneticists) "would have been led to do the experiment" of determining gene function, there will be no invention due to the lack of an inventive step.[80] Dealing with human genes or DNA sequences as the subject matter in question, it is highly probable (if not blatant) that the determination of gene functions is obvious to geneticists.

A key feature to an invention is that it "must progress beyond present technology" and usually includes the utilisation of existing technologies to do so.[81] When an alleged invention involves existing technologies, it is important to ascertain which features found in the alleged invention surpass the existing technologies incorporated into the invention.[82] I argue that it is difficult to grasp how exactly associating a specific gene with a disease or irregular expression in a phenotype goes beyond present technologies. Clearly, the association of the gene to a disease uses existing technologies in the analysis or screening process as a method of looking at the genotype, but the results obtained in the "looking"-process cannot be an invention.[83] It merely is looking and realising a fact –

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78 Adams & Adams 74. This principle was established in *Marine Construction & Design Co v Hansen's Marine Equipment (Pty) Ltd* at 196G-H.

79 *Testrup v Crosfield & Sons* Ltd 1913 Ad 1 at 14.

80 Adams & Adams 74.

81 Van der Merwe *et al* 364.

82 *Ibid*.

83 Russell 'Unlocking the genome: The legal case against genetic diagnostic patents' 2012 *Marq. Intell. Prop. L. Rev*. 81-118, 104-105.

a discovery by definition – rendering genes and their properties as matter excluded from the scope of patentability in terms of section 25(2)(a) of the Act due to these associations lacking a technical character.[84] Many scientists believe that it is more fitting for the technology used or a novel application of the gene to be awarded patent protection, rather than awarding patents for the gene sequence itself. [85]

The act of observing a link between a particular gene and an expression of that gene in an individual (that is, determining gene function then used in diagnostics) therefore is obvious to a person skilled in the art, which diminishes the inventiveness of such a discovery.[86] It is obvious to geneticists that one uses methods such as PCR, Southern analysis, sequencing and so forth (all patentable inventions themselves) to study the chemical composition of DNA in the evaluation of genes to draw conclusions from such observations.[87] The Alzheimer Disease patent, for instance deals with an observation of information and therefore is a discovery of a natural phenomenon.[88] South African courts have acknowledged that merely producing practical results by themselves will not comply with the inventive step requirement.[89]

McGee argues that such a discovery nonetheless should be patentable.[90] He argues that we are mistaken in saying that disease diagnostics through gene identification is simply a code to be read that was brought to light by mere coincidence.[91] He further argues that it is easy to look past the fact that unavoidably it is an enormously difficult task to establish and determine relationships between specific genes and the environments they find themselves in, as well as the relationships between different genes and groups of genes.[92] In McGee's opinion this fact makes discoveries of a similar kind to be deemed patentable.[93]

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84 Van der Merwe *et al* 366.
85 Klug *et al* 661.
86 Andrews 71.
87 Merz & Cho 426.
88 *Ibid*.
89 *Testrup v Crosfield & Sons* Ltd at 11.
90 McGee "Gene patents can be ethical" 1998 *Cambridge Quarterly of Healthcare Ethics* 417-420.
91 *Idem* 418.
92 *Ibid*.
93 Merz & Cho 426.

Merz and Cho rebut this contention by McGee in arguing that the question is not whether the statistical discovery was a difficult one to make in the first instance, but that the focus has to be on the fact that there merely was a statistical discovery - irrespective of how difficult that might have been – and as such (that we are dealing with nothing more than a statistical discovery) the discovery rightfully should be excluded from being patentable.[94]

A court in the US handed down a decision in 1948 where they established, as one of the primary role players in biological patents, that the discovery of a natural phenomenon will not be eligible for patent protection as such knowledge freely is accessible to all men and is not reserved exclusively for the benefit of one.[95] In 1980 the US Supreme Court reinforced this stance by which discoveries are excluded from patent protection, when it stated that novel discoveries remain non-patentable – even if the discovery is the result of remarkable effort on the part of the discoverer – as a mere association and observation of a naturally occurring event is insufficient for patent qualification.[96]

The reason the particular method of observation or analysis was developed in the first place was to observe a naturally occurring event, making it a natural next step for someone skilled in the art to look at DNA and link it to specific characteristics as expressed in individuals. Merz and Cho argue that the patent protection already afforded to the method of looking (such as the PCR, etcetera) should not be extended to protect the individually specific acts of looking at different compositions of DNA that result in a correlation between the genetic sequence and a disease or irregular expression in an individual.[97] They further point that as soon as an association between a specific gene and disease is made known, many independent research groups immediately clone and sequence the genes, which points to such an addition to human knowledge not being as innovative as it ought to be to justify the granting of patent protection.[98] An association between a genetic sequence or mutation and a physical expression for diagnostic

94 *Ibid*.
95 *Funk Brothers Seed Co v Kalo Inoculent Co*, 333 U.S. 127, 130 (1948).
96 *Diamond v Chakrabarty*, 447 U.S. 303, 308-9 (1980).
97 Merz & Cho 426.
98 *Idem* 427.

purposes are as innovative as inquiring into a patient's familial medical history, observing breathing patterns, feeling the patient's thyroid glands – all of which are not patentable.[99]

Furthermore, when the Human Genome Project (HGP) was initiated in 1988 the aim of the project was to decipher, map and understand every gene in human beings.[100] The objective of the project was to gain as much genetic knowledge and information about the human genome as possible, which would enable the practical application to be for the benefit of society in medicine through diagnostics and therapeutics. The concept of determining gene function to establish the role specific genes play in human health and diseases and the analysis of genetic information is the vocation of all geneticists. An entire scientific field is dedicated to the analysis of genetic information and to ascertaining gene function as produced by established technologies and techniques. Given the size of the human genome, it is a matter of time and is inevitable that we discover the function of every gene sequenced through the efforts of the HGP. Therefore, it is difficult to argue that associating a specific DNA sequence with a specific disease effectively is non-obvious and therefore is inventive when already we have the sequence at our disposal due to efforts such as the HGP. Associating functions to a genetic sequence therefore is a scientific competition with many skilled in the art participating by standing on the shoulders of those who came before them. I argue that the determination of gene function is the analysis of data provided by the communal efforts of others and monopolisation can be equated to awarding patent protection for discovering a new natural law or scientific theory based upon the efforts and contributions made by those who came before us, which in itself excludes it from the scope of patentability.

3.2.1.4 Capable of being used or applied in trade, industry or agriculture

3.2.1.4.1 "Utility" incorporated into section 25(1) of the Act

Section 25(1) of the Patents Act 57 of 1978 further requires a new inventive invention to be capable of being used or applied in trade, industry or agriculture. In other jurisdictions it equates with the utility requirement for the granting of patent protection,[101] though the

99 *Ibid*.
100 https://www.genome.gov/human-genome-project/What (accessed on 12 August 2018).
101 Ebermann 72.

South African Patents Act does not have an express utility requirement.[102] In terms of South African law it requires that the invention must be capable of performing the proposed function.[103] According to this very broad formulation of the final requirement something is incapable of being used or applied in trade, industry or agriculture if it falls within the scope of one of the exclusions to this requirement set out by the Act as it is difficult to imagine what otherwise is considered to be incapable of being used and applied in trade or industry or agriculture.[104]

Whether an invention is capable of being used or applied in trade, industry or agriculture will be evident from the invention itself and is a matter of fact.[105] Trade is understood to include all transactions in which a service or a commodity of any kind is traded for money or goods of value.[106] Industry is a certain division of "productive labour" and agriculture involves the "science of farming".[107]

Clearly, discovering a gene function is useful for many reasons, especially in the field of diagnostics and medical intervention.[108] The association of a particular gene to a particular function or a particular diseased trait allows for genetic testing and allows for the determination of a potential problematic variation of a gene in an individual.[109] I argue that genes can be used or applied to trade or industry as genetic diagnostics testing is a service provided in the field of medicine (commercially or clinically).

Therefore, evidently genetic information contained in a DNA sequence is useful. Consequently, any argument to the effect that HGM does not comply with the use and application requirement as it is featured in section 25(1) will be exceedingly difficult. However, the use of the gene as discovered by the patent holder is not one that has been created or invented by the "inventor".[110] The usefulness of the gene in diagnostics and genetic testing lies in the ability of the gene to encode for proteins or the ability to bind to

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102 Van der Merwe *et al* 381.
103 *Ibid*.
104 Dean & Dyer 251.
105 *Ibid*.
106 *Ibid*.
107 *Ibid*.
108 Klug *et al* 643.
109 Andrews 70-71.
110 *Idem* 71.

a complementary strand of DNA.[111] Such useful properties of the gene are inherent to the gene and therefore natural properties. Usefulness of the gene therefore cannot be attributed to the so-called inventor in a patent application.

Merz and Cho argue that the mere usefulness of the observation of a gene's association with a disease in itself should not render it patentable. They contend that the value of a discovery should not be a determinative factor in the patentability of material. They equate the discovery of a linkage between genes and human diseases to the discovery of gold and diamonds; as in the case of the discovery of gold and diamonds the association of genetic differences with a disease might be of great use and value and difficult to discover in the first instance, but that does not render it patentable.[112] Though the argument put forward by Merz and Cho is rational, the invention in question's usefulness is a matter of fact, which arguably too is evident in the case of genetic material.

3.2.1.4.2 Lack of utility

It should be noted that the usefulness or the utility of an invention as a requirement for patentability is addressed in section 61(1)(d) of the Patents Act as well. Section 61(1)(d) of the Act deals with the "grounds for application for revocation of patent" and reads as follows:

> Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds, namely –
> that the invention illustrated or exemplified in the complete specification concerned cannot be performed or does not lead to results and advantages set out in the complete specifications…

This section of the 1978 Act provides for the revocation of a patent due to the inutility of the invention or the lack of utility of an invention for which a patent has been issued.[113] A granted patent is revocable if the invention in question fails to perform or produce the

111 *Ibid.*
112 Merz & Cho 427.
113 Adams & Adams 89; Dean & Dyer 252.

results and advantages as “illustrated or exemplified” in the “complete specifications”. The grounds for revocation based on the lack of utility relate to the information as exemplified or illustrated in the descriptions, drawings and examples of the specifications, excluding the claims of a patent application.[114] It means a patent can be revoked if it lacks utility because the invention does not do what it promises.[115]

This section presupposes an invention has complied with the validity requirements of a patent whereas the purpose in this thesis is to demonstrate that HGM should not fall within the scope of patentability in the first instance. Furthermore, the section 61(1)(d) ground for revocation depends on the claims of the patent holder as set out in the complete specifications of the patent application. In order to argue in favour of the invalidity of an already issued patent based on a lack of utility therefore will depend on the merits of a particular case, taking into consideration the relevant and complete specifications drawn up by a competent and qualified patent attorney. An attempt to formulate a blanket argument for the invalidation of a genetic patent based on lack of utility in terms of section 61(1)(d) is problematic as this section deals with the revocation of a patent based on drafting issues specific to the invention in question.

3.2.1.4.3 Medical methods of treatment

Section 25(11) states that an invention shall be deemed not capable of being used or applied in trade, industry or agriculture if such an invention is a medical method of treatment relating to the animal or human body through surgery or therapy or diagnosis.[116] Such methods of medical treatment therefore clearly are excluded from the scope of patentability. Consequently, even if one were to argue the association of a specific disease phenotype to a specific gene should be regarded as an invention in the form of a method of diagnostics, this section excludes this method of treatment of the human body from patentability as it fails to comply with the final requirement for a patent.

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114 Dean & Dyer 252.

115 *Integrated Mining Systems (Pty) Ltd v Chamber of Mines of South Africa* 1974 BP 281 (CP) at 317E-F.

116 Ss 25(11) of the Patents Act 57 of 1978.

The reasoning behind the exclusion found in section 25(11) is to ensure that doctors and veterinarians are not deterred from performing their professional obligations based on a threat of patent infringement allegations hanging over them.[117] In chapter 5 I argue that granting patent rights over genes which inevitably results in the medical application of these genes in diagnostics unavoidably prevents medical professionals from performing their duties, which is contrary to the public interest. Monopoly rights render such therapies and diagnostics inaccessible due to excessive patent royalties and expensive licensing fees.

At the outset the purpose in gene function determination might not have been to monopolise diagnostics utilising the gene, however the protection affords the patent holder a claim upon all diagnostic methods of comparing the patient's genetic sequence to that of the control group.[118] As a result of viewing human genes as a patentable subject matter, the downstream effects of a patent over a gene entail that a method of diagnosis indirectly is patentable though specifically disallowed by section 25(11) of the Act.

Allowing genetic patents that unavoidably compromise medical treatment contradicts and undermines what section 25(11) sets out to achieve. In terms of its underlying rationale granting gene patents that deter medical practitioners from complying with their obligations (thereby compromising patient care) will render section 25(11) redundant. If the arguments supporting the rejection of genetic patents based on the previously mentioned requirements were to fail, this section offers sufficient grounds for regarding HGM as non-patentable subject matter.

It is contended in this thesis that any argument in favour of genetic material complying with all the validity requirements for a patent as set out in section 25 of the Patents Act of 1978 is problematic. This is the case since every one of the patent requirements needs to be complied with in order for a patent to be granted. Alternatively, if all the requirements are to be met, the so-called invention is to be deemed non-patentable as a consequence of the statutory exclusions provided in sections 25(2)(a) and 25(11).

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117 Dean & Dyer 244.

118 Russell 92.

3.3 The Constitution of the Republic of South Africa, 1996

A further argument can be made that even in circumstances of genetic material complying with the requirements set out by the Act (despite the reasons already provided) on constitutional grounds patents should not be awarded since granting patents is in conflict with fundamental constitutional rights.[119] The argument is put forward in this thesis that even if South African courts were to validate genetic patents based on the requirements of the Patents Act, constitutional grounds warrant the invalidation and rejection of such patents.

3.3.1 Constitutional protection of IPRs

IPRs, such as patents, qualify for constitutional recognition and protection in terms of section 25 of the Bill of Rights in the Constitution of the Republic of South Africa, 1996, which is known as the "property-clause".[120] This circumstance is effective if the intellectual

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119 As previously mentioned, where legislation has been enacted to give effect to a constitutional right (in this case in terms of s 25 of the Constitution property rights have been given effect in the Patens Act 57 of 1978) the legislation enacted serves as a starting point in any contention over the protection or rejection of the right before one advances to the constitutional right itself.

120 S 25 reads as follows:

(1) No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.
(2) Property may be expropriated only in terms of law of general application—
(a) for a public purpose or in the public interest; and
(b) subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.
(3) The amount of the compensation and the time and manner of payment must be just and equitable, reflecting an equitable balance between the public interest and the interests of those affected, having regard to all relevant circumstances, including—
(a) the current use of the property;
(b) the history of the acquisition and use of the property;
(c) the market value of the property;
(d) the extent of direct state investment and subsidy in the acquisition and beneficial capital improvement of the property; and
(e) the purpose of the expropriation.
(4) For the purposes of this section—
(a) the public interest includes the nation's commitment to land reform, and to reforms to bring about equitable access to all South Africa's natural resources; and
(b) property is not limited to land.

property right has been established and conferred according to the relevant legislative prescription.[121] Stated differently, only when IPRs are awarded according to the relevant statute are they deemed property and qualify for constitutional protection under section 25 of the South African Constitution. In the context of the discussion, a genetic invention qualifies for constitutional protection under section 25 once it has met the requirements for a patent and is registered in the prescribed manner established by the Patents Act 57 of 1978.

In the Constitutional Court decision of *Laugh It Off v South African Breweries* the court had to consider the situation in which property rights in the form of intellectual property conflicted with non-property constitutional rights.[122] This case dealt with IPRs in the form of trade mark rights.[123] When the

(5) The state must take reasonable legislative and other measures, within its available resources, to foster conditions which enable citizens to gain access to land on an equitable basis.
(6) A person or community whose tenure of land is legally insecure as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to tenure which is legally secure or to comparable redress.
(7) A person or community dispossessed of property after 19 June 1913 as a result of past racially discriminatory laws or practices is entitled, to the extent provided by an Act of Parliament, either to restitution of that property or to equitable redress.
(8) No provision of this section may impede the state from taking legislative and other measures to achieve land, water and related reform, in order to redress the results of past racial discrimination, provided that any departure from the provisions of the section is in accordance with the provisions of section 36(1).
(9) Parliament must enact the legislation referred to in subsection (6).

121 Du Bois & Shay 421.

122 *Laugh if off Promotions CC v South African Breweries International (Finance) BV t/a Sabmark International (Freedom of Expression Institute as Amicus Curiae*) 2006 (1) SA 144 (CC). Hereafter referred to as the *Laugh It Off* case.

123 A brief summary of the facts of the case are as follows: Laugh It Off was producing and distributing T-shirts that featured a trade mark of a Sabmark which was used by the license holders on bottles and other related products. The Sabmark trade mark held "America's lusty, lively beer, *Carling* Black Label *Beer* Brewed in South Africa". The T-shirts sold by Laugh It Off used the same writing and style as the original trade mark held by Sabmark, but the writing on the shirts stated "Africa's lusty, lively exploitation since 1652 *White* Black Labour *Guilt* No regard given worldwide". In 2001 Sabmark became aware of the production and distribution of the shirts and approached the Cape Town High Court where they successfully obtained an interdict based on anti-dilution provisions per the South African Trade Mark Act 194 1993 that would prohibit Laugh It Off from using their trade mark. Sabmark argued that Laugh It Off would be likely to gain an unfair advantage or do damage to the repute of their trade mark through the use thereof. Laugh It Off subsequently appealed to the Supreme Court of Appeal (SCA) but the SCA upheld the interdict in favour of Sabmark as awarded by the High Court. The SCA held that the T-

Supreme Court of Appeal was faced with the matter Harms JA noted that: [124]

> [T]rade marks are property, albeit intangible or incorporeal. The fact that property is intangible does not make it of lower order. Our law has always recognised incorporeals as a class of things in spite of theoretical objections thereto.

When the matter was heard before the Constitutional Court, Moseneke J agreed that intellectual property despite its incorporeal nature enjoys constitutional protection under section 25 of the Constitution as property.[125] Therefore it is accepted that IPRs are recognised as property rights worthy of constitutional protection under section 25 of the Constitution.

The South African courts have yet to deal with the validity of genetic patents, but the *Laugh it Off* case dealt with the domain property rights (specifically IPRs) occupy when in conflict with other rights protected in the Bill of Rights. An argument against granting property rights-status to HGM is that it would conflict with other fundamental constitutional

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shirts gave the appearance that Sabmark was guilty of racial discrimination and partaking in the exploitation of black labour. The Court conceded that the use of the Sabmark trade mark is likely to be detrimental to the repute of Sabmark, and that Laugh It Off would be likely to benefit through its use. The SCA further held that the constitutional right of freedom of expression as protected in s 16 of the Constitution of the Republic of South Africa, 1996, would not protect the T-shirts produced and sold by Laugh It Off since the repute of the trade mark is what boosted the sale of the shirts. It held that Laugh It Off could have exercised their s 16 constitutional right in ways that would not have been to the detriment of Sabmark. Following the judgment of the SCA, Laugh It Off applied to the Constitutional Court (CC) to appeal the decision of the SCA. Laugh It Off argued that their messages they tried to get across through the production and distribution of the shirts are protected by their constitutional right to freedom of expression and that the likelihood of economic harm suffered by Sabmark would have to be proven in order for an interdict in favour of Sabmark to be awarded. Sabmark's counterargument was that the use of the trade mark cannot be justified or protected by the right to freedom of expression, and the likelihood of economic loss would not have to be proven in order to obtain an interdict. The CC unanimously held that Sabmark was unable to prove the infringement of the trade mark. It held that in order for the Court to justify the limitation of Laugh It Off's freedom of expression, the harm suffered by the trade mark holder would have to be material according to ss 34(1)(c) of the Trade Marks Act. Sabmark was required to prove the likelihood of any economic detriment they would face with the sale of Laugh It Off's T-shirts, and it failed to do so. It held that the all speech is protected and that it should be balanced against other constitutional rights (such as property rights, and intellectual property rights) if it were to be limited. The CC therefore granted the application for the leave to appeal by Laugh it Off, and as such it set aside the order of the SCA.

124 *Laugh It Off* para 10.

125 *Laugh It Off* case, para 17.

rights protected in the Bill of Rights. I argue that genetic patents should not be granted as such patents unavoidably conflict with constitutional rights that gain effect by the limitation of the property rights. The argument is not that patents in general should *not* be constitutionally protected as property, but rather that *genes* do not qualify for patent protection as providing it always will affect adversely other non-property constitutional rights.

The Constitutional Court declared in *Laugh it Off* that even though IPRs enjoy constitutional protection under the property-clause, intellectual property "is not absolute but rather a value which must be weighed against other values of arguably equal importance".[126] Intellectual property is not immunised against the limitations imposed by competing rights and values enshrined in the Constitution, as permitted by section 36 of the Constitution.[127] It was reiterated in *Laugh it Off* that incorporeal property deserves the same constitutional protection afforded to corporeal property, but "like other property intellectual property does not enjoy special status under the Constitution. It is not immune from challenge and therefore its enforcement must be constitutionally tenable".[128] In this matter the court held that the Trade Marks Act 194 of 1993 had to be read and interpreted in light of the Constitution, and it had to be applied in a way that does not "unduly trample" upon the constitutional right to freedom to expression.[129] Consequentially, the protection afforded to property rights (and not being deprived arbitrarily of property) is to be weighed-up against any conflicting right.[130]

Even though the *Laugh It Off*-case dealt with IPRs in the form of trade mark rights that were in conflict with the right to freedom of expression, this case serves as a precedent in dealing with other forms of IPRs (protected by the property-clause) which conflict with other constitutional rights. I argue this case is definitive in determining whether HGM should be patentable if awarding IPRs unduly limits other constitutional rights.

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126 *Ibid*.
127 Du Bois & Shay 424.
128 *Laugh it Off* para 11.
129 *Idem* para 18.
130 Du Bois & Shay 424.

3.3.2 Property rights vs non-property fundamental rights

3.3.2.1 The "systemically modest status of property"

Van der Walt analysed the relationship between protecting property rights as opposed to protecting non-property rights enshrined in the Constitution.[131] He convincingly argues that property holds a status that is "systemically modest" in comparison with other non-property constitutional rights. He reasons that when non-property rights (such as the right to freedom of expression as in the *Laugh It Off* case)[132] conflict with property rights as protected in section 25 of the Constitution it is highly likely that the non-property rights take preference and are afforded protection. He states that in some instances there are comprehensive and significant arguments why "non-property rights in question should often, if not always, be secured before property rights are even considered and that property rights justifiably enjoy no more than a modest status in these cases".[133]

Only after the non-property right properly is protected will property rights be afforded protection "in whatever space remains".[134] It does not mean that property rights and their protection are trivial concerns, but rather that the protection of property rights is not the imperative objective when non-property rights conflict with the use of property.[135] Property rights therefore can be regarded as a weaker right in relation to non-property rights protected in the Bill of Rights.[136]

Van der Walt's argument focuses on the rights of the landowner to exclude non-owners' from gaining access to the land of the landowner.[137] I argue that the argument used by van der Walt in terms of the "get-off" exclusion rights of landowners and the exercise of non-property rights by non-owners be extended and equate the circumstance with non-patent holders exercising rights which are afforded only to the patent holder (to

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131 Van der Walt 'The modest systemic status of property rights' 2014 *J L Prop & Soc'y* 15-106.

132 Van der Walt does not reference intellectual property rights or the *Laugh it Off*-case in his discussion. However, I argue for the extension of his argument to IPRs that is exclusionary in nature.

133 *Idem* 30.

134 *Idem* 48.

135 *Idem* 31.

136 Ss 7-39 of the Constitution of the Republic of South Africa, 1996.

137 Van der Walt 43-44.

the exclusion of others) in order to give effect to non-property rights such as life, dignity and equality, among others. Gene patents afford property rights to the patent holder that give exclusive monopoly rights over a genetic sequence. Regarding patents covering human genetic sequences as being the property right in question presents a situation in which non-property constitutional rights of non-owners are in conflict with "get-off" exclusion rights of the patent holder and with the patent itself.

Van der Walt points out that these conflicts are of special interest when non-owners want access to the property in question to exercise their non-property constitutional rights for "life-supporting activities" that involve "life-dignity-equality rights"[138] or when non-owners are excluded from the use of the property based on grounds that relate to race or other physical or personal attributes.[139] The right to life, dignity and equality are considered "immutable" and as such are not conditional on negotiation, regulation and restriction, since an attempt to determine the restrictive scope within which these rights are exercised and regulated will be problematic.[140] Life-dignity-equality rights as the starting point for constitutional conflicts most likely will (in my opinion, should) be prioritised over property rights when fundamental non-property rights are in conflict with property rights that exclude people, and upholding non-property rights necessarily restricts the exercise of property rights to the exclusion of non-owners.[141] Property rights enjoy protection only to the extent that is permissible after non-property rights have been given proper effect.

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138 Van der Walt refers to begging as being such a 'life-supporting activity' based on his analysis *of Victoria & Alfred Waterfront (Pty) Ltd and another v Police Commissioner of the Western Cape and other*s 2004 (1) All SA 579 (C). In the context of F as the property subject, 'life-supporting activities' arguably can be interpreted to be the access to diagnostics or genetic testing to make informed decisions regarding health care which involves the rights to life and dignity.

139 *Idem* 45.

140 *Ibid*.

141 *Idem* 46 & 47.

3.3.2.2. Gene patents vs dignity

Dignity is mentioned numerous times in the Constitution, 1996.[142] It is set out in the Table of Non-Derogable Rights in the Constitution as being a right that is protected through the provisions in the Constitution in its entirety. Even without a formal hierarchy of the rights entrenched in the Bill of Rights the South African Constitutional Court has established that along with the right to life, human dignity is the most important right which serves as the source for all other rights expressed in the Bill of Rights.[143] The right to human dignity (along with the right to life and equality) features not only as an enforceable right in terms of section 10 of the Constitution but as "general constitutional values and aspirations" as well.[144] The Constitutional Court has expressed its perception of the role that dignity plays in South African constitutional jurisprudence as follows:[145]

> Human dignity… informs constitutional adjudication and interpretation at a range of levels. It is a value that informs the interpretation of many, possibly, all other rights…Human dignity is also a constitutional value that is of central significance in the limitations analysis. Section 10, however, makes it plain that dignity is not only a value fundamental to our

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142 To name a few: S 10 of the Bill of Rights in the Constitution of the Republic of South Africa, 1996 deals with human dignity and states the following: Everyone has inherent dignity and the right to have their dignity respected and protected. Other provisions in the Constitution of the Republic of South Africa, 1996 that are relevant to the discussion that mention and emphasise the importance of the role of dignity are the following: S 1 dealing with the Founding Principles: The Republic of South Africa is one, sovereign, democratic state founded on the following values: (a) Human dignity, the achievement of equality and the advancement of human rights and freedoms.
S 7 dealing with Rights: (1) The Bill of rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom.
S 36 dealing with the Limitation of rights: (1) The rights in the Bill of Rights may be limited only in terms of the law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom.
S 39 dealing with the Interpretation of the Bill of Rights: (1) When interpreting the Bill of Rights, a court tribunal or forum must promote the values that underlie an open and democratic society based on human dignity, equality and freedom.

143 Van der Walt 49, with reference to the decision of *S v Makwanyane* 1995 (3) SA 391 (CC) at 144, 146, 214, 217.

144 Van der Walt 50. See fn 142 in reference to s 1, 7, 36 and 39 of the Constitution.

145 *Dawood & Another v Minister of Home Affairs & Others* 2000 (3) SA 936 (CC) at para 35.

> Constitution; it is a justiciable and enforceable right that must be respected and protected. In many cases however, where the value of human dignity is offended, the primary constitutional breach occasioned may be of a more specific right such as the right to bodily integrity, the right to equality or the right not to be subjected to slavery, servitude or forced labour.

In the context of HGM and its patentability "dignity" as a constitutionally enshrined right is offended by denying those who cannot afford the prices of the patent holder the possibility of being informed of their medical prospects through genetic diagnostics. The property rights of the patent holder or licensee are prioritised above the dignity of the individual when gene patents hinder patients from making informed decisions regarding their health and well-being. An argument in support undermines the contention that dignity is protected as a first-order rule, which hardly ever could be the case.[146] As Woolman points out in his analysis of *Dawood*:[147]

> The first rule of South African dignity jurisprudence is that where a court can identify the infringement of a more specific right… s 10 will (ostensibly) not add to the enquiry.

Stated differently, dignity can be violated or offended through the breach of another and more specific constitutional right, which results in the application of dignity as a second-order rule.[148] The other more specific rights that are violated (and through such violation offends the dignity of those affected for example by the patent holder's exclusive monopoly over genetic information and associations) are equality and the right to health care services as entrenched in sections 9 and 27 of the Constitution,[149] respectively. The

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146 Woolman 'Dignity' in Woolman & Bishop (eds) Constitutional law of South Africa Chapter 36 (2013, 2nd Ed), 19.

147 *Idem* 19-20.

148 *Idem* 20.

149 S 9 deals with equality, while s 27 deals with the right to health care. S 9 of the Constitution, 1996 reads as follows: (1) Everyone is equal before the law and has the right to equal protection and benefit of the law.
(2) Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken.

application of dignity as a second-order rule in terms of sections 9 and 27 relate to the accessibility of genetic diagnostics. The inhibition of access to health care as a consequence of genetic patents is discussed in depth in chapter 5 below, but for the purposes of the discussion relating to the constitutionality of such patents access to health care is addressed in brief.

The application of dignity as a second-order rule features most prominently in instances where the right to equality is affected.[150] Section 9(3) of the Constitution lists the grounds on which no one directly or indirectly may be unfairly discriminated against. Woolman notes that to determine whether there was unfair discrimination on one of the grounds mentioned in section 9(3) the investigation often turns on whether there was an impairment of the affected party's dignity.[151] Of particular importance to the constitutionality of gene patents is indirect unfair discrimination on the listed grounds of

(3) The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.
(4) No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination.
(5) Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair.
S 27 of the Constitution, 1996 reads as follows: (1) Everyone has the right to have 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.
(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
(3) No one may be refused emergency medical treatment.

150 Woolman 20.

151 Woolman 25. Woolman elaborates on the three questions asked by the court to determine the unfairness of the discrimination under investigation: (1) Is the complainant a member of a class of persons subject to pats patters of systemic discrimination? (2) Does the discriminatory law or conduct in question impair the *dignity*, or some other fundamental right, of the complainant? (3) Is the discriminatory law or conduct in question designed to achieve an important societal goal and is the discriminatory law or conduct in question narrowly tailored to achieve this legitimate goal? For an elaboration as to what is being dealt with by the court when asking these three questions, please refer to Woolman 26-29.

race, ethnic and social origin and disability.[152] Clearly, many genetic disorders or diseases have genetic links to racial and ethnic origins and it can be argued that having a genetic disorder or disease qualifies as having a disability.

"Equality" is denied by granting genetic patents in that it enables the patent holder to dictate the royalty fees payable for the utilisation of the patented subject. It means that the patent holder of the genetic sequence determines the price to be paid if doctors or medical practitioners perform diagnostic testing on patients. The socio-economic conditions in South Africa and the dependence of the majority of South Africans on the public health care system have the consequence that patents inevitably limit accessibility to patented diagnostics of persons who systemically are disadvantaged. Most of those who rely on the public health system are Black and are without the means to utilise private medical care. The high costs of genetic diagnostic testing limit the ability of public health care facilities to provide such life-prolonging health care resources to patients who also historically have been marginalised. It can be argued that indigent South Africans (predominantly members of a group subject to a past pattern of systemic discrimination) therefore will not have access to life-prolonging health care resources due to a lack of funds for state institutions. Indirectly gene patents will violate the right to equality to life-prolonging health care resources.

Woolman further elaborates on the Constitutional Court's approach and commitment to human dignity and its relationship to socio-economic rights, such as those entrenched in section 27 of the Bill of Rights.[153] Of particular importance to the discussion are the cases of *Soobramoney v Minister of Health, Kwa-Zulu-Natal*,[154] and *Minister of Health v*

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152 Possibly an argument exists for the unfair discrimination of disabilities which flow from genetic disorders, but such an assessment entails an intricate and elaborate discussion of its own. It is not my wish for the purpose of this thesis to explore such an argument, as doing so exceeds the scope of the discussion.

153 Woolman 58-62. It is worth noting that when non-property rights, other than life-dignity-equality rights (such as the right to health care as entrenched in s 27), conflict with property rights, such conflicting rights would have to be weighed against each other to find a balance where both rights are protected simultaneously. Such an approach invokes s36 of the Constitution. This is unlike the case where life-dignity-equality non-property rights clash with property rights, in which case the non-property rights have priority and there is no weighing up of the rights in question (Van der Walt 62-71).

154 1998 (1) SA 765 (CC).

Treatment Action Campaign.[155] In the former case Mr Soobramoney sought admittance into a dialysis program at a state hospital after being denied. He applied to the Durban High Court asserting his right to receive such treatment in terms of section 27(3) of the Constitution, which application subsequently was dismissed by the court.[156] On an appeal to the Constitutional Court the court denied Mr Soobramoney access to the life-prolonging treatment based on the budgetary constraints of the state to provide such treatments to persons who find themselves in similar circumstances. The court could not give effect to Soobramoney's section 27 rights on the grounds that the state's lack of resources rendered doing so impossible. Sachs J however made the following noteworthy statement in his judgment:[157]

> In all the open and democratic societies based upon dignity, freedom and equality with which I am familiar, the rationing of access to life-prolonging resources is regarded as integral to, rather than incompatible with, a human rights approach to health care.

With regard to genetic patents, I argue that such patents ought *not* to be granted in South Africa as to do so is contrary to the rights entrenched in 27(1) and (2). These patents will place a financial burden on state resources to pay royalties to patent holders which the state cannot afford. To alleviate this financial pressure and in doing so give effect to rights entrenched in sections 27(1) and (2) of the Constitution (as well as give effect to human dignity as a right and a value) section 25 property rights will be limited in terms of section 36 of the Constitution. By denying HGM the status of a patentable subject matter the obstacle raised in *Soobramoney* is removed, and life-prolonging resources could be available and so protect the dignity of persons.

In the abovementioned *Treatment Action Campaign*-case the Constitutional Court's decision provided much-needed socio-economic relief and ensured that the dignity of the affected parties was protected.[158] The court had to decide on a matter in which an

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155 2002 (5) SA 721 (CC), 2002 (10) BCLR 103 (hereafter *Treatment Action Campaign*-case).

156 Ss 27(3) states that "[n]o one may be refused emergency medical treatment".

157 *Soobramoney* at para 52.

158 Woolman 59.

obligation was placed on the government to provide mothers and their newborn babies in public health facilities with the Nevirapine protocol as intervention and treatment for mother to child transmission of HIV.[159] The court established that the state had an obligation to provide the treatment despite the relatively significant implication for the budget. Any other conclusion would undermine the dignity of the parties concerned.[160] The state has an obligation to take reasonable measures to give effect to the socio-economic rights provided for in the Constitution and there is a "wide range of possible measures" which the state can adopt in doing so.[161] It is argued in this thesis that such a measure to be adopted that at least deserves some consideration is to prioritise socio-economic rights over property rights and by extension exclude genetic material from the scope of patentability.

If one considers the "modest space" property rights occupy in terms of South African constitutional law, I argue that (intellectual) property rights are subordinate to non-property rights when they conflict. The manner in which the exercise of property rights over HGM unavoidably leads to conflicts with non-property fundamental rights suggests that such material should be excluded from the scope of patentability to circumvent constitutional conflicts that could arise from the award of gene patents.

To reiterate, the contention is *not* that IPRs are unimportant in comparison to non-property fundamental rights and that IPRs as a whole are invalid and therefore excluded from constitutional protection. The argument holds that the monopolisation of HGM is peculiarly problematic given the nature of the property in question. The enforcement of patent rights by the patent holder probably will produce conflict with life-dignity-equality rights (as well as socio-economic rights) and non-property rights shall be (and should be)

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159 *Treatment Action Campaign* at p 724.

160 Woolman 60 in reference to Liebenberg's writings on the case in which he contends that denying women and their newborns the treatment disrespectfully disregards their dignity. (Liebenberg 'The Value of Human Dignity in Interpreting Socio-Economic Rights' 2005 *SAJHR* 1).

161 In the *Treatment Action Campaign*-case para 36 reads as follows: "The State is obliged to take reasonable measures progressively to reduce the large areas of severe deprivation that afflict our society… As the Bill of Rights indicates, their [the State's] function in respect of socio-economic rights is directed towards ensuring that legislative and other measures are taken by the State are reasonable. As the Court said in Grootboom, '(i)t is necessary to recognise that a wide range of possible measures could be adopted by the State to meet its obligations'."

secured first, especially since the property in question is inherent. Clearly, the nature of property rights allows the restriction or limitation of the right, whereas it is less likely these will be drawn when the rights in question are non-property rights. The notion that the permissible restriction of property rights should be extended to exclude HGM from the protection afforded by patent rights deserves consideration.

Patent rights in an international context will be contemplated next as South Africa is a member of international agreements that regulate the harmonisation of IPRs in the international sphere.

3.4 International harmonisation of IPRs

An essential characteristic of IPRs is that such rights have only territorial effect.[162] If an inventor wishes to enjoy protection for his/her invention (and reap the commercial and economic benefit of such an invention) in more than one country, then the inventor has to take the necessary steps to secure patent rights in each country according to the national laws of the relevant jurisdiction.[163] The patent requirements, accompanying procedures and the rights afforded to the patent holder therefore vary from country to country even though the basic requirements for patentable subject matter for the most part are universal.[164] For this reason efforts have been made to harmonise national laws regulating and governing intellectual property laws through international treaties, conventions and agreements which are administered by the World Intellectual Property Organisation (WIPO).[165]

Recently, the harmonisation of laws and procedures related to IPRs has become more pressing with the focus in the economy and trade having "shifted away from traditional manufactured products, to information- and technology-based products".[166] This shift has resulted in the increased importance of intellectual property as a component in

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162 Adams & Adams 3.

163 *Ibid.*

164 *Ibid.*

165 WIPO is an agency of the United Nations that is mandated to protect intellectual property, as well facilitate the administrative cooperation between countries and international institutions in the field of intellectual property*; idem* 4.

166 *Ibid*.

international trade and to the creation of the World Trade Organisation (WTO), and its accompanying international trade agreements package which includes the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement).[167] To date the TRIPs Agreement is recognised as the "most comprehensive multilateral agreement on intellectual property".[168]

3.4.1 Article 8.1 of the TRIPs Agreement

It is relevant to the purposes of this thesis to briefly consider provisions in the international sphere that regulate IPRs as they are entrenched in the TRIPs Agreement that affect the exclusion of HGM to the extent to which it was discussed under headings 3.2 and 3.3 above. In this context article 8.1 of the Agreement is of particular importance.[169]

Article 8.1 of the TRIPs Agreement (titled "Principles") reads as follows:

> Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the Agreement.

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167 April 15, 1994 Marrakesh Agreement Establishing the WTO (alternatively generally referred to as the Marrakesh Agreement). The agreement has been in force since 1 January 1995, which is the date on which South Africa joined as a member to the WTO.

168 WTO 'Trade-Related Aspects of Intellectual Property Rights: Background material' 2008 to be found at https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/8_bgd_trips_89_e.pdf (accessed 20 August 2018) at 24.4. Even though South Africa is a member and signatory to other conventions which regulate intellectual property rights, the TRIPS Agreement will be the only international agreement discussed, as the minimum standards of protection provided by each of the member states in terms of the TRIPs Agreement requires that all members comply with the most recent versions of the main conventions of WIPO, the Paris Convention for the Protection of Industrial Property (*Paris Convention*) and the Berne Convention for the Protection of Literary and Artistic Works (*Berne Convention*). The fundamental and central provisions of these conventions are incorporated by reference into the TRIPs Agreement, rendering such provisions obligations under the agreement as well.

169 There are most certainly other provisions of the TRIPs Agreement that relate to this study, such as Art 27 which is invoked in the following chapter. For the purposes of this chapter, the focus is on Art 8.1.

Slade extensively evaluates the meaning and interpretation of these provisions, however for the purposes of this study only a few aspects of this article will be addressed.[170] I recognise that article 8.1 should not be interpreted to serve as an exception to the exclusive rights granted by the Agreement or understood to encourage a disregard for the provisions of the Agreement. Member states, nevertheless, do not surrender their national sovereignty to international ideals or objectives by being a party to the Agreement. Article 8 recognises that member states have to attend to the needs specific to the well-being of their citizenry and the expectation is that member states implement article 8.1 to give effect to their national needs otherwise the inclusion of this article is redundant.

Article 8.1 recognises that member states face instances in which they will need to institute national legislative or regulatory measures to limit the adverse consequences of intellectual property protection and enforcement and that IPRs should not prevent them from realising social and economic objectives.[171] Slade points out "Article 8.1 could be most influential as an instrument to overcome the obstacles to development created by intellectual property protection", and the effective implementation of this provision likely will present as a decrease in the level of protection afforded to exclusive rights.[172] The parties to the TRIPs Agreement will respect the self-determination of the member states and their ability to afford intellectual property protection to the extent they deem appropriate. Article 8.1 permits member states to take steps they deem necessary to protect public health and to develop social and economic welfare within their borders, even if the consequence is relaxation of intellectual property protection.[173]

3.4.2 State autonomy and realising public interests

State autonomy is recognised in the context of the Agreement since article 8.1 specifically states that the measures taken by members have to be "consistent with the provisions of

170 Slade 'The Objectives and Principles of the WTO TRIPS Agreement: A Detailed Anatomy' 2016 *Osgoode Hall Law Journal* 948-998.
171 Slade 977.
172 *Idem* 978.
173 *Idem* 981.

the Agreement". Public interest measures taken by members are regarded as acceptable only if within the scope of an agreement that encourages the protection of intellectual property. This constraint on the adoption of necessary measures has been afforded a broad interpretation as it is recognised that states have different interpretations as to what the "public interest" entails and that the measures that public interest necessitates are contextual.[174] Only the member states themselves can establish what are the important measures to be adopted in order to develop the socio-economic conditions and "intellectual property protection can never prevail where doing so undermines other development objectives".[175] Therefore, the international harmonisation of intellectual property laws[176]

> was the agenda of the world's leading content and technology exporters (transnational corporations in the pharmaceutical, life sciences, chemical, motion picture, computer and software industries) and the subject of aggressive lobbying campaigns both domestically and internationally.

International treaties such as the TRIPs Agreement seldom reflect an agenda peculiar to developing countries in which there is recognition that the realisation of socio-economic objectives may be undermined by the promotion of the protection of IPRs through international instruments. Developing countries are encouraged to sign agreements such as the TRIPs Agreement on "the promise of greater technology transfer(s), which has largely been neglected".[177] As Coombe and Turcotte point out international trade agreements that regulate IPRs are driven by private interests in "Euro-America", which[178]

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174 *Idem* 984. Slade acknowledges that the "the national perceptions of public interest are tied to economic, cultural, political and historical influences that are as numerous as they are variable".

175 *Idem* 985.

176 Coombe & Turcotte 'Cultural, political, and social implications of intellectual property laws in an informational economy' 2012 *Culture, Civilization, and Human Society: A volume in the Encyclopedia of Life Support Systems, developed under the auspices of UNESCO* 11.

177 *Idem* 14.

178 *Idem* 12.

undermines the ability of governments in developing countries to promote their own national systems of innovation and erodes national control over provisions of diverse public goods.

In the context of HGM as a non-patentable subject matter the contention is that the recognised self-determination of a country such as South Africa as a member state should prevail over any agreement that attempts to harmonise IPRs internationally. Article 8.1 permits the adoption of measures that restrict the protection of exclusive rights if necessary to promote national socio-economic development. In 2001 the Doha Declaration on the TRIPs Agreement and Public Health was adopted due to pressure from NGOs and less developed countries.[179] This Declaration recognises public health problems faced by less developed countries[180] and acknowledges that the Agreement should not prevent them from taking the necessary measures to safeguard public health.[181] The Declaration reiterates flexibilities within the confines of the TRIPs Agreement that allow for the interpretation and implementation of the Agreement that will support and accommodate less developed member states to promote the realisation of public health rights and to incorporate measures to give effect to such rights through domestic laws.[182]

The realisation and promotion of the public interest in South Africa necessitates a decrease in the protection afforded to gene discoveries. Gene sequences contain genetic data or information and as Coombe and Turcotte point out the privatisation of informational products and their regulation through international trade agreements, such as the TRIPs Agreement, can lead to the inaccessibility and distributional inequity of vital goods (including health care) and can overlook the community's right to be autonomous.[183]

The investigation requires a consideration of the TRIPs Agreement of which South Africa is a member as an international instrument for the harmonisation of IPRs, but the discussion with regard to the non-patentability of HGM in terms of national legislation and

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179 *Idem* 17.

180 Declaration on the TRIPs Agreement and Public Health, released by the WTO at the Ministerial Conference, Doha, 14 Nov 2001, Art 1.

181 *Idem* Art 4.

182 *Idem* Art 4 & 5.

183 *Idem* 3.

the South African Constitution remains the crux of the investigation.[184] Despite the TRIPs Agreement placing certain minimum standards for the protection of intellectual property rights, the Agreement does not (nor should it) dictate the manner in which member states exercise their national autonomy in compliance with their socio-economic and welfare objectives;[185] especially since international harmonisation instruments do not always reflect the needs of different societies with varying needs and at different stages of development.[186] If "developed" member states view HGM as a patentable subject matter and promote the biotechnological industry, South Africa need not follow suit if its national social and economic development requires otherwise.

In the next chapter I explore a member state to the TRIPs Agreement in which gene patents are prominent and consider the value in following their example or whether South Africa should adopt a different approach.

184 Paras 3.2 and 3.3 above.
185 Slade 988.
186 Coombe & Turcotte 15.

4 CHAPTER FOUR: A COMPARATIVE ANALYSIS OF SOUTH AFRICA AND THE EUROPEAN UNION

4.1 Introduction

South Africa has yet to deal with a dispute regarding the validity of patents over human genetic material (HGM), so it is necessary to consider foreign jurisdictions in which such patents exist for guidance as to what needs be done or avoided.

For the purpose of this discussion guidance preferably should be sought from a jurisdiction with a legal system that regulates intellectual property law (more specifically patent law) in a manner that to some degree reflects the South African position. Since South African legislation regulating the law of inventions is modelled on the European Patent Convention (EPC),[1] it is appropriate to draw a comparison between South Africa and European Union members.

The European Union is an active player in the biotechnology field of gene patents. It offers one of the two systems, the other being that of the United States, against which countries test the efficiency and competence of their own patent law systems. For this reason, I will evaluate the approach followed in European patent law to determine whether South Africa should imitate their position on genetic patents or strike out on its own. To directly compare South African patent law with that of the European Union would be redundant as the South African approach has been discussed in paragraph 3.2 above. This chapter therefore discusses European law governing and regulating biotechnological patents, and then evaluates the main difference between the respective jurisdictions.

4.2 The European Union approach to biotechnological patents

4.2.1 The European Biotechnology Directive

As South African patent law is modelled on that in the European Union, the requirements that need to be complied with in order for a patent to be successfully granted in Europe

[1] Van der Merwe *et al* 360.

are the same as those reflected in section 25(1) of the Patents Act: there must be an invention, the idea must be novel, there must be an inventive step involved and the invention must be capable of industrial application.[2] It is redundant to restate these requirements in detail, so the focus is on addressing the European Union law that governs genetic patents in particular.

European Union patent law is governed by the EPC which regulates the patent process and disputes in the participating states.[3] Someone applying for the grant of a patent can choose either to apply for a European patent through the European Patent Office (EPO) or they can elect to apply for a national patent through the national patent office of the participatory state under whose jurisdiction they fall.[4] Another key document in European patent law is the Biotechnology Directive (the Directive).[5] The evaluation of this document is crucial.

The Directive was adopted by the European Commission in an effort to keep up with the US and Japan in the patenting of biotechnological inventions as these countries were investing actively in the development of the biotechnology industry.[6] The motivation for the Directive was to be successful in the patent field after the failure of prior efforts. [7] As a response to the encouragement of WIPO and the Organisation for Economic Co-operation and Development (OECD) to advance and contribute to the biotech-industry the first draft of the Directive was introduced by the European Commission in October 1988. In short, the purpose of this Directive was to encourage the development of biotechnology in Europe and to regulate biotechnological inventions by harmonising biotechnological patent laws throughout the European community.[8]

The European Commission stated that the implementation of the Directive would promote the "overall innovatory potential and competitiveness of [European] Community

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2 Ebermann 72. Refer to para 3.2 above for the discussion on the patentability requirements in ss 25(1) of the Patents Act 57 of 1978.
3 *Idem* 74.
4 *Ibid*.
5 *Legal Protection of Biotechnological Inventions Directive* 98/44/EC.
6 Gold & Gallochat 'The European Biotech Directive: Past and prologue' 2001 *European Law Journal* 331-366, 335-336.
7 *Idem* 334.
8 Ebermann 75, Gold & Gallochat 336.

science and industry in this important field of modern technology".[9] It was the aim of the Commission with the adoption of the Directive to encourage research and investment in European biotech-development and to close the biotechnological gap between Europe on the one hand, and the US and Japan on the other.[10] A ten year struggle to finalise the adoption of the Directive followed the first draft[11] as a consequence of the ethical and social concerns of members of the European Community regarding the patentability of biotechnological inventions and products.[12] Finally, in July 1998, the European Parliament and Council approved the Directive for the protection and promotion of biotech inventions.[13] The EPO has implemented the Directive in its own regulations making the Directive the standard for European biotechnology patents.[14]

The Directive consists of eighteen articles which are preceded by 56 recitals. Even though the articles are the components of the Directive that carry binding force as the obligations of the Directive, the recitals serve a dual purpose of providing courts with the context in which the articles are to be interpreted and provide substance to the binding and enforceable articles.[15] The recitals acknowledge the controversy associated with genetic patents but emphasise that genetic material or DNA sequences nonetheless are considered patentable subject matter when implementing the Directive provided that the sequence complies with the three patent requirements and if the sequence has a known function or the proteins produced by the sequence have a known function.[16] The reasoning for including these recitals in the Directive was to address past attempts by the National Health Institute (NIH) to patent sequences which had no function or of which the functions were unknown.[17] Therefore, before the enforceable articles of the Directive are even considered the Directive makes it clear that the document is to be interpreted to allow for the monopolisation of human DNA.

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9 Gold & Gallochat 336 (in reference to the European Commission's 'Proposal for a Council directive on the legal protection of biotechnological inventions').
10 *Ibid.*
11 *Idem* 332.
12 *Idem* 341-342.
13 *Idem* 331. The Directive was to be implemented into national laws by 30 July 2000.
14 *Idem* 344.
15 *Ibid*.
16 R 22-24 of the Directive.
17 Gold & Gallochat 336.

The recitals are followed by binding articles that further elaborate on what is patentable subject matter and on the circumstances under which genes fall within the scope of patentability. The Directive makes it clear that biological material will be patentable if such material complies with the patentability requirements.[18] Biological material (which includes material that contains genetic information)[19] will be patentable even if such material already is to be found in nature if the material is "isolated from its natural environment or produced by means of a technical process".[20] It means biological material as it is found in nature is rendered non-patentable. However, biological material containing genetic information will be patentable if a technical process is applied to remove an element from the human body or to produce an element by artificial means.[21] This artificial and/or isolated material is considered an invention even if the material is identical to that found in nature.[22] Consequently, it does not matter whether those who isolated or artificially produced the biological material merely made an identical copy of something that already exists in nature, the act of artificially manipulating something external to the human body suffices as an invention.

The Directive further expressly clarifies in Article 5(2) that a gene sequence or a partial gene sequence isolated from the human body will be patentable even if the sequence is structurally identical to the element found in nature. The Directive goes further by incorporating a provision that ensures that patent protection for genetic information (as permitted by Article 3 and 5(2) of the Directive) extends to all material "in which the product is incorporated and in which the genetic information is contained and performs its function".[23] The Directive therefore clarifies any uncertainty as to the patentability of genetic material despite the concerns of member states pertaining to the ethicality of such patents. It further specifically permits the award of exclusive rights for any use of the genetic sequence to which a function has been associated. Anyone who wishes to utilise the gene sequence for diagnostic or research purposes once the sequence and the

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18 Art 3(1) of the Directive.
19 Art 2(1)(a) of the Directive.
20 Art 3(2) of the Directive.
21 Gold & Gallochat 341.
22 *Idem* 341 & 344.
23 Art 9 of the Directive.

function have been disclosed to the patent office is prevented from doing so unless they pay royalties or licensing fees to the patent holder.[24]

4.2.2 The Biotechnology Directive and morality considerations

However, as is the case with the EPC[25] the Directive prohibits the patenting of inventions which are contrary to the *ordre public* or morality in Article 6, which reads as follows:

> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary *to ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
>   (a) processes for cloning human beings;
>   (b) processes for modifying the germ line genetic identity of human beings;
>   (c) uses of human embryos for industrial or commercial purposes;
>   (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Article 6(1) might offer consolation to those sceptical of the patentability of HGM due to ethical concerns however this provision has been interpreted narrowly by the EPO. At its core morality is defined by law which amounts to a rather limited definition.[26] The EPO asserts that the promotion of the *ordre public* or morality through the inclusion of Article 6 is a matter of "principle to safeguard the patent system as a whole".[27] The vagueness as to what is meant by "*ordre public*" and "morality" has led to difficulties in interpretation, requiring the implementation of dictionaries, literature and precedent for clarification.[28]

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24 The effects of such patents in terms of the inhibition of research and development, and the prevention of access to diagnostics will be considered further in chapter 5.
25 Art 53(a) of the EPC.
26 Sideri 4.
27 Prifti 'The limits of "ordre public" and "morality" for the patentability of human embryonic stem cell inventions' 2019 *The Journal of World Intellectual Property* 2-15, 4.
28 *Idem* 5.

The consideration of morality could include the inaccessibility of diagnostic tests or accommodate the granting of compulsory licensing to medical research institutions, but is not the case though the absence of socio-economic considerations may be detrimental to the health of the public.[29] In foreign jurisdictions such as the European Union and the United States ethical issues surrounding gene patents have diminished under severe financial pressure and the commercialisation of academic research and medicine.[30]

Effectively, Article 6.1 provides for certain inventions to be deemed non-patentable and be excluded from the protection afforded by the Directive if the invention's "commercialisation violates *ordre public* (public order) or morality",[31] and Article 6.2 declares certain inventions to offend or breach morality and public order in their entirety.[32]

The *ordre public* in general refers to "public policy" in the sphere of international treaties, however the understanding of what offends public policy has been awarded a narrower meaning in terms of the EPC and the Directive.[33] In terms of the EPC the protection of public security, physical integrity of humans and the environment are covered by *ordre public*.[34] According to the EPO guidelines a declaration of the violation of the *ordre public* will be invoked in extreme and rare instances only.[35] This clause, as explained by the EPO, rejects the protection of inventions that are "likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour".[36]

When the government of the Netherlands requested the Court of Justice of the European Community (ECJ) to annul the Directive based on the offense to human dignity among other grounds, the ECJ held that Article 6 of the Directive excludes "processes for cloning humans, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes" from patentability as it would offend morality not to do so.[37] The argument for the exclusion of genomic

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29 Ebermann 63.
30 Merz & Cho 428.
31 Gold & Gallochat 333.
32 *Idem* 345.
33 *Idem* 358.
34 *Ibid*.
35 Prifti 5.
36 *Ibid*, in reference to the *EPO Guidelines* 2018.
37 *Kingdom of the Netherlands v European Parliament and Council of the European Union*,

technologies based on the contention that such technologies offend human dignity was unsuccessful.

Whereas the *ordre public* is a specific standard which excludes a specific list of inventions from patentability, the reference to morality in Article 6(1)[38] is associated with "the belief that some activity is overwhelmingly accepted as wrong within the totality of deeply held European norms".[39] "Morality" involves the evaluation of what is acceptable or right behaviour taking into consideration the "totality of the accepted norms which are deeply rooted in a particular culture".[40] What is considered to be right or wrong in terms of the Directive and the EPC will be assessed and determined in light of European values and morals. The inclusion of a list in Article 6(2) of what is considered a breach of *ordre public* or morality (therefore non-patentable) ensures that only the most apparent violations of morality or *ordre public* result in exclusion from patentability.[41] By listing specific exclusions on the grounds of *ordre public* and morality in the Directive, the European Commission aggressively restricted the scope of ethics in the Directive.[42] Morality and public policy violating inventions are limited further by *not* considering the "original creation of the invention" causing moral dilemma and controversy in terms of what is eligible for exclusion based on Article 6.1.[43] Article 6.1 only considers whether the commercial exploitation of the invention violates European standards of *ordre public* or morality.[44]

Gold and Gallochat criticise the approach taken by the European Commission with regard to how they take decisions that concern the morality and *ordre public* in patentability exclusion,[45] as the EPO and national patent offices are required to review patent applications to safeguard against inventions that are contrary to the morality-clause. However, the examiners who conduct the ethical review process had little

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E.C.R.I- 07079 (case C-377/98) (as sited cited by Carvalho 709). The exclusions are listed in Art 6(2) of the Directive.

38 Further incorporated into Art 53(a) of the EPC and Art 27.2 of the TRIPs Agreement.

39 Gold & Gallochat 358-359.

40 Prifti 5.

41 Gold & Gallochat 359.

42 *Ibid*.

43 *Idem* 360.

44 *Ibid*.

45 *Ibid*.

experience in making decisions regarding the *ordre public* or morality.[46] This approach resulted in ad-hoc decision-making about the ethicality and morality of inventions and left much to be desired in terms of substantive and consistent decisions taken.

This Article of the Directive reflects Article 27.2 of the TRIPs Agreement which permits members to the Agreement to exclude inventions from patentability if their commercial exploitation violates *ordre public* or morality.[47] The "*ordre public"* therefore is a standard to be complied with internationally to assist in the international harmonisation of intellectual property rights (IPRs) by members to the Agreement. However, the *ordre public* standard is applied and interpreted differently in various jurisdictions. For instance, "*ordre public"* has been afforded a "significantly narrower meaning within the context of the EPC" in comparison with other jurisdictions as discussed above.[48]

4.2.3 The Patents Act 57 of 1978 and morality considerations

South Africa as a member state must comply with Article 27.2 of the TRIPs Agreement and a similar morality provision is in the South African Patent Act in section 25(4)(a), which reads as follows:

> A patent shall not be granted -----
>
> for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour…

This section refers to the immoral or offensive behaviour that will result from the patentability of a certain subject matter, therefore it looks at the consequence or the behaviour that follow the exploitation of a certain type of invention and prohibits the

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46 *Ibid*.

47 Article 27.2 of the TRIPs Agreement reads as follow: '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 exclusions is not made merely because the exploitation is prohibited by their law.

48 Gold & Gallochat 358.

monopolisation of an invention that will result in immoral conduct. Even if an invention complies with the patentability requirements as set out in section 25(1) of the Act, the patent must be refused by the Registrar if the publication or exploitation of the invention in question will incite immoral behaviour.[49] It raises a question whether the monopolisation and exploitation of HGM would encourage immoral behaviour. Or, to rephrase the question to accommodate Burrell's assessment of offensive or immoral behaviour for the purposes of excluding an invention from patentability on the grounds of section 25(4)(a): Would the use of genes as inventions (and the consequences that flow from such gene patents) be viewed as immoral or offensive 'at a given time to the extent that such use in South Africa would be visited with sanctions in a major section of society'?[50]

The problem with excluding genetic material from the scope of patentability based on the argument that such patents are contrary to morality is that what is considered moral or immoral is dependent on the beliefs and values of the community in which the moral dilemma arises.[51] In consideration of the values respected in South African society and the spirit in which South African law and the Constitution should be interpreted and applied this thesis argues that the main difference between European and South African patent law (and the approach to genetic patents) is to be found in their respective and distinctive interpretations of morality. The narrow interpretation and capitalist-based ethical standards in the Directive permit granting exclusive rights over DNA in Europe and reflect a sense of morality which is not necessarily that in South Africa.

The approach in other African states regarding the patentability of human genetic or biological material may serve as a guideline as to what an African approach to the patentability of HGM may be. In an African context states have adopted contradictory approaches to issuing patents. The recently released and amended Harare Protocol on Patents and Industrial Designs takes an approach that mirrors that of the European Directive, allowing for the patentability of biological materials that include genetic

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49 An example of such an invention is the invention of a drug that is utilised as a date-rape-drug which by extension encourages rape (i.e. offensive and immoral behaviour); Dean & Dyer 243.

50 Burrell *Burrells South African Patent and Design Law* (2016) 4.66.

51 Carvalho 709.

information if such material is isolated from its natural environment.[52] The morality-clause in section 3(10)(j)(i) of the Harare Protocol reflects Article 6 of the Directive almost word-for-word. The eighteen signatory countries (South Africa is not one) to the African Protocol have elected to adopt the same narrow and rigid approach followed in the European Union, reflecting an acceptance of these norms and values.

On the other hand, the African Union (AU) adopted the African Model Legislation for the protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources in 2000.[53] In this Model Law the AU (South Africa is a member state)[54] declares in the preamble that

> all forms of life are the basis for human survival, and, therefore, the patenting of life, or the exclusive appropriation of any life form or part or derivative thereof violates the fundamental right to life

The AU has taken a definite stance regarding the patentability of life forms or their derivatives from the outset in this Model Law. This Model Law further addresses the accessibility of biological resources, and expressly prohibits the granting of "patents over life forms and biological processes".[55] The Model Law does not mention specifically the applicability of the legislation to HGM but includes genetic resources with actual or potential use to humanity as a biological resource worthy of protection under the scope of the Model Law.[56] Even if this law does not regulate the patentability of HGM, the approach taken by the AU in the adoption of this legislation reflects values that recognise that genetic resources are "of a collective nature" held by the community and "take precedence over rights based on private interests".[57] The AU has 55 member states.[58] It

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52 Regulations for Implementing the Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO), Adopted by the ARIPO Office, Harare, Zimbabwe, 2019, Rule 7bis.1(a) & 7bis.2i.

53 OAU (then Organisation of African Union) Model Law, Algeria, 2000 - Rights of Communities, Farmers, Breeders, and Access to Biological Resources.

54 https://au.int/en/member_states/countryprofiles2 (accessed 17 September 2019).

55 OAU Model Law, Algeria, 2000, ss 9(1).

56 *Idem* ss1.

57 *Idem* Preamble.

58 As opposed to the Harare Protocol's eighteen.

might be argued that the values underlying the Model Law are more reflective of an African approach to morality. The outright blanket-ban on life-form patents based on this approach should then find an echo in the ethos of South African morality.

In this thesis I contend that an African philosophy offers guidance in a South African context as to what is right or wrong (ethical or unethical). The distinction drawn between a South African approach and a European approach to genetic patents asks whether an African approach to gene patents would qualify the consequences that flow from the privatised exploitation of human DNA as immoral behaviour. An attempt to answer this question and draw a distinction between South African and European patent law and the morality-clauses to be found in these respective systems, requires a consideration of what generally is understood to be an African philosophical approach to morality.

4.3 An African approach to morality

The aim is not to present a critical analysis and evaluation of African philosophy as that exceeds the scope and purpose of this study. However, it is claimed that an African morality should serve as a compass in evaluating what is moral or ethical in a South African context when considering the patentability of HGM in terms of the exclusion stipulated in section 25(4)(a) of the Act. In my opinion to undertake an examination of what should be regarded as (im)moral requires a discussion of African philosophy.[59]

Even though our law (in particular patent law) is modelled on European foundations, a European notion of morality cannot simply be applied to the African experience. What is considered moral or ethical in a Western society is not always considered moral for Africans. There are legitimate grounds for distinguishing between the moral approaches of various societies.[60]

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59 Some authors question the existence and validity of an African philosophy, however, for the purposes of this study it will be accepted that an African philosophy is indeed a valid and recognised philosophical approach and theory.

60 Wiredu 'The moral foundations of an African culture' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 287-296, 287. Wiredu explains that the reason for moral diversity is three-fold: (1) different groups and individuals have different understandings as to what morality is; (2) the definitive cultural context within which a specific moral principle is applied will give it a unique appearance; (3) morality is further informed by junctures in time, space and climate.

In his paper titled *The critique of Eurocentrism and the practice of African philosophy*, Serequeberhan points out that "[b]y violently inseminating itself globally, after having properly tilled, turned over, and reduced to compost the once lived actualities of the historicity of the non-European world" Europe successfully conceived and "administered replicas of itself and does so with an air of normality" throughout the world.[61] The European colonisation of Africa reflected the notion that non-European civilisations were uncivilised prior to their subjugation, and that the European "normality" ought to inform non-European "uncivilised" societies. In this view Eurocentric interests justified the invasion of non-European communities reasoning that they could not reach their full potential (at least according to European opinion) without European intervention.[62] Europe considered it its mission to bring the voice of reason to non-European peoples by conferring (forcing) its laws, morality and philosophy on such communities.[63] Furthermore, Serequeberhan in his critique of Eurocentrism through his assessment of texts by the philosopher Immanuel Kant points out:[64]

> The 'others' (non-Europeans) will receive the Law of Reason from Europe or, in Kant's words, 'our continent … will probably give law, eventually, to all others'. Those who cannot reason…cannot be expected to effect 'man's release from his self-incurred tutelage', since they lack the faculty for this human possibility. Thus, Europe has to give the 'law' to 'all the others'. Indeed, *de facto*, we of the present – Europeans and non-Europeans alike – exist in a world in which Europe has bestowed the 'law' by means of conquest and violent hegemony. This is the case even if this act of 'bestowing' abrogates – in the very act of giving – the Enlightenment's own notion of the self-liberating capacity of human reason.

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61 Serequeberhan 'The critique of Eurocentrism and the practice of African philosophy' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 64-78, 66.

62 *Idem* 66-70.

63 Outlaw 'African 'philosophy': Deconstructive and reconstructive challenges' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 137-157, 141: "The most frequent rationalization offered was that the European encroachment on Africa brought 'progress', in the form of the spread of Christianity and 'rational' *civilisation*, which would lead to the improvement of individual and social existence".

64 Serequeberhan 70.

The scenario Serequeberhan identifies might be considered to be reflected in the South African patent law regime which is modelled on the EPC.[65] In a post-colonial era it is argued that "Euro-America today rules through its hegemony of ideas, through its 'models' of growth and development, through the statist and other structures which … are today adopted everywhere".[66] I argue in this thesis that though "European" reasoning unequivocally is the foundation of the South African legal regime the implementation and interpretation of these laws does not depend on following a philosophy that informs them against an African perception of morality.

Serequeberhan illustrates how a philosophy informed by Eurocentrism embraces the notion that human existence is valued by the extent to which human beings exercise control over nature.[67] He claims referencing Kant's writings that his views on human superiority are associated with the monopolisation of nature, Kant's example of man's ability to utilise sheep (as an extension of nature) is a sample.[68] Serequeberhan avers Kant equates non-Europeans with sheep and by extension they are a tool to be exploited.[69] I argue that the idea that humans utilise nature to illustrate their humanness is reflected in the unwillingness to deem the monopolisation of HGM (unquestionably a part of nature) as immoral or rather to interpret its perception of what is moral to include dominion over what is inherently natural and shared by humanity as a whole or to manipulate patentability requirements to exploit genetic information identical to that found in nature by deeming it "artificial" and "isolated".[70] These views not necessarily are reflective of an interpretation of morality valid in South Africa or mean that what is to be considered ethical should include the privatisation of the natural, especially when privatisation could have dire consequences.[71]

The need to not only utilise nature but to dominate, exploit and monopolise nature as proof of humanity does not reflect a universal relation to nature. Stated differently, the

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65 Adams & Adams 63.
66 Serequeberhan 75.
67 *Idem* 70-71.
68 *Ibid*.
69 *Ibid*.
70 Reference is drawn to the Biotechnology Directive, as discussed in paragraph 4.2 above.
71 The mentioned consequences of genetic patents will be elaborated on in chapter 5 below.

(successful and violent) monopolisation of nature by scientific and technological means need not set the tone of how to engage with nature. An attempt to keep up with developments in a manner that is untrue to an African philosophy is a betrayal of humanness in an African context. It is an approach that further excludes the African experience and reinforces a perception of inferiority. A core feature in the critique of colonialism is that it aims to "organise and transform the non-European world through European constructs".[72]

Ya-Mona contends that economically "developed" countries (in Europe) are driven by their personal interests rather than the material needs of the global population.[73] The economic perspective centres on whether a product will result in profit rather than whether the product will contribute to the humanness of humanity.[74] Self-serving interests (such as patents) are viewed as reinforcing the exploitation of "developing" nations by dictating the terms on which access to resources are granted. It is argued that economic interests should be subordinated to ethics and morality in safeguarding human dignity.[75] The state's responsibility (in "developing" countries) is to commit to an ethical economy which is not guided by the economic interests of developed nations.[76] The "western philosophical rationales historically used to justify [IPRs] are criticised as biased towards a particular and narrow set of values",[77] and are not reflective of African values.

In order to assess the role of African philosophy in African morality there is a need to demonstrate *what* such a philosophy entails and what gives an African philosophy its unique character.[78] It is claimed that the basis of an African philosophy is emotional (in contrast to the logicality of Greek tradition) and is communal (as opposed to the

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72 Cornell & van Marle "Exploring ubuntu: Tentative reflections" 2005 *African Human Rights Law Journal* 195-220, 197.

73 Ya-Mona 'Primacy of the ethical order over the economic order: Reflections for an ethical economy' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 331-342, 333.

74 *Ibid*.

75 *Idem* 335 & 336.

76 *Idem* 339.

77 Coombe & Turcotte 13.

78 Oruka 'Four trends in current African philosophy' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 120-124, 120.

individualist nature of European or Western philosophy).[79] This contention is shared by Himonga, who submits that[80]

> the "western" concepts of human rights places greater emphasis on individualism (ie it stresses the individual interest and rights) than on communal interests and rights, while the "African" concept places greater emphasis in the opposite direction: on communal interest and rights rather than those of the individual.

Wiredu remarks "African conceptions of morals would seem generally to be of a humanistic orientation".[81] Okura argues in her assessment of trends in African philosophy that communalism has to be embraced for effect to be given to the "cardinal ethical principle of traditional humanist Africa".[82] Communalism imposes equal mutual obligations on both the individual and society. As Okura points out:[83]

> [N]o individual would prosper at the expense of the society and the society would not ignore the stagnation of any of its members. In traditional Africa, Julius Nyerere argues, the individual was rich or poor only to the extent that the society was rich or poor, and vice versa.

An Africanised approach to society as Biko points out is a "…society whose sacred tradition is that of sharing", and not one that glorifies an "individualistic cold approach to life".[84] Interestingly, Biko points out that an African culture requires the reduction of "the triumph of technology over man and the materialistic element that is slowly creeping into society" and that "Black culture above all implies freedom on our part to innovate without

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79 *Idem* 121. Ramose, however, criticises this notion of attaching emotional-ness to African-ness in 'The philosophy of *ubuntu* and *ubuntu* as a philosophy' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 230-238, 234-235.

80 Himonga 'The right to health in an African cultural context: The role of Ubuntu in the realization of the right to health with special reference to South Africa' 2013 *Journal of African Law* 165-195, 176.

81 Wiredu 287.

82 Okura substantiates such an approach through reference to Nkrumah; *idem* 122.

83 *Ibid*.

84 Biko 'Black Consciousness and the quest for true humanity' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 79-85,84.

recourse to white values".[85] It is questionable if an African approach to morality condones an individualistic and privatised monopolisation of something inherent in all life as DNA, particularly if privatisation effectively detrimentally excludes the community to the benefit of rights holders.

Okolo addresses the "notion of self" in an African context and points out that "[i]ndividuals become real only in their relationships with others, in a community or a group", and that without a community the individual does not exist.[86] To understand what morality entails in an African context is to appreciate that an individual is valued as an extension of the community in which they find themselves, an individual occupies a place in which she is valued in relation to relationships and interconnections with others in the community. Coetzee notes that an African philosophy involves a morality based on commonality, which is informed by distributive patterns, social good and decisions informed by "cultural capital" through tradition.[87]

Moral decisions and moral progress can be realised only in a culture that allows for growth,[88] but how an individual decides to live is confined to the community's quest for the common good and takes precedence over the ends chosen by the individual. This common good is then understood to be "the good life" within a particular community and what is considered to be good for the community, by extension, is good for the individual.[89] This community supports mutual obligation among individual members comprising the community and any obligation to outsiders (such as seeking patent protection for gene discoveries) is secondary to the obligations *within* the community.[90] What is considered to be moral is attributed to the harmonisation of interests within a specific society.[91] The obligation to South African citizens will be prioritised before any trade obligations to rights holders or to individuals in the community that remove themselves from the common good

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85 *Ibid*.

86 Okolo 'Self as a problem in African philosophy' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 209-215, 213.

87 Coetzee 'Particularity in morality and its relation to community' in Coetzee & Roux (eds) *Philosophy from Africa* 2002 273-286, 274 & 275.

88 *Idem* 275. Coetzee denotes such an approach as the 'social thesis'.

89 *Idem* 276.

90 *Ibid*.

91 *Idem* 280.

of the community by valuing their own interests above the health and happiness of the collective.

Immoral conduct is viewed as conduct that disregards the community, and foregrounds what is defined as the "root" or "basis" of African philosophy[92] and as a concept of which the attributive values are "an integral part of that value system which had been established by the Interim Constitution" of South Africa,[93] that is the concept of *ubuntu*. The difficulty and the complexity in defining the notion of *ubuntu* means a singular definition is "unattainable".[94] Hence, as does Mokgoro, the thoughts of various authors on the concept and the attributes of the concept will be offered.

Ramose explains *ubuntu* philosophy to mean that one is required not only to "be" human but that one is to prove that he/she is the embodiment of *ubuntu*[95] because the "fundamental ethical, social, and legal judgement of human worth and human conduct is based upon" *ubuntu*.[96] *Ubuntu* encompasses the "fundamental law" that peace is to be established through the "concrete realisation of justice".[97] Since what is considered to be just is contextual and relative, the social value of *ubuntu* is reliant on the approach taken in its evaluation as a concept as well as on the reason for the implementation of *ubuntu*.[98] Metz declares since there is no single way in which *ubuntu* is to be understood, modern South Africa requires an interpretation of *ubuntu* that allows for its distinctive elements to be understood in a manner that gives effect to what is morally acceptable.[99] This view echoes the position of Himonga, in that[100]

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92 Ramose 230.

93 Mokgoror 'Ubuntu and the law in South Africa' 1998 *Potchefstroom Electronic Law Journal* 6.

94 *Idem* 1.

95 Ramose 231.

96 *Idem* 231-232.

97 *Idem* 237.

98 Mokgoro explains that the social values associated with *ubuntu* therefore include, among others, compassion, humanistic orientation, human dignity, collective unity, the basis for a morality of co-operation and communalism (Mokgoro 3).

99 Metz 'Ubuntu as a moral theory and human rights in South Africa' 2011 *African Human Rights Journal* 532-559, 536.

100 Himonga 180.

> *ubuntu* is not only an ethic that defines what humanity is from an African perspective; it is also a vision that provides some guidance on what constitutes good action and conduct; as well as guidance on what should be condemned as bad actions and conduct normatively in relation to the dignity of a human being.

Cornell and van Marle explain that *ubuntu* implies an ethic which is interactive, how who we *are* as human beings (and how we *can be* as human beings) continuously is being moulded through our interactions and relations with each other.[101] This interaction does not promote communalism in the ordinary sense, that the individual is secondary to the community, but promotes the notion that the individual cannot be removed or extracted from the community. The community therefore continuously is shaped by those who comprise the community. *Ubuntu* necessitates a symbiotic or interactive relationship between the individual and the community in that the community is being formed continuously, and *that* notion is valued for its ability to empower people.[102]

As a moral theory *ubuntu* as many contend is found in the maxim that "a person is a person, through other persons".[103] This maxim not merely denotes an interdependence between members of a community but represents what ought to be valued most,[104] that a person is to develop and be the embodiment of humanness through the community.[105] *Ubuntu* as a concept naturally then is represented and exercised by means of "anti-individualistic conduct towards the survival of the group if the individual is to survive".[106] This relationship allows both the community and individual to partake in the "process of coming into being" through justice and freedom.[107] What is considered to be humanness in the context of *ubuntu* is moulded by the interactions of those who are part of the community, which in turn is formed and supported through those same interactions; thus an individual's humaneness is lessened by the "violent actions of others".[108] Disregard for the community and all it encompasses is considered immoral in light of a morality

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101 Cornell & van Marle 205.
102 *Idem* 206.
103 Metz 536.
104 *Idem* 537.
105 *Ibid*.
106 Mokgoro 2.
107 *Ibid*.
108 Cornell & van Marle 207.

grounded in *ubuntu*. *Ubuntu* includes the principle of solidarity which allows people in need to count on others in the community to contribute to their well-being and, in turn, is good for the community.[109] Acting in a purely self-serving and self-centred manner disregards humanity and not only fails the individual and the community but actively injures others.[110]

It is opined that *ubuntu(-ism)* and its accompanying values have the ability to shape South African jurisprudence.[111] To give effect to this contention a South African approach is to interpret morality in light of *ubuntu(-ism)*. Based on an understanding of the concept of *ubuntu* as it is discussed above it is difficult to argue that the condonation of the monopolisation of genes to further an agenda which forcefully and violently promotes individualism and threatens trade sanctions and exclusion is reflective of an African interpretation of humanness.[112] *Ubuntu* necessitates caring for and the promotion of a quality of life experienced by the community. An African morality as formulated in the values of *ubuntu* requires the state to give due regard to solidarity if it is to promote the interests of the community.[113] In doing so the state is obliged to better the quality of life of its citizens and to give effect socio-economic rights as enshrined in the Constitution.[114] Furthermore, the State's obligation in terms of socio-economic assistance involves the promotion of a sense of community.[115] This obligation is given expression in the argument that if the wealth divide and socio-economic disparity are disproportionate, the dignity of citizens as a part of a community is undermined.

In the context of genetic patents and the question of their morality in South Africa there is a question whether the exploitation of human DNA catapulted by the award of exclusive rights will encourage or incite offensive or immoral behaviour. An African approach to

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109 Himonga 179.

110 *Ibid*.

111 Mokgoro 8.

112 Trade sanctions refer to the WTO's decision to bring IPRs into the sphere of trade in 1995, and thereby ensures that 'a country's failure to adequately protect the IP of foreign nationals effective constitutes a non-tariff trade barrier and may be subject to sanctions in other fields of trade, such as agricultural exports, as well as fines by other states who seek to force IP compliance' (Coombe & Turcotte 12).

113 Metz 550.

114 *Ibid*.

115 *Ibid*.

morality as discussed in this chapter, it is my contention, answers the question in the affirmative. South Africa, informed by the values of *ubuntu,* will steer away from an individualist approach to the social welfare of its citizens. I contend that prioritising property rights and failing to prioritise community health by excluding genetic material from patentability in order to promote access to genetic diagnostics will encourage immoral behaviour as such behaviour neglects the community.

An African philosophy based on the embrace of *ubuntu* demonstrates the morality need not be "Western" even if the patent regime is based on European law. Interpreting what is best for South Africans (when the welfare of citizens is at stake) is not a matter of blind obedience to contemporary values.

In order to guard against the "corruption of public morals", inventions of "sufficiently unacceptable character" should not be afforded patent protection.[116] I argue that an African morality requires that HGM and the information it contains is accessible to all and for the benefit of the community as represented by the blanket-ban on life-form patents by the African Union. In a paper on the second enclosure movement to privatise common property by fencing it off, Boyle references the possibility of "the enclosure of the intangible commons of the mind".[117] He mentions that those who oppose the patentability and privatisation of the human genome claim the genome is "the common heritage of humankind", and therefore incapable of private ownership.[118] It is suggested that rendering the genome capable of private ownership will have dire consequences and that it is better the genome belongs to everyone.[119]

If we consider the role community and collectivism play in the determination of what is ethical or moral in a (South) African context, as discussed in this chapter, then it is important to contemplate awarding genes the status of common property incapable of private ownership and freely available to benefit the community. A moral philosophy grounded in *ubuntu* condemns a proposal that favours the exclusion of the community from something as inherent as their genetic makeup; even more if the exclusion results

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116 Burrell 4.66.

117 Boyle 'The second enclosure movement and the construction of the public domain' 2003 *Law and Contemporary Problems* 37.

118 *Ibid*.

119 *Ibid*.

in the neglect of the well-being of the community. Section 25(4)(a) is more accommodating than the European Directive for the exclusion of genetic material from the scope of patentability based on the belief gene patents will incite immoral behaviour by the neglect of the well-being of the South African people, whereas *ubuntu* necessitates caring for and the promotion of the quality of life experienced by the community.

The notion of an African philosophy (and by extension the "application" of *ubuntu*) serves as an underlying principle in addressing and assessing the ethical implications or the controversy surrounding human genetic patents in the chapter to follow.

5. CHAPTER FIVE: ETHICAL CONSIDERATIONS AND ISSUES CONCERNING GENETIC PATENTS

5.1 Introduction

Alongside legal arguments why human genes should not be patented there are arguments rooted in ethics that support this conclusion. As observed, morality is an element considered at a statutory level in evaluating the statutory requirements of for example a patent. However, it is suggested that whatever the argument in terms of non-compliance of the patent requirements in legislation, the controversial aspect of genetic patents relates not to that compliance (even if it renders genes non-patentable), but the controversy regarding the granting of private monopoly rights in the form of intellectual property rights (IPRs) over the human genome is against morality since the human genome belongs to all.[1] This chapter therefore takes the question of the appropriateness of genetic patents beyond the scope of a legalist approach and takes into consideration the effects of these patents on society.

There are many ethical issues surrounding gene patents. Some of the dilemmas identified in this study relate to the right to health care. Article 25(1) of the Universal Declaration of Human Rights of 1948 states:[2]

> *Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including* food, clothing, housing and *medical care* and necessary social services, and the right to security in the event of unemployment, sickness, disability widowhood, old age or other lack of livelihood in circumstances beyond his control (emphasis for own purposes).

In terms of South African law the 1996 Constitution recognises the right to access to health care as a fundamental right in section 27 and the National Health Act 61 of 2003

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1 Kevles & Berkowitz 234.

2 General Assembly Resolution 217A (III), United Nations Document A/810, December 10, 1948.

was introduced to realise and regulate this constitutional right.[3] The impact of genetic patents on this right is two-fold: First, gene patents render genetic diagnostic tests inaccessible and unaffordable and, secondly, gene patents inhibit research and development (R&D) which negatively affects progress in the medical field.

There is evidence that these patents inhibit biomedical research as scientists tend to avoid areas of research due to patent constraints;[4] the property rights held by patent holders restrict downstream research and development.[5] These patents limit access to diagnostic methods and health care as a consequence of a restriction that only certain institutions perform the patented diagnostic methods that require patented genetic markers. The patents over these genes further inhibit the ability to improve these tests through further research which results in access to less accurate tests which impacts on health care and patient treatment. The cost associated with diagnostics relating to these patented genes as established by the patent holder means they are inaccessible for the majority of the public again reducing access to proper health care.[6]

The ethical concern to be addressed is the impact patents have on the rights of the individual. There is a growing fear that technological advances in the field of genetics can be used to further institutionalised discrimination, legislative limitation on the rights of individuals or social prejudice.[7] Therefore it is essential to consider the adverse effect IPRs can have on the exercise of human rights.

In the discussion of the ethical issues associated with the monopolisation of the human genome a consequentialist approach is adopted and will consider the ethical element through the lens of Utilitarianism. Then the genetic patents are evaluated against a human rights perspective, assessing the acceptability of gene patents and the effect on individual rights. Lastly, this chapter reiterates a warning in relation to eugenic concerns associated with genetic advances.

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3 *Supra* fn 149 Chapter 3.
4 Andrews 66.
5 Carvalho 702.
6 Sideri 5-6; Andrews & Paradise 407-409.
7 Ledley 'Distinguishing genetics and eugenics on the basis of fairness' *1994 Journal of Medical Ethics* 158.

5.2 Inaccessibility of health care and limitation of scientific research and development

5.2.1 Patent royalties as an incentive for technological advancements

The patents system as originally established and developed was based on a vision driven by the public good;[8] a belief that affording patent protection for inventions and granting monopoly rights was in the best collective interest of society as it leads to the disclosure of information used for the good of the public once the patent term has expired.[9] The recognition of IPRs benefits the inventor as well the general public. This view is reflected in terms of Article 7 of the TRIPs Agreement in which the objectives of the international agreement state that the expectation is for the protection of IPRs to contribute to the promotion of technological innovation, as well as to the transfer and spread of technology in a manner advantageous to both producers and users of intellectual property.

Traditionally, the value associated with IPRs was apparent in the ability they afforded to introduce new creations and inventions which required protection. More recently, there has been a clear increase in the value of intellectual property as a corporate asset and it is regarded as the "new global currency".[10] Patents are viewed as necessary if there is to be a capital injection into the biotechnological field.[11] Many economists and policy makers agree that the patent system is a valuable tool in any jurisdiction dedicated to technological development and it has been coupled directly with economic growth in the United States.[12] To accommodate the necessity of accessing capital for technological development IPRs have been extended to grant rights not only to individuals but to corporations possessing the fictional status of individuals.[13]

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8 Kingston 'Why patents need reform, and some suggestions for it' Arup & van Caenegem (eds) *Intellectual Property Policy Reform: Fostering Innovation and Development* (2009) 13.

9 *Ibid;* Adams & Adams *3*.

10 Adams & Adams 4 & 9.

11 Merz & Cho 208.

12 Cornish, Llewelyn & Adcock 'Intellectual property rights (IPR) and genetics: A study into the impact and management of intellectual property rights within the healthcare sector' 2003 *Public Health Genetics Unit, a care facility of Cambridge Genetics Knowledge Park* 18*;* Adams & Adams 9.

13 Coombe & Turcotte 5.

Cornish, Llewelyn and Adcock explain the basic purpose of patent law as a: [14]

> technique for attacking the inevitable tendency to under-invest in research and development (R&D) which arises because the initial costs of invention and innovation are usually considerable when compared with those of imitations.

It is argued that patents are a two-way street that encourages economic growth; innovation ensures the development of new technologies that are worthy of protection and safeguards an exclusive right for the exploitation of those inventions[15] and IPRs require the sharing of scientific knowledge through the publication of knowledge in the specifications, which enables other enterprises (that are not responsible for the information published by the patent holder) to contribute to the underlying research and development to improve technologies and further stimulate economic progress.[16] Therefore, granting a patent prevents the inventor's ideas from being reproduced without permission or to their financial detriment and simultaneously requires that important details of the invention are accessible to the public and will allow for the development of downstream inventions.[17]

In 2001 the UK Government mandated the Barton Commission to investigate the correlation between development policy for developing countries and intellectual property rights.[18] The Commission established that for developing countries to benefit from IPRs and the resulting economic growth will require the promotion of inventions and technological development.[19] However, the evidence supporting a positive link between patents and economic growth mainly refers to developed countries in which there is an advanced innovation capability and a scientific and industrial infrastructure to support it.[20]

Those in favour of gene patents argue that if it were not for the economic incentive patents provide there is no reason to invest capital and resources in genetic research and

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14 Cornish, Llewelyn & Adcock 18.
15 Adams & Adams 9.
16 *Ibid*.
17 Coombe & Turcotte 5.
18 Adams & Adams 10.
19 *Ibid*.
20 *Ibid*

genetically-driven biotechnological development. They argue that genetic research at its core is a financial endeavour based on the monopoly rights that accompany gene patents and that a moratorium on gene patents will lead to a competitive disadvantage and hamper research leading to the loss of much-needed medical breakthroughs.[21] The contention holds that in the absence of such an incentive (patents) in the technological field, research in that particular field is discouraged as patents determine where capital is invested to advance existing developments.[22] If patents are not granted, capital for research is guided towards a field in which patents are granted in that patents are a business tool.[23] Proponents of gene patents who structure the awarding of IPRs as a "purely economic" tool neglect the "cultural, social and political implications of these rights, as well as the consequences they may yield".[24]

In the development of drugs the rationale for incentivised investments can be justified considering the expense of clinical trials primarily sourced from private funds.[25] For pharmaceuticals the incentive of monopoly rights in the form of patents fuels the investment of capital into research and development. However, this claim for a required investment incentive in the field of drug development is controversial in the field of gene discovery.[26]

The rationale of the expense of clinical trials is not relevant in relation to gaining knowledge about a gene and then identifying whether an individual has a mutation in that particular gene that leads to an irregular expression (diagnostics).[27] Unlike in the case of pharmaceuticals there is no trial period to ensure the safety of gene analysis in genetic diagnostic tests. Genetic discoveries "often entail basic scientific principles that can be immediately applied by laboratories and medical facilities" once published.[28] Once a correlation between a gene and a disorder or disease is known diagnostic tests rapidly develop to meet clinical needs despite the threat of patent enforcement proceedings.[29]

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21 Kevles & Berkowits 242.
22 Prifti 4.
23 *Ibid*.
24 Coombe & Turcotte 3.
25 Andrews & Pradise 406.
26 Andrews 77.
27 *Idem* 77.
28 Russell 111.
29 *Ibid*.

Furthermore, gene discovery largely has been funded out of public funds, negating the need for incentives.[30] Andrews and Paradise point out that in 2000 more than US$1.8 billion of taxpayers' money was spent on genomics by governments and non-profit institutions.[31] Myriad Genetics used over US$5 million of the funds it received from a government agency when researching the BRCA1 patent and utilising DNA sequences derived from public databases.[32] Effectively, the public is expected to pay not only for the research that leads to discoveries, but *also* the patent costs associated with the use of the genetic discovery.[33] Compensation for the money spent in testing drugs in a clinical trial in the form of royalties once a patent is awarded is an incentive which offers protection in the pharmaceutical industry, but in genetic testing through gene analysis trials are not a consideration and the need to be compensated for genetic diagnostic trials is not a justification for offering an incentive to cover expenditure.[34] The Association for Molecular Pathology notes that "most discoveries of pathogens or human disease genes can be effectively translated into genetic tests without recourse to the incentives provided by patents or exclusive license agreements".[35] Furthermore, the US Supreme Court recognised in 1980 in the *Chakrabarty*-ruling that genetic research in all likelihood will continue, with or without the protection afforded by patents.[36]

Research in the field of genetics and the pursuit to identify genes and their role in genetic diseases and disorders long precede the patentability of genes. Human genetics has been a field of great scientific interest before genes became patentable.[37] Genetic discoveries have been driven by clinical interests and academic curiosity.[38] It appears that the clinical need for new diagnostics sufficiently serves as a motivator to incentivise

30 Andrews & Paradise 406.
31 *Ibid*.
32 *Ibid*. Myriad Genetics is a company that patented the BRCA1 and BRCA2 genes associated with breast cancer and ovarian cancer. The case of Myriad is evaluated in detail in para 5.2.2 below.
33 *Ibid*.
34 *Ibid*.
35 Andrews 78.
36 Kevles & Berkowits 241.
37 Andrews 79.
38 Andrews & Paradise 406.

the development of genetic tests[39] as pointed out in the Report of the Secretary's Advisory Committee on Genetics, Health and Society Draft:[40]

> [T]he prospect of patent protection of a genetic research discovery does not play a significant role in motivating scientists to conduct genetic research. Scientists typically are driven instead by factors such as desire to advance understanding, the hope of improving patient care through new discoveries, and concerns for their own career advancement.

Patents as an incentive for advances in the medical profession are unnecessary as innovative medical practices often ensue in the ordinary course of medicine without the substantial investment of capital.[41] The argument put forward by the proponents of gene patents that technological advance and development will suffer resulting in falling behind in terms of the progress that might be made (if we permit genes to be patentable) if we were to take away research and development incentives in the field of genetics by declaring human genetic material (HGM) non-patentable is unfounded. Some argue that biotechnological advance of any kind will completely come to a halt if we were to exclude genes from the scope of patentability, but that is unlikely. Caulfield points out that there is almost no empirical data that supports the notion that the innovation process requires patents.[42]

The commercial value of the subject matter should not dictate whether or not the subject matter should be patentable. The fact that there might be a financial incentive to apply for a genetic patent in itself is not grounds for awarding patents. The arguments used to justify monopoly rights at the expense of the masses invoke a feeling of unease considering South Africa's past and the disregard for dignity. The rationalisation of monopoly recalls Dr Biko's description of the economic function of apartheid:[43]

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39 Russell 111.

40 *Idem* 110, through reference to 'Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, Rep' handed down April 2010.

41 Russell 109 & 110.

42 Caulfield 135 & 136.

43 Biko 79.

> [T]radition has it that whenever a group of people has tasted the lovely fruits of wealth, security and prestige it begins to find it more comfortable to believe in the obvious lie and to accept it as normal that it alone is entitled to privilege.

It is not the aim in this thesis to argue for the invalidation or dismantling of the patent system in its entirety or to suggest that IPRs should not be recognised as property or worthy of protection. The benefits associated with the disclosure and utilising of inventions are not disputed, and it is recognised that patents encourage technological development and progress in countless fields. Patents motivate innovation and technological development in two fundamental ways: (1) "by stimulating research and innovation activities" and (2) "by stimulating investment to commercially develop promising inventions".[44]

The thesis questions the patentability of HGM and argues that such material in particular should be excluded outright from the scope of private ownership or at the very least be regulated restrictively. If consideration is given to the nature of the material and the adverse consequences patents hold, genetic material should be regarded as unique in its ability to undermine what patents seek to achieve. Gene patents serve to illustrate the exploitation of IPRs for private interests rather than pursuing the benefit to the public.[45] Gene patents offer an example of how market rationality has been structured to the detriment of social objectives.

It has been argued that the incentive associated with IPRs is not relevant to genetic diagnostics. In the rest of the chapter it will be argued that the aims awarding patents sets out to achieve (the motivation of innovation through the stimulation of R&D) is undermined in the special case of diagnostic or genetic-testing patents. Further, it will be argued that patents inhibit access to quality health care. The discussion that follows illustrates how enabling the privatisation of genetic information through the grant of patents can be a "major pillar[s] of economic and political power under informational capitalism".[46]

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44 Russel 109.
45 Coombe & Turcotte 6.
46 *Idem* 10.

5.2.2 Effects of gene patents on access to health care

Genetic diagnostic tests and genetic therapy or treatment technologies are considered to be fundamental to future health care.[47] Testing for genetic disorders and diseases "can lead to true preventative medicine" which enables individuals to make crucial decisions in terms of treatment options or to make lifestyle changes that will enable them to control their disease in order to better their quality of life.[48] However, even though genetics can be seen as a cornerstone of modern medicine, the applicational value of genetic sequences in testing, diagnostics and treatments is inaccessible to most. The patent holder or exclusive license holder of the disease gene is able to dictate any diagnostic or treatment use of the patented gene, enabling the holder to prescribe the costs of tests according to their own wishes to the extent they effectively deny people access to such technologies.[49] A study published in 2003 indicated that 25% of participating laboratories elected no longer to offer a genetic test due to patent or licensing restrictions, whereas 53% elected no longer to invest in the development of genetic tests for the same reason.[50]

As a direct result of gene patents some laboratories are not able to perform genetic tests to determine whether patients exhibit genetic differences associated with a disease, thus inhibiting access to diagnostics.[51] Patent holders require the payment of royalties for laboratories to apply the patent holder's gene in diagnostics or they dictate that the tests be performed only in their *own* laboratories.[52] For example, physicians had to send away samples for testing at specified laboratories owned or established by the patent holder in the *Myriad Genetics* case.[53] The effects of such restrictions extend even further than merely not offering a service or being able to treat vulnerable patients or not being able to do research in the field relating to that specific genetic difference. Not being able to perform these tests leads to pathologists being unable to keep up with new developments

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47 Andrews 69.

48 *Ibid*.

49 *Idem* 69 & 70.

50 Caulfield 140, in reference to a study completed by Cho *et al*.

51 Merz & Cho 205.

52 Andrews 89. See discussion below regarding the BRCA 1 and BRCA genes, as well as the Alzheimer's Disease gene.

53 Park 'Gene patents and the public interest: Litigating *Association Molecular Pathology v Myriad Genetics* and lessons moving forward' 2014 *N.C.J.L & TECH* 519-536, 522; Caulfield 142.

in their field, it inhibits the proper training of residents and it prevents the efficient management of these laboratories.[54] All these implications associated with gene patents have an adverse impact on the realisation of the right to health care.

In the *Myriad Genetics* case the genes relating to the risk of cancer were patented. These genes were the BRCA 1 and BRCA 2 genes, which, if mutated, result in five to ten percent of breast cancer cases as well as an increased risk for developing other cancers such as ovarian cancer.[55] Myriad successfully applied for the patent rights over the BRCA 1 and BRCA 2 genes in the United States Patent and Trademark Office as well as the European Patent Office.[56] Their patent rights covered the mutations of the genes which could be used to determine whether someone had a predisposition for an increased risk of breast and ovarian cancer.[57] Myriad Genetics had a monopoly controlling the diagnostic testing which detected the mutations of the genes concerned.[58] They charged more than 3000 euros or 3200 US dollars to test whether an individual had a predisposition to develop breast cancer and forbade other institutions from performing the test.[59] Despite a technological advance resulting in a fall in the cost of testing, Myriad's prices consistently increased to the point where they charged 4000 US dollars for a standard test.[60] The tests were performed at Myriad's laboratories and they instituted civil claims against universities that did not hold exclusive licences offering to test for the gene at no cost.[61]

These patents where highly contested by various governments, coalitions, research institutions, hospitals, Greenpeace and numerous other institutions.[62] Many scientists felt that Myriad was exploiting the work of other scientists who contributed to the body of public knowledge, and disregarded contributing research funded by parties with no

54 Merz & Cho 206.
55 George & Kaushik 'Gene patents and rights to health' 2010 *NUJS LAW REVIEW* 323-336, 331.
56 Carvahlo 705 & 706.
57 Caulfield 142.
58 Andrews 89.
59 Sideri 10.
60 Park 522.
61 Sideri 10.
62 *Ibid*.

commercial interest which was made possible by blood donations from many families.[63] After extensive litigation and appeals the US Supreme Court concluded in a unanimous decision in *Association of Molecular Pathology v Myriad Genetics* that "genes and the information they encode are not patent eligible … simply because they have been isolated from the surrounding genetic material".[64] The Court invalidated the patents over isolated genomic human DNA but rendered cDNA molecules patent-eligible.[65]

Myriad applied for these patents in 1995 for them to be declared invalid only in 2013.[66] The manner in which Myriad exercised their rights during this period harmed many patients for who BRCA testing was crucial.[67] Such exclusionary monopoly rights over genes hinder the "creation of new tests, tools, and drugs".[68] The aggressive enforcement of the BRCA gene patents by Myriad meant that not only was it monopolising the genes themselves but the clinical testing market as well.[69] Various laboratories were capable of performing the BRCA tests[70] but were prevented from doing so when Myriad sent out "cease and desist" letters to laboratories all around the world.[71] In 2005 the Yale DNA Diagnostic Laboratory requested Myriad's permission to perform tests that would predict cancer risks other than those covered by the test offered by Myriad at that stage.[72] Myriad denied their request and threatened the laboratory with a lawsuit, leaving women without crucial information pertaining to cancer risks until a year later when Myriad was able to offer the tests in their laboratories.[73]

The patents held by Myriad prevented many patients from accessing vital tests.[74] Their gene patents and the aggressive way in which they enforced their patent rights caused

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63 *Idem* 170.
64 133 S. Ct. 2107 at 2120 (2013).
65 *Idem* at 2119. Refer to discussion on page 4 above.
66 Tallmadge 'Patenting Natural Products after Myriad' 2017 *HARV. J. L. & TECH* 569-600, 580.
67 Park 529.
68 *Idem* 523.
69 *Idem* 529.
70 *Ibid*.
71 Caulfield 142. These letters limited all testing to that provided by Myriad or one of their licensees.
72 Kumar 'Gene Patent and Patient Rights' 2014 *Whittier L. Rev.* 363-372, 366.
73 *Ibid*.
74 Park 529.

harm and disregarded the right to health care.[75] On the day on which the Supreme Court invalidated Myriad's patents over the BRCA genes and their mutations, three genetic testing companies announced that they will be offering testing BRCA gene mutations.[76] It would have been simple *not* to compromise patient care if genes are rendered non-patentable, making tests more accessible to patients by increasing the number of facilities that offer genetic tests. Myriad's aggressive tactics to block any use of their gene by other institutions was "particularly harmful to ethnic minorities who do not carry the same risks for inherited diseases as Caucasians and who can receive inaccurate results from standard genetic testing".[77]

Another example of where genetic patents impeded laboratories from providing diagnostic testing is that of the haemochromatosis gene. Merz, Kriss, Leonard and Cho's study on the patents of the HFE gene mutation associated with haemochromatosis and the impact these patents had on research and access show that the patents inhibited the development and validation of clinical assays for the haemochromatosis test.[78] The moment the discovery of the haemochromatosis gene was made public laboratories immediately started providing tests for the mutation in the HFE gene.[79] Seventeen months later, when a patent on the gene was granted,[80] a survey of 119 laboratories in the US reported that 30% of these laboratories (36 out of the 119) ceased to provide the genetic tests they developed *prior* to the granting of the patent or had to cease the development of genetic tests in which the HFE gene is used[81] when the patent rights were enforced by the holder of the exclusive licence.

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75 *Ibid*.

76 Ingram '*Association Molecular Pathology v. Myriad Genetics, Inc*: The product of nature doctrine revisited' 2014 *Berkley Technology Law Journal* 385-417, 386.

77 Kumar 367.

78 Merz *et al* "Diagnostic testing fails the test: The pitfalls of patents are illustrated by the case of haemochromatosis" 2002 *NIH Public Assess* 2.

79 *Idem* 2-3.
Of the 58 laboratories still performing the HFE tests at the time of the survey, 60% of these laboratories had introduced the clinical testing of the gene prior to the issuing of the patents.

80 The patents for the haemochromatosis genetic test were issued in 1998 and gave the patentee the exclusive right to test for two mutations of the HFE gene, namely C282Y and H63D. The patentee then licensed the patents exclusively to SmithKline Beecham Clinical Laboratories.

81 Merz *et al* 2-3.

The licence holder expressed a readiness to grant sub-licences to laboratories performing tests using the gene, but asked academic laboratories to pay an upfront fee of $ 25 000 and required commercial laboratories to pay between five to ten times more.[82] It further required royalties to be paid at $20 per test done in terms of the sub-licence agreements.[83] Merz *et al* raise the high costs of diagnostic tests for the genes due to the patents covering the HFE gene mutations as a point of concern.[84] The fact that the exclusive licence holder for the HFE gene charged an upfront fee as well as royalties of $20 per test performed might be considered reasonable, but this fee is only the fee paid to the licensee and does not include any of the costs of the sub-licensed laboratory performing the test.[85] Further, it should be noted that the diagnostic tests are often performed in a panel of tests, and each of those tests performed in the panel result in royalties to the respective patent holders, called "stacking of royalties". [86] With clinical-diagnostic testing constantly developing new tests and more tests being added to panels the costs continue to rise, making them inaccessible to more and more patients, particularly in the financial circumstances of developing countries.

The study illustrates the measurability of the effects that gene patents have on the availability of HFE testing and its development in the United States.[87] Many laboratories with a competency to offer and perform the test for haemochromatosis refrained from doing so because of the HFE patents.[88] The unwillingness to adopt, develop or validate the HFE tests likely relate to the financial risks laboratories assume combined with the threat of being prohibited from doing so when patents are enforced.[89]

The facts relating to the Alzheimer Disease gene follow a similar pattern. The exclusive licence holder of the Alzheimer Disease gene had its own laboratory perform

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22 out of the 36 laboratories said that the patents were "the reason" they ceased to perform the test or were not developing the test, while 10 out of the 36 laboratories reported that the patents were "one of several reasons" they no longer offer the test or are developing the test.

82 *Idem* 2.
83 *Ibid*.
84 *Idem* 4.
85 *Ibid*.
86 *Ibid*.
87 *Idem* 3.
88 *Ibid.*
89 *Ibid.*

the test for the gene and prohibited any other laboratory from doing so.[90] The moment the licence holder made known the sequence associated with the disease any other laboratory would have been able to run a genetic test for the presence of the Alzheimer Disease gene.[91] However, they were prevented from doing so as they faced the threat of legal action by the licence holder if they performed the test. [92] The events surrounding the discovery of the gene responsible for the neurological disorder known as Canavan Disease mirror this development; the patent holder of the gene (Miami Children's Hospital) prohibited doctors from testing for the genetic disorder without the payment of a fixed royalty fee.[93]

The accessibility of quality health care is compromised by gene patents as the threat of patent-infringement lawsuits serves to deter medical practitioners using the most accurate and safe technologies available.[94] Gene patents have the potential to "inhibit doctors from using their best medical judgment" as they have to rely on less accurate diagnostic methods, as well as raising "the cost of health care while inhibiting its effective delivery".[95] In the same way that there is a fear that gene patents impede the development of better and more accurate genetic tests[96] there is the fear that due to medical practitioners not being able to (or wanting to) pay the royalties associated with the patent and not wanting to risk patent infringement they resort to less accurate or lesser quality procedures and techniques on patients. Patent holders can forbid companies from introducing "inexpensive, quick public health testing" for diseases, and require that anyone who wishes to be tested uses their more expensive test.[97]

Gene patents place medical professionals in a situation of requiring physicians to violate either patent laws or their ethical duty;[98] either they perform the diagnostic test themselves (with the threat of a patent infringement lawsuit), require their patients to pay for a test which they cannot afford or compromise patient health care by not providing the

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90 Andrews 89.
91 *Ibid*.
92 *Ibid*.
93 Carvalho 705.
94 Andrews 74.
95 Russell 116.
96 This will be addressed in the following sub-heading of this chapter.
97 Andrew 90.
98 Russell 115.

test at all. The inaccessibility of diagnostics can have real and dire consequences for patients, as is evident from the events surrounding the Long QT syndrome gene (LQTS).[99] In this example the patent holder awarded an exclusive licence over the "isolated genetic mutation associated with LQTS" to DNA Sciences.[100] After obtaining this exclusive license DNA Sciences was declared insolvent, which led to an eighteen-month period in which patients were unable to test for LQTS.[101] At least one laboratory approached DNA Sciences during this time to allow them to perform the test, only to be refused;[102] the unavailability of the test for LQTS contributed to the death of one person.[103]

The adverse impact gene patents have on the access to quality diagnostics is evident from the abovementioned examples, but the adverse impact is amplified when these consequences are considered against the reality in developing countries where access to public health care is a necessity, and is over-burdened and financially exhausted. Access to diagnostics and the quality of clinical diagnostic testing are crucial factors in a country where public medical resources are overwhelmed. I argue that the effects of gene patents on a public health system can be catastrophic when a large part of the population is completely dependent on public provision of adequate access to health care, which includes access to quality diagnostics.

I argue that the inaccessibility of health care services as a result of gene patents undermines the right to access health care services, as entrenched in section 27 of the South African Constitution. In the socio-economic circumstances in South Africa diagnostic testing is unaffordable for the majority of the population. Gene patents cause diagnostics to be economically as well as physically inaccessible by prohibiting practitioners from offering genetic tests[104] and/or requiring the payment of royalties for the use of "their" gene. Section 2(a)(ii) of the National Health Act states that it is the objective of the Act to

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99 Kumar 365.
100 *Ibid*.
101 *Ibid*.
102 *Ibid*.
103 *Ibid*.
104 George & Kaushik 327.

> [E]stablish a national health system which … provides in an equitable manner the population of the Republic with the best possible health services that available resources can afford …

Gene patents effectively prevent public health systems from realising the objectives of the Act by rendering genetic diagnostic testing inaccessible to those dependent on the public health system if the state is unable to afford the payment of royalties to the patent holder for the use of the patented gene in diagnostics. Gene patents exclude the clinical use of a gene from what the state considers to be an "affordable" and "available" resource. If genes are considered to be patentable subject matter, then patent protection afforded to the patent holder will diminish the legislative measures implemented to give effect to the fundamental constitutional right to health care services. Declaring genes non-patentable will assist the state in realising these rights, which undoubtedly is in the interest of the public.

5.2.3 Effects of gene patents on scientific R&D

The human genetic sequence contains all the information that the human body requires in order for it to function.[105] It follows that genetic information contained within genes will enable the development of new therapies and treatments or help to diagnose a patient with a genetic disease.[106] The genetic information contained within a (patented) gene therefore is crucial to downstream research and development relevant to the gene, rendering the substitution of genes in research or "inventing around" genes problematic, difficult and impractical.[107] This situation is a cause for concern in the scientific field as "free access to data is of critical importance to the future of genetic discoveries".[108] Undermining the opportunity to practice research indirectly affects the development, quality and availability of important health care services, which adversely impacts medical resources and retards advances that could improve lives.

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105 *Idem* 325.
106 Caulfield 140.
107 *Ibid*; George & Kaushik 327.
108 Russell 112.

Gene patents cover every method of diagnosis related to the particular gene,[109] inevitably this makes it hard for research into development and progress in the medical and biotechnological field around the patented gene and results in delays in the development of treatments, therapies and diagnostics.[110] Once a patent has been issued over a particular gene the patent holder can "block" any use of that gene during the twenty-year period for which the patent is awarded, including blocking any downstream research related to the patented gene.[111] This is a possibility even if someone other than the patent holder merely seeks to clarify the precise role the patented gene plays in the human body or to build upon the scientific discoveries made by the patent holder.[112]

5.2.3.1 Impeding R&D before patents are granted

As discussed, the point of the patent system is to incentivise the disclosure of information and to encourage the bringing forth of information and developments that are useful to society. The scientific community as well as the public should not have to wait until the end of the patent period or for the patent to lapse before they are able to learn something new from the disclosed discovery for the first time or before they are permitted to improve upon the genetic "invention" in question.[113]

Researchers have delayed the publication of their findings to secure patent protection before making their findings known. More than a year went by after the first United States patent application was filed and before the first publication on the cloning of the HFE gene associated with haemochromatosis was submitted.[114] This practice is worrisome as laboratories are able speedily to develop tests and validate the findings as soon as the information on the discovery is made known.[115] The longer the finders of the new discovery wait to publish their findings to secure patent protection for the monopoly rights associated with the discovery of the gene, the more time goes by in which many other

109 Merz & Cho 204.
110 *Idem* 207.
111 Russell 114; George & Kaushik 327.
112 Carvalho 705.
113 *Ibid*.
114 *Ibid.*
115 Russell 111.

laboratories are unaware of the breakthrough and of the discovery. That period between the discovery and the publication is time lost; tests could have been developed, adjusted and offered to the patients who have the disease. In the case of the HFE gene mutation it left many undiagnosed and untreated patients for more than a year. It also meant a year delay in validating tests and developing and improving the accuracy of tests offered to patients.[116]

In her critique of the validity of gene patents, Andrews discusses how studies have shown that one in five medical scientists that participated in a survey admitted to delaying the publication of their research results by no less than six months to secure financial interests.[117] The studies further indicate that scientists who had a direct commercial interest in the their research were three times more likely to stay the publication of their findings, and twice as likely to stay the sharing of findings with their colleagues than those who did not have a direct financial interest in the discoveries.[118] It was further shown that geneticist were most likely to refuse sharing their findings and 28% of geneticists who partook in the survey held that they were not able to replicate the results as other scientists would not communicate their findings.[119] In the medical and biotechnological fields delays in genetic technology advances and the development of new and better tests and therapies are a gamble with human lives.

The incentive attached to genetic patents clearly impedes research in genetics as clearly there is withholding of information and discoveries by those trying to protect their commercial interests. The intentional withholding of information that could assist in the development or improvement of biotechnology inevitably delays advances, which undermines and invalidates the notion that a patents system that allows for the

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116 Andrews 80. An example in which progress was delayed and impeded due to the financial incentive attached to being the first to discover gene function is that of the autism gene. Researchers withheld patient tissue samples in an effort to prevent other researchers from bypassing their research in order to secure financial interests.

117 *Ibid*. The studies referred to were done by Blumenthal *et al* in "Withholding Research Results in Academic Life Sciences" 1997 *JAMA.*

118 *Ibid*. Andrews mentions that it took over a year after the filing of the patent for the discoverers of the haemochromatosis gene to submit their findings for publication.

119 *Idem* 81. The study by Blumenthal *et al* further indicates that 20% of geneticists withholding data were doing so to secure and protect their own financial interests related to the results.

monopolisation of HGM will result in a quicker turnover in technology since the incentive attached to IPRs will guarantee development. The fact that researchers are refused information by those who seek to secure their financial interests means that there are periods where research *could* have been done and technologies could have been developed and improved, but no advances are realised. The time is wasted since researchers must wait until the discoverers elect to share their results. Thus, even *before* a patent has been granted, research is impeded intentionally by keeping findings secret for the sake of monopoly interests associated with patent rights.[120]

5.2.3.2 Impeding R&D after patents are granted

Research is further impeded by genetic patents, *after* the genes actually are patented.[121] Once the patent has been awarded and the findings pertaining to the gene and its irregular expression in individuals have been made known to other scientists, they will not be able to verify the findings of the patent holder.[122] The verification of genetic tests and gene or mutation prevalence in a population is crucial to science and in clinical services. Some bodies which offer genetic testing as a service exaggerate their findings on the prevalence or occurrence of a disease in a population,[123] this exaggeration of the occurrence of disease in a population frightens people into having the genetic test and is done with the aim of boosting profits.[124]

Other researchers cannot verify the findings of the patent holder as the patent holder's right allow them to prohibit others from duplicating the results or prevent them from verifying the research done by the patent holder.[125] In a survey published by Caulfield *et al* it was reported that more than half of the participants (all gene patent holders) admitted that they would want other researchers to pay for a licence if they wished to study gene mutation prevalence in a population.[126] It means that if other researchers and scientists

120 Andrews 80 & 81.
121 *Idem* 81.
122 *Ibid*.
123 *Ibid.*
124 *Idem* 74.
125 *Idem* 81.
126 Caulfield *et al* 'Patenting human genetic material: Refocusing the debate' 2000 *Nature Reviews* 230.

wanted to evaluate whether claims of the patent holder in his patent application were accurate (that a certain fraction of the population had the patented gene related to a specific disease, thereby encouraging members of the population to undergo genetic testing through their laboratories or motivating other laboratories to pay licensing costs in order for them to offer the test to their patients), then these other researchers and scientists are required to pay a licensing fee to confirm whether such results are accurate or authentic.[127] Research to ensure the accuracy of genetic diagnostics therefore can be done only *if* the patent holder decides to issue a licence to those wanting to validate the findings.[128] Without this licence other researchers and scientists will not be able verify the accuracy of the findings and face the threat of patent infringement proceedings.

If the patent holder does not outright refuse to issue licences to study the gene, then licensing costs required by the patent holder deplete research funds and obstruct the studies needed to verify the findings of the patent holder.[129] The obstruction of gene patent verification unavoidably results in cases where the only material published on the accuracy of genetic tests and prevalence assessments are those written by people with a vested financial interest in the commercial success of the genetic tests.[130] Peer review and objective assessments of genetic tests available to the public assist in the public not being misled by biased and exaggerated prevalence statistics and ensure the accuracy of the tests in determining whether a certain mutation(s) has a specific disease expression and whether an individual has that specific mutation.[131]

The blocking of scientists from conducting research into genes due to patent protection has the potential to undermine efforts to develop genetic tests that are offered at a lower cost as well as of a higher quality and greater accuracy.[132] Patents effectively lead to scientists underutilising resources that could assist in research and development and preventing productive innovation.[133] Patents over genes participate in a phenomenon that has been called “the tragedy of the anti-commons”, which describes instances in

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127 Andrews 81.
128 *Ibid*.
129 *Ibid*.
130 *Idem* 82.
131 *Idem* 82 & 83.
132 Andrews & Paradise 408.
133 Russell 112.

which "competing rights held by independent parties prevent any one party from engaging in productive innovation".[134] The granting of gene patents in an era when genetic discovery arrives at an exponential rate leads to the "stacking" of overlapping gene patents.[135] Sometimes scientists require multiple licences if they are researching a gene(s) in terms of which many patents have been granted, which dramatically increases the costs of researching certain genetic disorders or diseases.[136] It is not always financially feasible for scientists to do research on such disease genes, which deters scientists from investing time, effort and resources in the investigation of patented disease genes.[137]

Russell points out that even though the "tragedy of the anti-commons" relating to intellectual property is controversial and disputed, empirical data relating specifically to gene patents paints a very clear picture.[138] A survey found that 53% of laboratory directors refrained from developing novel clinical tests due to patent protection rights, and 67% perceived gene patents to hamper their ability to do research.[139] Another study found that patents held by Myriad Genetics prevented other scientists from having a better understanding of the BRCA 1 and BRCA 2 genes and that Myriad Genetics' patents adversely influenced the knowledge the public had regarding these genes by five to ten percent.[140]

Historically, it was sufficient to identify only one mutation in a gene (resulting in the associated genetic disease) to be afforded patent protection that covered the gene in its entirety, including the mutation and all subsequently discovered mutations.[141] This circumstance is troubling when considering that some diseases can be caused by different mutations in the gene and not just by the one mutation identified by the patent

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134 *Ibid* (citing Heller & Eisenberg 'Can patents deter innovation? The anticommons in biomedical research' 1998 *SCIENCE* 280).

135 *Idem* 114.

136 *Idem* 112. The accumulative and increasing costs of doing research on a gene covered by patents held by different parties are attributed to the costs and time spent on conducting searches into existing/pending patents, and the creation of complex licensing agreements.

137 *Idem* 114.

138 *Idem* 113.

139 *Ibid*.

140 *Ibid*.

141 Andrews 88.

holder.[142] The expression of a particular disease can result from numerous and differing mutations of the same gene, but researchers and scientists are prevented from exploring the possibilities of whether other mutations in the patented gene might cause the same disease expression[143] as the patent prohibits them from investigating the gene in its entirety if they cannot pay the required licence fee or royalties.

States in which the haemochromatosis and Alzheimer Disease genes were not covered by patent protection permitted researchers to study the genes once they became public knowledge and in so doing discovered other previously unknown mutations associated with the respective genes.[144] French physicians were able to locate and identify new mutations in the BRCA gene - a mutation that went unnoticed by the tests that Myriad offered while preventing other institutions from screening for other mutations.[145]The discovery of other mutations associated with a genetic disease is critical to the proper diagnosis of a patient.[146] Patients paying to be tested by the licence holder for the single or few known patented mutations might test negative for the presence of these known mutation(s) associated with the particular disease, whereas the gene in question might include a different unknown mutation in the same gene which results in the same expression of the disease.[147] The more free access to genetic information is encouraged the more research will be conducted and more people will be tested, enabling the development of better tests and greater knowledge on genetic diseases that influence the lives of many.[148]

In dealing with any genetic disease there is a point at which some mutations found in the genetic sequence associated with a diseased expression are unknown until they are discovered. This is the natural course of research, in that research involves the quest for something that is unknown being brought to light and explored. However, this normal element becomes an ethical concern when the knowledge yet to be gained remains

142 *Idem* 82.
143 Andrews & Paradise 407.
144 *Ibid*.
145 Andrews 90.
146 *Idem* 89.
147 *Idem* 89 & 90.
148 Russell 114.

elusive due to patent holders and licence holders blocking access to information pertaining to the gene in question.

Indirectly, patents intervene in patients making a well-informed decision regarding their health care when better quality tests cannot be developed or when researchers are unable to determine whether unknown mutations of the patented gene might result in an increased propensity to develop a disease. Scientists delaying the publication of their findings or not sharing their discoveries in order first to secure financial interests means that other scientists and medical practitioners are not able to offer patients vital preventive health care resources, even though any laboratory is able to perform such tests the moment the genetic sequence and gene function are made known, without their having to use a product or tool devised by the holder.[149]

Developing countries suffer the most as a consequence of the enforcement of patent rights. In countries where there is a great dependence on the public health system, often already overburdened, people are marginalised by not having access to proper diagnostics as the state cannot afford the royalties payable to the patent holder. An obvious solution to the problem is not to grant patent rights for the gene discovery in developing countries, but to do so creates the concern that there will be a withdrawal of investment in gene-function discoveries that relate to genetic diseases or disorders in these countries and to a focus on diseases and disorders predominant in developed economies where monopoly interests are protected in that the proponents of gene patents contend that monopoly rights in the form of patents are the driving-force behind investments in a field of research.

Effectively, genetic patents have the possibility of preventing researchers from conducting verification studies to confirm the accuracy, completion and correctness of the claims of the patent holder;[150] from offering a second opinion to diagnosed patients (crucial in instances in which invasive and life-altering treatments or procedures are being considered);[151] from investigating whether other mutations in the patented gene might also lead to a the genetic disease in question;[152] and whether the patented gene

149 *Idem* 111.
150 Andrews 89-91; Parks 522.
151 Russell 116.
152 Andrews 89.

influences other genetic disorders or diseases. The stifling of research in the field of genetics through the award of patents has a negative impact on the scientific and medical progress that undoubtedly would be of great value in addressing health care issues. By excluding people from investigating patented genetic discoveries, we gamble with lives and waste years of potential research and development in the field of genetics and medicine in the name of intellectual property rights. As discussed above, this is interference in the right to health care in terms of international law as well as domestic South African law.[153]

5.2.4 Declarations of the United Nations Educational, Scientific and Cultural Organisation

International measures have been adopted to address the consequences that flow from genetic research and development and to guard against the adverse and unjust effects. In 1997 the United Nations Educational, Scientific and Cultural Organisation (UNESCO) introduced the *Universal Declaration on the Human Genome and Human Rights* in response to the Human Genome Project (HGP). This Declaration provides for the availability of benefits derived from advances made in relation to the human genome in the field of biology, genetics and medicine.[154] It further provides that states "should make every effort" to advance the international dissemination of information concerning the human genome and genetic research gained through scientific pursuit.[155] Dissemination should encourage co-operation between states, specifically between "industrialised and developing countries". Measures that states are encouraged to adopt to promote international co-operation with developing nations include measures that allow for the free exchange of information and knowledge in genetics, medicine and biology; as well as allowing developing countries to reap the benefits of research to enable their beneficial use in the promotion of economic and social objectives.[156] The accessibility of information pertaining to the human genome therefore is safeguarded by the Declaration.

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153 Discussed above on p 93.
154 Art 12(a) of the Universal Declaration, 1997.
155 Art 18 of the Universal Declaration, 1997.
156 Art 19(iii) & (iv) of the Universal Declaration, 1997.

This Declaration was followed by the UNESCO *International Declaration on Human Data* in 2003. The Declaration on Human Data requires international co-operation as well by enabling fair access to and dissemination of genomic data through mutual respect and the publication of their findings.[157] Further, this Declaration not only requires all people to be granted access to their own genetic data[158] but encourages the international sharing of the benefits derived in the scientific sphere from genetic data.[159] The Declaration on Human Data goes on to elaborate the forms in which such beneficial results may present themselves, including the beneficial sharing of medical care, the provision of new diagnostics and support for health services.[160]

It is evident, taking into consideration the manner in which genetic patents impede research and the impact that patents have on access to adequate health care as discussed above, that patents effectively undermine the goals these UNESCO declarations set out to achieve and encourage.

5.2.5 Utilitarianism as an ethical theory for gene patents

Utilitarianism is a moral theory that considers something either right or wrong (ethical or unethical) based on whether the consequences of such actions or scenarios are good or worse.[161] Followers of Utilitarianism consider something ethical or right if the outcome of the action (in our case granting or not granting patents over human genes) results in the greatest good for the most people, evaluated from an impersonal standpoint that weighs up all affected parties' legitimate interests equally.[162] The aim is to attain a result that has the greatest balance of positive value of well-being, such as freedom, happiness, health, knowledge, and so on.[163] The ethical acceptability of human gene patents through the lens of Utilitarianism is assessed by looking at the consequences of granting such patents, specifically the limitations they place on research and access to diagnostic care

157 Art 18 of the International Declaration, 2003.
158 Art 13 of the International Declaration, 2003.
159 Art 19(a) of the International Declaration, 2003.
160 Art 19(a)(ii)-(iv) of the International Declaration, 2003.
161 Beauchamp & Childress *Principles of biomedical ethics* (2009) 336.
162 *Idem* 337.
163 *Ibid.*

as well as the effect they have on the individual's right to have access to adequate medical care and the potential violation of this right if patents are granted. Utilitarianism endorses the notion that ethical considerations speak to our altruistic disposition towards other people and animals by defining the highest good as being the general good of humanity or perceptive animals.[164] This theory prescribes what one ought to do based on the general highest good for humankind.[165]

Utilitarianism derives from the word "utility", which in this instance refers to happiness or pleasure rather than usefulness.[166] As a philosophical theory, Utilitarianism is broadly based on three features. First, it is rooted in consequentialism, meaning that something is right or wrong as determined by looking at the consequences or the outcome of the actions in question and therefore entails balancing good and bad consequences.[167] Secondly, Utilitarianism promotes happiness to be a good in itself. The notion of "happiness" is inherently good and everything that results in happiness is good as happiness is the decisive objective.[168] The total intrinsic value that an action produces therefore should be assessed to determine the greatest good for the most people and dictates the course of action to be taken in order to give effect to what is considered ethical.[169] Lastly, Utilitarianism holds that the "greatest happiness principle" is the most important moral principle in order to determine whether something is right or wrong.[170] This principle considers the right action to be the thing that brings the greatest happiness to the greatest number of people, and if your actions bring unhappiness to a great number of people, your actions are deemed wrong or unethical.[171] What one considers to be the right thing to do in a given scenario is that which produces the best overall result based on an impersonal evaluation of the respective interests of the affected parties.[172]

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164 Deigh 93.
165 *Idem* 94.
166 Stewart *Ethics: An introduction to moral philosophy (*2009) 13.
167 *Ibid*; Beauchamp & Childress 340.
168 *Ibid*.
169 Beauchamp & Childress 341.
170 *Ibid*.
171 *Ibid*; George & Kaushik 333.
172 Beauchamp & Childress 341.

Utilitarianism is of particular relevance in considering intellectual property rights because the protection of IPRs primarily has been influenced by Utilitarianism,[173] as Article 7 of the TRIPs Agreement acknowledges where it is stated that IPRs are to be protected and enforced to promote innovative and technological contributions "in a manner conducive to social and economic welfare". This statement has been understood to signify that IPRs are subject to "higher social values".[174] It is further understood that the utilitarian principles that motivate the formulation of patent laws aim to establish incentives for research and development as well as the conception of novel ideas and products.[175]

However, the fact that patents are grounded in Utilitarianism cannot be understood to mean that in all instances it will give effect to social and economic welfare objectives as such rights can have adverse consequences as well.[176] The adverse consequences of monopoly rights on social and economic welfare are considered a "necessary evil" to ensure the further development of technologies that will be greatly beneficial to the realisation of social and economic rights and objectives of the global population – this is the foundation on which *quid quo pro* exclusionary IPRs are based.[177] As Slade points out:[178]

> The predominant objective [of intellectual property protection] is to achieve a balance between the problems created by the scarcity of production with the benefits that intellectual property protection brings for encouraging creation.

The requirement is to evaluate if in human genetic diagnostics the medical breakthrough made by those who discovered the link between particular mutated genes and the expression of a particular disease serves a purpose. For those in favour of genetic patents, and arguably those who benefit financially from the commercialisation of HGM

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173 Slade 970.
174 *Ibid*, in reference to Correa 'Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement' Oxford University Press 2007.
175 Coombe & Turcotte 5.
176 Slade 971.
177 *Ibid*.
178 *Ibid*.

by the award of patents, the purpose of such a discovery is to serve an economic function to be obtained through the monopolisation of genetic discoveries. If one were to approach genetic discoveries or medical breakthroughs from the perspective of medical practitioners or the public who benefit diagnostically from gene discoveries, the purpose of these discoveries is to assist in the treatment of patients and they serve a humanitarian purpose.

The interests to weigh against one another in the evaluation of genetic patents (through the lens of Utilitarianism) are that of the patent holder versus that of the public. Proponents of genetic patents argue that without the economic incentive attached to patents there will be no reason to invest in the research and development of genetic technologies and that gene patents therefore saves lives[179] and will frame their interest as the interest of the public. Stated differently, it can be argued that in considering the patentability of genetic material the interests at play and to be balanced are the interest of the public (as per proponents of genetic patents) versus the interest of the public (as per opponents of genetic patents).

The former considers the need for an incentive to encourage and motivate the development and improvement of genetic technologies to be of benefit to society, and that without such an incentive R&D in the field of genetics and by extension the health of the public possibly suffers and is adversely affected if we are to exclude genetic material from the scope of patentability. The latter considers that research and development will suffer (and by extension the public) if genetic material were *not* to be excluded from the scope of patentability and that the public suffers by rendering genetic diagnostics inaccessible to those who need diagnostics to make informed and crucial medical decisions. A Utilitarian approach to the conflicts posed therefore entails balancing the intrinsic interests of the public, taking into consideration the greatest good for the greatest number of people. The focus of this study is to assess a South African position regarding the patentability of HGM so the public interest to consider will be that of the South African population.

The question to be answered regarding the patentability of HGM in terms of Utilitarianism can be framed in the following way: Is it in the best interest of the public to

[179] Boyle 37.

prioritise the interest of the potential future population of South Africa by protecting intellectual property interests as protecting these interests arguably incentivises investment in genetic technologies without which (it is argued by proponents of genetic patents) research and development and medical care (of hypothetical South Africans) possibly suffer? Or is it in the best interest of the South African public to reject and exclude genetic material as a patentable subject matter and in so doing allow for the dissemination of information that will permit other researchers and medical practitioners access to the information associated with genetic discoveries and allow downstream R&D to progress, rendering genetic diagnostics freely available and accessible to real people who currently require diagnostics to make informed and crucial medical decisions.

Utilitarianism is based on balancing good and bad consequences and that the ethical thing to do is whatever leads to the greatest good and happiness for the most people. So, do Utilitarian principles justify the award of genetic patents that function through a mechanism of exclusion based on hypothetical potential benefits although this exclusion results in tangible adverse consequences? Which means it is difficult to establish a balance.

I argue that though IPRs in general are justifiable in Utilitarianism, it not necessarily condones IPRs in all instances. Utilitarianism is regarded "as [being] responsive in constructive ways to changing social practices";[180] instances in which the actual "bad" associated with the grant of IPRs outweighs the potential "good" such rights might encourage means we have to reconsider the award of these rights. In dealing with people's lives and the dignity with which they live their lives the blanket application of a justification of intellectual property rights cannot be condoned.

In most instances where IPRs are granted based on the principle of Utilitarianism the adverse consequences associated with IPRs arguably *can* be seen as a so-called "necessary evil". However, I argue that there are instances in which the "evil" outweighs the associated beneficial purpose these rights serve, and in such instances we ought to reconsider granting rights that enable and encourage these associated evils. Even though IPRs find a justification and rationale in Utilitarianism, there are instances Utilitarianism

[180] Beauchamp & Childress 341.

rather justifies such a right *not* being awarded, and I contend that genetic material illustrates an instance in which this is the case.

In principle, Utilitarianism as a moral theory allows for the interest of the minority to be overridden by the interest of the majority.[181] Beauchamp and Childress point out in their evaluation of Utilitarianism as a moral theory that it can be problematic in some instances.[182] One such critique of Utilitarianism relates to a situation when the interest of the majority (which overrides the interest of the minority) promotes an unjust social distribution.[183] This approach is especially problematic if Utilitarianism condones greater value being awarded to the lives of a group of persons who already enjoy prosperity in contrast to the value which attaches to the lives of indigent persons.[184] That such an unjust social distribution is seen as problematic implies that there are instances in which Utilitarianism as a moral theory does not promote substantive justice.

I argue that excluding HGM as a patentable subject matter promotes access to diagnostics by most people as well as contributing to downstream research and development by permitting the dissemination of genetic information that will serve the social interests of all, promoting social justice objectives. In a South African context the majority of the population would benefit from the exclusion of HGM from patentability (in that the majority of people are unable to afford the cost of genetic tests) its exclusion serves both social justice objectives as well as Utilitarian objectives.

There is no definitive proof by which to determine that science no longer will invest time, effort and/or resources in the field of genetics if genes are considered to be non-patentable but rendering this material patentable definitively inhibits research and development and impedes access to diagnostics, then Utilitarianism might well favour the latter. If it is in the interest of the majority to exclude HGM from the scope of patentability to promote the intrinsic happiness of the greatest number of people (as I contend it does), then Utilitarianism deems such an exclusion the most appropriate and ethical action.

181 *Idem* 342.
182 *Idem* 341.
183 *Idem* 342.
184 *Ibid*.

Utilitarianism plays a substantial role in the formulation of public policy;[185] as well it "sees morality primarily in terms of the goal of promoting welfare".[186]

5.2.6 Eugenic concerns associated with genetic progress: the slippery slope

The science of genetics has made a vital contribution to medicine; it has enabled the prediction of potential disease and disorders and people to make informed health care decisions and empowered them to seek early therapeutic intervention and treatment. Genetics is the present and future of medical progress.[187] Despite its vital role, genetics comes at a societal cost. Were we to disregard the consequences of permitting the monopolisation of what is inherently human, the human genome, the ethical concerns about widening inequalities, is to suggest the probable future approach to ethical dilemmas that flow from genetic knowledge.

Decisions made now influence future responses to controversial developments as a result of breakthroughs in the field of genetics. It is a platitude to declare "knowledge is power", however in the case of genetic information it is trite that that "with great power comes great responsibility". Even though the genetic revolution is invaluable, it would be irresponsible and reckless to disregard consequences the costs of which are not inconsequential.

In the rest of this chapter I highlight some of these other concerns. The concerns I wish to address pertain to the fear that by encouraging the monopolisation of the human genome and the exploitation of human DNA we promote a skewed sense of morality that condones a contemporary form of eugenics. Genetic technology has a capacity to direct society towards moral bankruptcy and should be approached with care in order to control the consequences.

A consideration of the future can raise the spectre of extreme cases as depicted in the dystopian science fiction film *Gattaca*.[188] In this futuristic society controlled by eugenics not only is the genetic information of each individual freely accessible but children are

185 *Idem* 343.
186 *Ibid*.
187 Klug *et al* 634-661.
188 *Gattaca*, Niccol, Columbia Pictures, US (1997).

born with specifically chosen traits through genetic engineering. Those who are products of chance and are born without human genetic intervention are outcasts and viewed as inferior to those who are born from scientific interference. Genetically modified individuals have prestige whereas the "products of chance" are discriminated against. In *Gattaca*, genetically engineered individuals are valuable commercially; they have specific qualities selected for specific occupations and are designed to reduce liability, while increasing productivity and efficiency. The outcasts are there to serve the others.

In this fictional scenario of the distant future there is a suggestion of what might happen; *Gattaca* represents an extreme example of what private property rights over the genome could result in but I argue that already we are promoting genetic discrimination by the exploitation of human DNA as a commodity. Genetic discrimination has accompanied the project setting out to map the genome from the very beginning and the pace of developments in biotechnology stimulates a fear of a dystopian eugenically-driven future.[189] This threat appears plausible as a consequence of the matter that genetics historically has promoted and rationalised injustice.

The historical abuse of genetic information is behind human rights violations in the twentieth century. In the US genetics justified the sterilisation of those deemed to be carriers of unwanted or inferior traits that without evidence were declared to be genetic dispositions.[190] An ideology was presented as a benefit to all (except those with the unfavourable genetic traits) and eugenics was regarded as a legitimate scientific field that motivated the implementation of eugenic laws and policies. Mandatory sterilisation was justified by the US government as fiscally beneficial as those with undesirable genes placed an unwanted and unnecessary financial burden on the state. Stated differently, the eugenic agenda was warranted in that those with "good" genes literally should not have to pay for those with "bad" genes.[191] On a similar eugenic model the National Socialists in Germany introduced laws for forced sterilisation giving effect to their race

189 Koepsell 15.

190 Andrews 'Past as prologue: Sobering thoughts on genetic enthusiasm' 1997 *Seton Hall Law Review* 839-918, 894-896.

191 *Idem* 904.

ideology[192] These blatant examples of discriminatory practice are less common but the commodification of the human genome could promote a more subtle version.

Resnik in his paper *DNA Patents and Human Dignity* avers the commodification of human DNA through the award of patents can send us on a "slippery slope" towards moral corruption and threatens human dignity. This issue he suggests can be addressed by excluding DNA from the scope of patentability.[193] He contends that by assigning a market value to and by applying market rhetoric to a patentable invention the material or invention is then treated as a commodity.[194] It reflects that the language used to describe the human DNA sequence by those who assert patent rights over genes promotes a form of commodification.[195] It is argued that even if we recognise DNA as a chemical compound or molecule similar to others found in the body and classify them as a commodity,[196] DNA or genes warrant "special treatment" due to the intimate connection between DNA and human identity.[197]

Science understands that human physiology, psychology and behaviour (what makes a person a *person*) are products of our genetic makeup in association with our development and environment.[198] The genome contains enough genetic information to create the human body and along with environmental factors "exhibit[s] a great deal of influence over physiology and behaviour throughout a person's lifetime".[199] It is under this condition that we confer genes with symbolic significance as being intimately linked to personal identity, which is why commodification is a threat to morality. This notion is indicated by Article 1 of the UNESCO *Declaration on the Human Genome and Human Rights*, which states:[200]

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192 *Idem* 895.

193 Resnik 'DNA Patents and Human Dignity' 2001 *Journal of Law, Medicine & Ethics* 152-165.

194 *Idem* 157.

195 *Idem* 158.

196 Resnik points out that proponents of DNA and gene patents equate the DNA sequence to other molecules or body parts such as water, iron, proteins, hormones, lipids, hair and sperm. These 'body parts' are marketable and treated as a commodity by rendering it either patentable or by permitting the sale thereof (*idem* 158 & 159).

197 *Idem* 159.

198 *Ibid*.

199 *Ibid*.

200 Declaration of 1997.

> The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Commodification of a part clears the path for further commodification and exploitation of human beings,[201] in Resnik's opinion in supporting the arguments put forward by opponents of genetic and DNA patents who contend that the commodification of the human body has detrimental social and cultural consequences:[202]

> Using market language to describe the body, they would argue, can lead us to change our attitudes towards and beliefs about the body. [With such a shift] we will find market language more acceptable, which will encourage additional changes in our attitudes and beliefs. Eventually, we (the people in society) will come to view the body as a complete commodity and will be more inclined to *treat* human beings as such, which may lead to exploitation, theft, manipulation, and other abuses against human beings. The only way to stop this slide toward further commodification of human beings, one might argue, is to prohibit practices that partially commodify people, such as the patenting of human DNA…

Society already condones many forms of human body commodification, yet I contend that DNA and gene patents create circumstances different to other forms of commodification (such as using surrogacy, selling sperm, prostitution, etcetera),[203] because patents exclude everyone other than the patent holder from utilising, investigating and benefitting from material we all have. IPRs hinder the exercising of autonomy in making an informed decision about our health without the permission of the patent (or licence) holder or without paying royalties or fees.

Other forms of human commodification involve a consensual act or agreement on the part of those who participate or the commodity in question is regarded as being impersonal and removed from human identity. For example, surrogacy, the sale of sperm

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201 George & Kaushik 333.
202 Resnik 161.
203 *Ibid*.

and prostitution are forms of commodification in that the human body is being used in services rendered in exchange for money but in a sense these are consensual acts and their conduct does not result in the non-consensual commodification of other members in society. In case of the commodification of the human body by permitting the sale of something such as hair the process is impersonal and is not general.

I argue that HGM is different to such forms of commodification in that the commodification intimately and symbolically is linked to personal human identity and is given a metaphysical value. Unlike the other forms of commodification HGM not merely affects those who consent, but has the effect of extensively excluding everyone from utilising or accessing such material and information without paying royalties or fearing infringement proceedings and inhibits the exercise of autonomy. It is in this sense I argue that any form of monopolisation of genetic information associated with the human genome precipitates the act of sliding down the slippery slope.

This path already has been taken and the information taken from DNA is exploited by health care insurance providers and employers to justify discrimination based on financial logic.[204] Policy makers, insurers and employers rely on a rationale similar to that resorted to by those who historically advocated the mandatory sterilisation of individuals with undesirable traits.

The South African government has a progressive view in addressing issues of genetic discrimination and in realising the social implications of scientific advances in the field of genetics.[205] In December 2018, a panel of geneticists, bioethicists, lawyers and specialists presented a report for the Academy of Science of South Africa (ASSAf) titled *Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications*. The aim of this study was to serve as "an authoritative report" that responds to the needs of members of society.[206] The Report acknowledges that "[g]enetic information may lead

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204 Andrews 904.

205 *Ibid*. Genetic discrimination is referred to as "the situation in which persons are treated, or treat others differently because they have a specific genetic condition that causes or may increase the risk of an inherited disorder" (The report by the Academy of Science of South Africa 'Human Genetics and Genomics in South Africa: Ethical, Legal and Social Implications' November 2018, 56. Hereafter referred to as 'the Report').

206 The Preamble of the Report, 17.

to both direct and indirect forms of discrimination"[207] and that the South African Constitution prohibits discrimination. It further recognises that genetic information may lead to stigmatisation as well as "legal ramifications in the context of finance, education and employment".[208] To guard against genetic discrimination and stigmatisation the Report recommends and emphasises the following:[209]

> Increased public awareness of the legal framework protecting against unfair discrimination, and specifically protecting against unfair genetic discrimination in the context of health care, insurance, employment and education, may assist in emphasising the rights of persons not to be subjected to unfair discrimination (and stigmatisation) on the basis of genetic condition or disorder.

The Report eloquently addresses real concerns and reflects an ethical and social awareness by recognising the need to show responsibility in regulating the consequences of genetic progress. The Report presents advice and offers recommendations but the implementation resides in the hands of the legislature and policymakers. The Report lacks legal force but it reinforces an approach which declines the unethical consequences flowing from genetic advances.

The UNESCO *Universal Declaration on the Human Genome and Human Rights* recognises that genetic discrimination threatens human rights and specifically declares against genetic discrimination.[210] The UNESCO *International Declaration on Human Data* includes a non-discriminatory and non-stigmatisation clause; article 7(a) provides that "[e]very effort should be made" to guard against the infringement of human rights and human dignity through discrimination or stigmatisation based on the use of genetic information. This Declaration specifically condemns the disclosure or facilitating the accessibility of genetic data to employers and insurance providers.[211] There are

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207 The Report 56.

208 *Idem* 63.

209 *Idem* 65.

210 *No one shall be subjected to discrimination on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity* (Art 6 of the UNESCO *Universal Declaration on the Human Genome and Human Rights*, November 1997).

211 Art 14(b) of the International Declaration, 2003.

international measures taken to guard against the malevolent consequences however they have no legal force.

The ethical concerns that flow from the monopolisation of human DNA need to be addressed and the first step is to evaluate the appropriateness of monopolisation and commercialisation. Safeguarding our ethos (humanity) means an unwavering attention to what is right and wrong and serves as the foundation upon which genetic progress is built. The advances in genetics benefit all in that they promote improvements in health care and the realisation of social and economic development. But the approach needs to be cautious and aware of real concerns regarding the consequences.

That which supports the commercial exploitation of HGM and promotes rights that exclude people from access to information and resources unavoidably encourages the development of inequality and a disregard for human dignity. The exclusion of HGM and genetic information, including in its isolated and purified form, from the scope of patentability can express a wish that ethics and morality are not subordinated to biotechnological advance. It is important to act at an early stage and to safeguard against a return to the ideology of eugenics. The manner in which we address the commercialisation of the human genome will shape how we approach and regulate the social effects of biotechnological progress

6. CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Genetic patenting is a controversial issue, especially the commercialisation of genetic material for developing countries. The value associated with genetic material is apparent and applies to the commercial application of genetic information by way of diagnostic testing. Advances in genetics and the way in which gene patents apparently impede downstream research and development and inhibit access to adequate medical care calls for the scrutiny of current regulation. The validity of patents in this context can be questioned on legal as well as ethical grounds, specifically if the treatment of human genetic material as a patentable subject matter complies with the patent requirements as set out in section 25 of the Patents Act 57 of 1978.

First, discoveries are excluded specifically from the scope of the Act; the association of a function with a particular gene through recognised and well-known techniques is considered to be a discovery, and not an invention. Gene function already exists in nature prior to the unveiling of previously unknown information regarding the function of the gene. The association of a function with a specific sequence of nucleotides is the observation and understanding of a natural phenomenon and renders genes non-patentable in terms of section 25(2)(a) of the Act.

Section 25(1) of the Act requires the invention to be novel, involve an inventive step, and be capable of being applied or used in trade, industry or agriculture. Each of these patent requirements is problematic in relation to HGM. First, proponents of gene patents contend that the genes over which protection is sought are novel in that these isolated and purified genes or gene fragments do not exist in that state in nature. However, they carry pre-existing genetic information in their natural state. The genetic sequence (which is claimed to be novel) was published in 2003 with the successful mapping and sequencing of the human genome through the efforts of the Human Genome Project (HGP). The only novelty associated with the genes is the associated function, which is a non-patentable discovery.

Secondly, genes cannot be considered to be non-obvious to someone skilled in the practice as is required by the compulsory inventive step. To a skilled person determining gene functions (geneticists or scientists) through the utilisation of the published human genomic sequence and well-known laboratory techniques seems obvious. The results obtained through a process of looking cannot be deemed to involve an inventive step when there is an entire scientific field which is dedicated to the "looking" process. Existing technologies are used to observe a link between a specific sequence of nucleotides and a genetic disorder or disease, which is obvious to anyone trained in gene function associations. The ability of independent researchers to use the genetic sequence in diagnostics the moment the sequence and function of the gene is made known supports the notion that innovation is lacking.

Lastly, even though genetic material is of clear use, as in the case of diagnostics, the use and genetic functionality are the natural properties of the genes in question and not necessarily are attributable to the "inventor". Furthermore, section 25(11) of the Act clearly eliminates medical methods of treating the human or animal body through surgery, therapy or diagnosis from being capable of being used or applied in trade, industry or agriculture.

Apart from the statutory obstacles in terms of the Act that dispute the validity of genetic patents, there are constitutional arguments to be made in favour of rendering HGM non-patentable subject matter. The Constitutional Court's approach to intellectual property rights recognises that these rights are not absolute when weighed-up against conflicting non-property rights. I argue that intellectual property rights (IPRs) - as incorporeal property - enjoy a "systemically modest" status when they conflict with non-property constitutional rights. In all likelihood, non-property rights (such as dignity, equality and the right to adequate health care) will be prioritised over the property rights, and the property rights will be protected "in whatever space remains".

With reference to gene patents the value of dignity is of great importance as a constitutionally enforceable right and can be enforced as both a first-order and second-order right in relation to the accessibility of genetic diagnostics. The inaccessibility of genetic tests due to the enforcement of patent rights affects the constitutionally entrenched right to equality in terms of discrimination based on the prohibited grounds

set out in section 9(3) of the Constitution. Certain grounds mentioned in section 9(3) have a genetic linkage and historically disadvantaged groups will be marginalised by the costs to be paid the patent holder associated with life-prolonging medical diagnostic resources. Socio-economic rights (that include the right to health care services) may be promoted and give effect to dignity through the exclusion of genetic material from the scope of patentability. In determining the relation of property rights to non-property fundamental rights when they conflict, I argue that HGM should be excluded as a patentable subject matter since ownership in most instances (if not all) will result in a constitutional ruling that secures non-property fundamental rights whereas the property rights associated with genetic material will be treated as secondary.

It is argued that as well as the domestic legal position in terms of the national regulation of genetic material as a patentable subject matter the TRIPs Agreement, an international instrument to harmonise IPRs, recognises the national sovereignty of states to realise social and economic objectives within their borders. The member states themselves establish what important measures to adopt to develop the socio-economic circumstances, and "intellectual property protection can never prevail where doing so undermines other development objectives". These provisions justify the exclusion of genetic material by means of legislative and constitutional interpretations in order to promote socio-economic objectives.

The approach to genetic patents in the European Union was evaluated to see if it serves as a guide to how South Africa might approach gene patents since the South African Patents Act is modelled on the European Patents Convention. This thesis maintains the South African approach to gene patents drastically should differ from that of the European Union in the exclusion of inventions that violate morality. The European Biotechnology Directive (which regulates genetic inventions in Europe) has a narrow understanding of what is an immoral invention although the Directive specifically lists certain kinds of inventions which are considered to be contrary to *ordre public* or morality. The South African Patents Act considers an invention to be immoral (and therefore non-patentable) based on the exploitation of the invention encouraging conduct that is deemed to be immoral. In order to compare these approaches demands a consideration

of what is moral in each context. Morality depends on the beliefs and values of a specific community and an African approach to morality differs from that in Europe.

An African approach to morality suggests the embrace of communalism and relates to a tradition of sharing and therefore rejects the privatisation of matter inherent to life forms that results in the exclusion of some. An individual is valued by their contribution to the community through the collective, an integral element in *ubuntu* thought. *Ubuntu* cannot be understood in terms of a single definition, it is a broad moral theory typified by a symbiotic or interactive relationship between the individual and the community in that the community is being formed continuously, and *that* notion is valued by its ability to empower people. The survival of the individual is dependent on the survival of the group, and the humanness of an individual (central to a philosophy founded in *ubuntu*) can be diminished by the violent and exclusionary actions of others.

An African morality founded on *ubuntu* cannot condone an exclusion from life-saving medical care (such as genetic tests) for the economic benefit of a few individuals. The values associated with *ubuntu* require the promotion of the interests of the community. An African approach to morality rooted in the values of *ubuntu* rejects the practice of exclusion from something as personal as DNA and would regard an attempt to do so at the expense of the community as immoral.

Proponents of gene patents rely on the rationale behind patent systems to justify exclusive monopoly rights over HGM. They contend that granting patents is in the best interest of society by encouraging the sharing of information and is a motivation for innovation. Patents safeguard the investment of capital into genetic technologies and without gene patents research and development are discouraged. The opponents of gene patents argue that gene discovery does not require the same incentive as does the pharmaceutical industry as tests do not require expensive trial periods and largely are funded publically. The pursuit of knowledge about gene function precedes the patentability of genes and historically was driven by medical interest, clinical need and academic reputation rendering patents as an incentive unnecessary for gene discovery. I argue that HGM is unique in that perceiving it as patentable subject matter effectively undermines the purpose patents supposedly support.

Patent holders are able to dictate the applications of “their” gene by monitoring who may use the gene and the price that needs to be paid for the use of the gene. The aggressive enforcement of patent rights covering genes and mutations deter and prohibit laboratories from offering diagnostics to patients. The cases of breast and ovarian cancer, haemochromatosis, Alzheimer Disease, Canavan Disease and LQTS are examples of how gene patents made genetic testing inaccessible and compromised patient health care. Gene patents force medical practitioners to rely on less accurate techniques or tests to diagnose patients and/or fail patients from having tests due to the cost. I argue that these adverse effects of gene patents are exacerbated by the situation in developing countries where the public health system is over-burdened.

Gene patents inhibit downstream research and development indirectly affecting the right to health care. Patent holders can “block” any research on the gene, preventing other scientists from improving on the discovery of the patent holder. Financial interests associated with patents motivate scientists to delay the publication of their findings, consequently delaying progress in the medical field. Scientists through the refusal to grant user rights or because of the payment of fees are prevented from verifying the findings or claims of the patent holder, from lowering the cost of testing and increasing the quality of tests and from offering a second opinion. Any laboratory is able to perform these tests the moment the genetic sequence and gene function are made known and without having to use a product or tool devised by the patent holder.

The inaccessibility of diagnostics and the inhibition of downstream research and development directly and indirectly affect the right to access health services, which undermines the realisation of rights in terms of Article 25(1) of the Universal Declaration of Human rights, section 27 of the South African Constitution, as well as the South African National Health Act 61 of 2003.

I argue that patent rights are supported by the principles of Utilitarianism, but the unique nature of HGM renders the patenting of genes unethical according to Utilitarian principles. Weighing-up the alleged good that gene patents serve against the tangible bad consequences in a South African context, I argue that the greatest good for the greatest number of people would exclude genes from patentability. In a South African

context the exclusion of genetic material as a patentable subject matter serves social justice as well as utilitarian objectives.

Lastly, I argue that favouring the patentability of HGM advances a eugenic agenda and sets the tone for approaching other ethical concerns raised by progress in genetic research which creates a threat to public morality. Genetic discrimination and eugenic practices that arise from the commodification of DNA are a threat to society's moral foundations. It is essential to respond early on so as not to be led down a path of moral decay when we address the problematic consequences that accompany the advances made in genetics.

6.2 Recommendations

There is no simple solution to the dilemma these issues raise. The notion of using private rights to protect innovators and using patents as an incentive to produce products to the advantage of humankind creates benefits for society.[1] Patents serve to incentivise the development of genetic technologies and to evolve research in genetics to benefit the public, but by the commercialisation of HGM the patent holders prioritise their financial interests above the welfare interests of the public.

Presently we trade the common good and public health for the *hope* that companies will (*might*) make genetic and medical breakthroughs that will enable them to develop treatments that save lives. The trade-off can be summarised in one sentence; expensive tests and treatments now or no tests and treatments later.

It has been suggested that the problems associated with the patentability of gene-related technologies can be addressed or corrected by changing the laws that regulate or permit the granting of patents over HGM.[2] Carvalho suggests that these changes fall into three main categories, two of which are:[3]

(a) those that would exclude genes from patentability regardless of their potentially inventive nature;

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1 Sideri 155.
2 Carvalho 706.
3 *Ibid*.

(b) those that accept their patentability but impose limitations or exceptions to rights conferred; …[4]

6.2.1 Exclusions of genes as a patentable subject matter

The obvious solution to the problems relating to human genetic patents is the complete exclusion of gene-related technologies from the scope of patentability, despite the inventiveness underlying the scientific discovery or technology. This exclusion of genetic material from the scope of patentability purports to facilitate research in the field of genetics.[5] This position has been adopted by countries such as Egypt where legislation asserts that genetic material is regarded as non-patentable relying on the right to so do.[6] Other countries, such as Brazil, exclude HGM from patentability by deeming genetic technologies not to be an invention and therefore not eligible for patent protection.[7]

Carvalho indicates the two main arguments put forward for the exclusion of genetic material from the scope of patentability: that it offends morality or that genetic patents are inconvenient.[8] Arguments in favour of the exclusion of genetic material from the scope of patentability based on morality have been unsuccessful in Europe.[9] I have argued in this thesis that a South African approach to the exclusion of genetic material from the scope of patentability based on morality will have positive results.

Examining the constitutional conflicts that need be adjudicated if HGM is regarded as patentable, the promotion and protection of human dignity and the promotion of values

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4 Carvalho suggest a third change to accommodate the effects of gene patents that reads "those that accept patentability of genes without modifying the standards of protection, but adopt a different approach to the conditions of patentability, in particular, with regard to utility". This proposal will not be considered as an appropriate alternative to the exclusion of gene patents. This proposed alternative is based on the patent model followed by the US, in terms of which discoveries are patentable if they have utility. Since the US model is excluded from consideration for the purposes of this study, this proposal is not be included as a recommendation.

5 *Ibid*.

6 *Idem* 707. Art 2(5) of Law No 82/02 specifically excludes the following material from the scope of patentability: "organs, tissues, live cells, natural biological substances nuclear acid and genome".

7 *Idem* 708.

8 *Ibid*. Inconvenience refers to the inhibition of downstream scientific research and development.

9 *Idem* 709.

that advance socio-economic rights are elevated above the advancement of IPRs. The values upon which such an interpretation is based are drawn from a reflection on an African morality grounded in *ubuntu*. In a South African context the exploitation of genetic "inventions" and technologies through the commodification of HGM encourages immoral behaviour as such exploitation promotes disregard for the community and their welfare; an approach contrary to a moral theory grounded in *ubuntu*. If it were to deem HGM a non-patentable subject matter, the legislature would ensure the avoidance of constitutional conflict that unavoidably is the consequence of the commodification of genes through patents. Egypt and Brazil pre-empt the situation in which gene patents violate fundamental non-property rights and so doing assist in the promotion and realisation of socio-economic rights. By specifically excluding genes from being a patentable subject matter, the South African legislature will ensure that exploiting genetic technologies will not encourage behaviour that offends morality that is prohibited by section 25(4)(a) of the South African Patents Act and will set the tone for addressing future developments.

I argue that the exclusion of genetic material from patentability based on "inconvenience" can be linked to argument based on morality or ethics. The argument asserts that a limitation of scientific research and development which has the capability to ensure advancements in the medical field (to the benefit of society) is contrary to the values of *ubuntu* as well as to the theory of Utilitarianism. Taking into consideration the alleged implications of the effects genetic patents have on downstream research and access to quality health care services, in my opinion it is inappropriate and unethical to wait for empirical data to substantively illustrate and support the argument that genetic patents have a definite negative effect on research and development and health care and warrants policy-driven intervention before the effects are realised.

Genetics advances have solved many medical problems. The development of genetic diagnostic testing and gene therapies saved countless lives, however that is not the full picture. The exclusion of HGM from patent eligibility will not end biotechnological advances and does not prevent inventions associated with genetics or used in diagnostics or therapies or analytical methods from being patented.

In order to advance the public interest while continuing to give an incentive for innovation in the field of genetics It is suggested the patent holder has a monopoly over the product dependent on what the gene is being used for and who is using it. Public institutions will be given the right to use the product free of charge while profit-based entities pay royalties the amount of which will be determined by the purpose of use.[10]

In conclusion, this thesis proposes that most appropriate and best approach in dealing with the consequences and implications that flow from the commodification of HGM is to exclude genes from patentability and amend the South African Patents Act to reflect this proposal.

6.2.2 Imposition of limitations or exceptions to the rights conferred to patent or exclusive licence holders

The complete exclusion of HGM from the scope of patentability might be too drastic a measure despite some jurisdictions already supporting exclusion.[11] The second proposed solution to address the problem is that there should be exceptions to monopoly rights associated with gene-related technologies.[12] This approach acknowledges the "inconvenience" and the implications of gene patents, but permits granting patent rights over HGM based on the assumption that they are a "necessary evil" in order to incentivise the advancement and development of genetic technologies.[13] The rationale holds that there is a reduction in the inconvenience that results from gene patents without discouraging biotechnological innovation and investment.[14]

The limitation of rights conferred by gene patents include research exemptions (in terms of which the non-commercial use of patented genes will not result in patent infringements) and liability exemptions (in terms of which medical practitioners will be

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10 Palombi "TRIPs, Bilaterism and Patents: How they are Failing Both the Developed and the Developing World and What To do About it" 2007 *Journal in Communications, Information, and Innovation in Health* 71-81.

11 *Carvalho* 703. This is based on jurisdictions regarding (albeit in broad terms) genetic material as scientific discoveries, excluding such material and advancements in the field of genetics from the scope of patentability.

12 *Ibid*.

13 *Ibid*.

14 *Idem* 713.

relieved of patent infringement liability in the use of genetic tests or diagnostics).[15] This goal can be realised by granting broad or compulsory licences in terms of a licensing agreement that will not ”limit access through excessive royalties and other unreasonable terms”.[16]

If the exclusion of genetic material from patentability is not regarded as a viable option for South Africa, adopting regulations that exempt legal practitioners and public health facilities/institutions from liability as a result of providing the public with diagnostics or when conducting research is a better alternative. The great dependence on public health resources by the majority of South Africans and the need to support the realisation of fundamental socio-economic rights necessitates limiting the rights conferred by patents.

This proposal to limit and create exceptions to the rights conferred by gene patents poses problems of its own. The administrative burden of regulating the non-commercial use and the medical use of the exceptions would be onerous and most if not all use of the patented genes would be exempted from patent infringement effectively rendering the patent redundant.

The proposal to grant compulsory licences to all non-commercial and medical users of gene patents is problematic as well. The award of compulsory licences is to be considered on the merits of the individual case.[17] The South African Patents Act provides for the award of compulsory licences on a dependent patent and in the case of abuse.[18] However, granting a compulsory licence involves a judicial process in which the seeker of the licence is required to approach the court for an order to grant the licence.[19] The Commissioner of Patents decides the matter and determines through the submission of evidence whether a compulsory licence in favour of the applicant is to be granted.[20]

The Companies and Intellectual Property Commission in 2017 reported that only five applications for the grant of compulsory licences had been decided by the courts, all of

15 *Idem* 711.
16 *Idem* 712.
17 *Idem* 716.
18 S 55 & 56 of Act 57 of 1978.
19 Companies and Intellectual Property Commission ‘Submission by South Africa: Exceptions and Limitations’ 2017, 5.
20 *Idem* 6.

which were unsuccessful.[21] In a South African context the application for compulsory licences for patented genes entails lengthy litigation. This approach places a great burden on the courts which are to decide on such matters and medical practitioners and public health institutions will be required to pay litigation fees to obtain the compulsory licences. Many South Africans cannot afford the costs associated with diagnostics – let alone the cost of bringing an application.

The imposition of limitations and exceptions to the rights conferred by gene patents does not address the issues in terms of the inhibition of research and development and the inaccessibility of medical care resources which stem from the grant of gene patents. Consequently, the complete exclusion of genetic material from patentability is the preferred option.

6.2.3 Shorter protection periods

An ideal solution is to find the middle ground between the promotion of the private rights of the patent holder and the public's right to health. To strike a balance between the two could mean continuing to grant patent rights but to a limited extent that promotes accessibility to adequate health care. In order to address the high social costs associated with gene patents and still allow the grant of patents over HGM, the South African legislature could elect to shorten the period for which genetic patents are granted. This approach will include granting full and extensive monopoly rights over the use of the patented genes for a period less than 20 years in order to encourage the earlier entry of the invention into the public domain and to enable the earlier unrestricted use of the patented gene.

This approach already has been adopted by some developing countries to meet the health care needs of citizens through the rapid introduction of generic pharmaceuticals.[22] However, the implementation of a protection period less than twenty years is problematic as the TRIPs Agreement (South Africa is a signatory) specifically requires all member

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21 *Idem* 9.

22 Andrews 75 & 76. Andrews refers to Thailand as an example of a state in which a shorter protection period of three years has been implemented to encourage the earlier introduction of generic drugs in order to meet the health care needs of the public.

states to provide a protection period of no less than twenty years.[23] The period of twenty years covers health care-related technologies[24] consequently any alternative time period applied to genetic-related technologies is in direct violation of the Agreement.

If the protection period were shortened what would be an appropriate length of time. Based on the high social costs associated with gene patents and South Africa's socio-economic circumstances, I argue that a short period (no more than five years from the filing date) is justified.

Since a genetic diagnostic test can be performed in any laboratory the moment the genetic sequence associated with a specific function (associated with a disease) is made public, a limited protection period appears arbitrary. Taking into consideration the values of the South African Constitution and its commitment to the realisation of socio-economic rights, I argue that *any* protection period granting the patent holder the right to exclude others from using "their" gene, regardless of how short, undermines constitutional objectives. The limitation of the protection period could be considered a viable option in an effort to balance monopoly rights and socio-economic rights (the TRIPs Agreement is an obstacle), but I argue that the most appropriate recommendation for addressing the social costs of gene patents is to exclude genes from patentability.

In this thesis I argue that in light of the unique character of human genes and the consequences that flow from the privatisation of genes through institutional structures this material universally should be excluded from patentability and in particular in South Africa. In accommodating a legislative interpretation that encourages the monopolisation of the human genome (nature) and enables the marginalisation of parties seeking genetic information in order to make informed health care decisions, in my opinion means we are complicit in supporting a morally corrupt institution that neglects the needs of vulnerable members of society. Ethics, morals and values should guide decisions about technological developments and advances that lead to unknown futures. To conclude, although I oppose many sentiments expressed by the "father of evolution",[25] Charles

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23 Art 33 of the TRIPs Agreement reads as follow: "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."

24 Andrews 76.

25 I wish to clarify this statement. Darwin's cousin, Sir Francis Galton (considered by some

Darwin, I wish to leave the reader with his following words that I believe hold true: “If the misery of the poor be caused not by the laws of nature, but rather by our institutions, great is our sin”.[26]

to be the father of eugenics), based his justification and rationale for the eugenics movement on Darwin’s ideas. Eugenics led to many historic atrocities in the name of “cleansing the gene pool”. Darwin himself had some contentious thoughts on eugenics; in his work titled “The Descent of Man” (1871) he opined that some races (those of European and/or Caucasian descent) were superior to others (Africans and Aboriginal Australians). He suggested that the procreation of “savages” will adversely affect the human race. Darwin was opposed to practices of segregation, sterilisation and slavery. I feel it necessary to distance myself from any notion or sentiment associated with eugenic views. However, the thought expressed in the quote accurately portrays the injustice and unethical nature of institutions that exacerbate suffering and misfortune. Despite my disagreement with some opinions expressed by Darwin, I acknowledge the exactitude of this statement.
(https://evolutionnews.org/2005/12/suppressing_the_truth_about_da/ accessed 4 October 2019; http://eugenicsarchive.ca/discover/tree/523377f35c2ec50000000050 accessed 4 October).

[26] Charles Darwin *The Voyage of the Beagle* (1909-1914) Chapter XXI; https://www.bartleby.com/29/21.html (accessed 4 October 2019).

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