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Owning Life – IPR in Biomaterials

The Legal Challenge to the Patent Eligibility of Human DNA

Master's Thesis in Commercial and Tax Law

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Abstract

The scientific and technological progresses in biotechnology have made knowledge an even greater key competitive advantage for corporations and governments. Patents are generally considered to be advantageous instruments promoting innovation, however, it has been established that exclusive rights in the genetics marketplace, where information is assessed to be an intangible good could have a substantial impact on the usage, control and distribution of genetic materials. The purpose of this thesis is to investigate the legal challenge to the patent eligibility of human DNA.

The patent system established in the European Union (EU) since the 1970's has been profoundly influenced by practices and policies developed by the United States (US), although with a few central differences. The current approach adopted by the two world leading competitors in the field of biotechnology, the US and the EU, is that an innovation, in order to be eligible for patent protection, must meet three fundamental substantive requisites: (i) it must be new, (ii) it must involve an inventive step (the non-obviousness criteria in the US) and (iii) be capable of industrial application (the utility criteria in the US). As it is generally accepted that exploiting something that before now existed in nature is a discovery and consequently is not patent eligible subject matter, the modern system of granting patents on genetic resources appears to challenge one of the most central principles of patent law: the novelty requirement. The legal requirements needed to be satisfied in order for an invention to be considered new are stated in Article 54 of the European Patent Convention Furthermore, according to Article 52 (2)(a) of the European Patent Convention, discoveries are excluded from patentability, however, as the achievements of genetic engineering and gene sequencing have extended the range of potentially patentable subject matter, the demarcation between invention and discovery has become progressively problematic to determine. Based on the investigation, the author has concluded that the legal challenge is originated from incorrect application of the law.

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1 Introduction

1.1 Background

The scientific and technological progresses in biotechnology have made knowledge an even greater key competitive advantage for corporations and states.[1] It has been established that biotechnology as a research area comprises "any technique that uses living organisms or substances from those organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses"[2]. Since the 1970's[3] biotechnology, more specifically the evolution of the science of genetics has increasingly advanced into modern practices developing new approaches to observe, foresee and treat human disease raising numerous ethical, social, legal and regulatory issues.[4] As human genetic resources are progressively assessed to be commodities for commercial use, it has been argued that the significance of human DNA and genes ought not to be delimited to its financial importance since the value of a genetic resource is essentially regulated by its informational content. Patents are generally considered to be advantageous instruments promoting innovation, however, it has been established that exclusive rights in the genetics marketplace, where information is assessed to be an intangible good could have a substantial impact on the usage, control and distribution of genetic materials. [5] The patent system established in the European Union (EU) since the 1970's has been profoundly influenced by practices and policies developed by the United States (US), although with a few central differences.[6] In June 2013 the US Supreme Court delivered its, much anticipated, groundbreaking judgment answering the question: is human DNA patentable?[7] The judgment, having significant impact on the legal certainty and predictability for numerous interest groups in society,

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[1] Tony Howard, *"The legal Framework Surrounding Patents for Living Materials*" in Johanna Gibson (ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008) p.9.

[2] U.S. Congress, Office of Technology Assessment, *Biotechnology in a Global Economy, OTA-BA-494* (Washington, DC: U.S. Government Printing Office, October 1991) p.5.

[3] Ibid, p.4.

[4] Nicola Lucchi, *Governing Control over Human Genetic Resources: Promises and Risks,* 2 The European Journal of Risk Regulation, (2013), p.245.

[5] Ibid, p.246.

[6] Graham Dutfield, Uma Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), p. 301, Nicola Lucchi, *"Issues and Rights in DNA-based Inventions"* in Bin R., et al. *"Biotech Innovations and Fundamental Rights"* (Springer), 2012, p.100.

[7] In Association for Molecular Pathology v. Myriad Genetics,Inc., 132 S. Ct. 1794, 182 L. Ed. 2d 613, 2012 U.S. LEXIS 2356, 80U.S.L.W. 3545 (U.S. 2012).

raised the question of where to draw the line between patentable and non-patentable biotechnological innovations.

1.2 Purpose

The purpose of this thesis is to investigate the legal challenge to the patent eligibility of human DNA.

1.3 Delimitation

Due to the limited scope of this thesis, it will consequently not cover other aspects of the patenting system deemed to be irrelevant in response to the purpose stated above. The analysis will be delimited to the US and the EU jurisdictions. The study will not cover the patent eligibility of other biological materials, except where relevant references have been deemed necessary for the purpose of this analysis. Other practices, than those applied by the US Patent and Trademark Office (USPTO) and the European Patent Office (EPO) will not be considered. The thesis is furthermore delimited to the applicable statutory limits providing the basic and general requirements that must be satisfied in order to obtain a patent, in the US and the EU respectively.

1.4 Method and material

In order to properly treat the sources of law relevant to the study, the thesis is based on a legal dogmatic approach. This means that statutes, legal practices and doctrine are examined, in that order. As the primary source of law is statutes, the thesis will be based on the regulations provided in Article 27 of the TRIPs agreement, U.S.C Patent Act § 101 and Article 52 of the European Patent Convention. The effectiveness of a well-motivated statute is demonstrated by its application in practice and thus, established legal practice is considered in order to understand the practical application and interpretation of relevant statutes in the study. Doctrine is used as a complement in so far as the interpretation of superior sources of law is difficult. Furthermore, doctrine is used in order to account for different views on the regulatory framework.

1.5 Outline

Chapter 1 The thesis is initiated with the background to the chosen issue under consideration. The chapter also includes the purpose of this study with related demarcations as well as the method applied and the materials used when executing this analysis.

Chapter 2 This chapter discloses a presentation on the creation of the science of genetics as well as the system of patents for innovations. The chapter also provides a comprehensive presentation on what constitutes genetic information. The chapter is concluded with a presentation of the opportunities and challenges resulting from these advancements.

Chapter 3 This chapter initially relates to judicially-created principles and regulatory framework for exclusive property rights on biological materials. The chapter also discloses an examination of potential consequences interrelated to the patent eligibility of genetic resources. The chapter is concluded with an analysis in which the issues considered to constitute the foundation to the legal challenge to the patent eligibility of biological materials are highlighted.

Chapter 4 This chapter discloses a comprehensive presentation of the analysis established by the courts in a central case in which the legitimacy of patent eligibility of human DNA was challenged.

Chapter 5 In the fifth and last chapter, I will summarize the study in order to respond to the purpose of the thesis.

2 The Evolution of Bioscience and Biotechnology

2.1 The Science of Genetics and Patents for Innovations

When the Austrian monk Gregor Mendel (1822-1884) in the 18th century performed breeding experiments with plants with different traits and found patterns of inheritance across generations, his discoveries laid the foundation to what we today refer to as the science of genetics. Mendel's work suggested that, at that time still unknown, elements today known as genes are transferred from one generation to another. His work indicated that when these elements were combined, different characters were produced and some of these were dominant while others were recessive, today referred to as traits or phenotypes. As Mendel's work was ignored by scientists of his time, his discoveries were not respected until the early 19th century when scientists established a new discipline based on Mendel's efforts known as Mendelian genetics. This new discipline became assimilated into the recognized sciences during the 1900's as scientists desired to understand the functioning of inheritance in cells, and the correlation between genetics and its progression. As scientists applied Mendel's doctrine to different species they found exclusions to Mendel's genetics, such as codominance which challenged Mendel's discoveries that genes are either dominant or recessive and gene linkage which contradicted the principle of random assortment. As the research advanced, scientists during 1900's-1920's found that structures in the cell nucleus, chromosomes, are carriers of genetic information and they discovered how chromosomes line up and divide. By 1930's, scientists had identified and clarified a large number of cell structures, their functions and mechanisms of development. However, they still had no knowledge of how chromosomes divide and communicate genetic information. Also, the biologists still needed to understand how the genetic information in chromosomes affected the activities of cells, tissues and entire organisms.[8] In 1973, one of the first major events in the commercialization of biotechnology occurred when the first gene was successfully cloned.[9]

[8] David B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.13.

[9] U.S. Congress, Office of Technology Assessment, *Biotechnology in a Global Economy, OTA-BA-494* (Washington, DC: U.S. Government Printing Office, October 1991) pp.4-7.

It has been established that patents for inventions have their origins in Renaissance Italy when the Republic of Venice passed a patent law in 1474. The principal purpose of the legislative act was to attract men with the incentive of a ten-year period of exclusive property rights for their works and devices, and thus, by preventing others from exploiting the invention and taking the inventor's honor away, it was believed that more men would then apply their genius, would discover, and would build devices of great utility to our commonwealth.[10] It has been held that the prosperous emergence of the US pharmaceutical industry after World War I was much due to the exceptional need for antibiotics and with successful lobbying, the industry's achievements were demonstrated as supportive language was incorporated in the 1952 Patent Act ensuring that antibiotics discovered by methods of systematic screening would be patented. In order to be granted a patent the inventor had to demonstrate in the application that the invention satisfied the legal requisites. In today's modern era, a patent is often exploited commercially although this is not compulsory as it is possible to own a patent but not to use or enforce it. Numerous patents are instead licensed by the owner to other parties for commercial use. It is a common misapprehension that owning a patent entitles the inventor to exploit their invention. Exploiting the invention is dependent on whether other inventors have been granted patents that overlap with the subject matter of the invention, and will be subject to other laws, such as those concerning health and safety. The Paris convention for the protection of industrial property, signed in 1883 in Paris, was the first directive implemented to secure intellectual property rights on biotechnological inventions. The treaty did not explicitly exclude living material or material derived from living material which resulted in patents granted for isolated biomaterials, including Louis Pasteur's yeast invention which was granted a patent in 1873.[11]

In today's modern system of patents, the most comprehensive internationally recognized legal framework on intellectual property is the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). Administered by the World Trade Organization (WTO), the treaty sets down the minimum standards for protection, domestic enforcement and

[10] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), p. 106.

[11] Johanna Gibson (Ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008), pp.9-11.

dispute settlement.[12] A key provision as to the patentability of inventions in the agreement is Article 27 which states that an invention is eligible for patent if the invention is (i) new, (ii) involve an inventive step and (iii) is capable of industrial application. In the US, patents are today governed by the Patent Act Law under Title 35 of the United States Code (U.S.C.) where the patentability of inventions is defined under §§ 100-105. More specifically, § 101 of Title 35 U.S.C. sets out the subject matter eligible for patent, § 102 defines novelty and loss of right to patent and § 103 sets out what constitutes non-obvious subject matter. In order to obtain protection under U.S law the applicant must submit a patent application to the USPTO, where it will be reviewed by a qualified examiner to determine if the invention is eligible patentable subject matter. As the 1970's patent law in Europe was principally developed by the European Patent Convention (EPC or the Convention), which has been amended and the current version is EPC 2000,[13] and patent applications were reviewed and granted by the EPO, this was considered an important toward harmonization of the patenting system. A central provision in the Convention for patentable subject matter is Article 52 which establishes that an invention will be granted patent protection if (i) it is new, (ii) involve an inventive step and (iii) is capable of industrial application. When the TRIPs agreement was developed, it is somewhat expected that, it was based on the wordings by previous legislation, such as the EPC. Nevertheless, the provision in Article 52 states a fundamental difference between the two legal frameworks as Article 52(2) explicitly excludes discoveries from patent protection. However, as the biotechnology industry gained more market influence and dominance, it was brought to attention that the established patent laws were deemed not suitable to be applied on biotechnological inventions and in an attempt to achieve further harmonization, the EU member states adopted the European Directive on the Legal Protection of Biotechnological Inventions[14](the Biotech Directive) in 1998. The Biotech Directive was has also incorporated into the EPC, and contracting states were directed to implement the Biotech Directive in national legislation by July 2000[15]. The Biotech Directive confirmed that biotechnological inventions, including

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[12] Agreement on Trade Related Aspects of Intellectual Property Rights available at http://www.wipo.int/wipolex/en/other_treaties/details.jsp?group_id=22&treaty_id=231

[13] Trevor Cook, "*EU Intellectual Property Law*", (Oxford University, 2012), under 7.01, p.528.

[14] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213 , 30/07/1998 P. 0013 – 0021.

[15] T. Cook, *EU Intellectual Property Law*, (Oxford University, 2012), under 7.10, p.536.

DNA and genetic sequences, may be eligible for patent protection.[16] Unlike in the US patent system, the Biotech Directive also imposes a prohibition for the patentability of immoral inventions. In Article 6, inventions which are contrary to ordre public or morality are not patent eligible. This is a key difference between the two jurisdictions in the field of biotechnology which indicates that the patent law in the EU explicitly requires decision-makers to consider moral standards as part of the process of deciding whether or not a patent should be granted. In contrast, however, the Fifth Amendment of the US Constitution does state that private property is not "to be taken for public use, without just compensation"[17], also referred to as the Takings Clause, which has been held playing a central role in regard to the judicial doctrine on exclusive property rights associated with human biological materials.[18] It has been argued for quite some time that patent law is a forum which should remain neutral vis-á-vis ethical issues;[19] however it has also been held that patent law and ethics are connected as the establishment, procedures and interpretation of the patent system concerns a public ethic of community values and economic and social interests.[20]

2.2 DNA, Genetic Sequences and Genetic Information

As the science of genetics emerged and deeper knowledge regarding deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) was established, scientists within the field of molecular biology attempted to further understand the biochemical foundation of genetics and inheritance. During the 1940's and early 1950's biologists acknowledged that chromosomes contained DNA and proteins, however they still did not comprehend how chromosomes transmit genetic information, neither did they distinguish whether genetic information is contained in DNA, RNA, or proteins. A major breakthrough in DNA research was made public in 1953 when James Watson and Francis Crick established a model of the structure of DNA providing the fundamental understanding to how cells encode and transmit genetic information. Watson and Crick revealed that DNA is a long macromolecule comprising

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[16] J. Gibson (Ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008) pp.9-10.

[17] US Constitution Amendment V.

[18] Samantak Ghosh, *"The Taking of Human Biological Products",* 102 California Law Review 511 (2014), p.516.

[19] Enrico Bonadio, *"Biotech patents and morality after Brüstle",* 34 European Intellectual Property Review (2012), p.433 et sqq.

[20] Peter Drahos, *"Biotechnology, Patents and Morality"*, 21 (9) European Intellectual Property Review, (1999), pp.441-449.

of two complementary strands composed of four deoxyribonucleotide pairs (nucleotides). The four nucleotides came to be known as deoxyguanosine monophosphate (G), deoxycytidine monophosphate (C), deoxyadenosine monophosphate (A) and thymidine monophosphate (T). These nucleotide bases form altered pairs as A pairs with T and G pairs with C. With the exception of RNA viruses, virtually all organisms encode their genetic information in DNA, forming the organism's genome. As DNA is predominantly contained in chromosomes, although also found in small amounts in mitochondria (MtDNA), these chromosomes are composed of proteins intertwined with strands of DNA. These long strands of DNA are found in the cell nucleus, becoming tightly coiled after condensing and prior to cell division. In the course of cell division, DNA replicates itself when DNA-polymerase, an enzyme, causes the complementary strands to separate and bond with other nucleotides present in the cytoplasm to form the absent, corresponding strands. Once the DNA has replicated the cell splits in half and each new cell (daughter cell) obtains a copy of the entire genome. Whereas most genetic information is conveyed from one generation to the next without any alterations, mutations in the DNA often occur. These mutations are natural and not considered always harmful but indeed fundamental as evolution by natural selection cannot happen without them. Mutations occur for various reasons; some are caused from exposure to chemicals or radiation, some are the result from errors in DNA replication while others are caused by diseases. They can also be artificially produced through genetic engineering. Mutations are characterized by four different sorts: deletions, which include the removal of one or more base-pairs; insertions, which involve the addition of one or more base-pairs; substitution, concerns the replacement of one or more base-pairs by other base-pairs; and transposition, referring to a change in the order of one or more base-pairs. Although all cells have DNA repair mechanisms whose function is to locate and correct mutations, mutations constitute a fact of life. Even a minor mutation, for instance the insertion of one base pair, resulting in altering the frame in the DNA can have various effects due to the DNA frame being the sequence of amino acids that encodes a protein.[21]

The human genome comprises approximately three billion base-pairs. It is established that there are about 30.000-40.000 different genes in the human genome enclosed in 23 pairs of

[21] D. B. Resnik, *Owning the genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.15-16.

chromosomes, which comprise 22 pairs of non-sex chromosomes and one pair of sex chromosome, the X chromosome and the Y chromosome. However, as the estimates of the number of genes differ, it has been documented that approximately 20% of human genes are protected by patents.[22] A typical gene consists of approximately 3.000 base pairs, although some genes have over 2 million base-pairs. An average chromosome comprises 150.000 base-pairs. As human beings share around 99.9 percent of their DNA, there is genetic variation in only 0.1 percent of human DNA. Approximately only 2 percent of the DNA codes for proteins and the regions noncoding regions are referred to as "junk" DNA. These noncoding regions consist of repetitive sequences of DNA and although they do not have biological functions, junk DNA sequences are useful for DNA fingerprinting and when studying genetic diversity by identifying and analyzing shorter sequences of DNA or gene fragments known as single nucleotide polymorphisms (SNPs).[23]

2.3 Opportunities and Challenges in Genetic Engineering

In 1990, after a series of discussions, the U.S Department of Energy (DOE) established the Human Genome Project (HGP) with the aim of mapping and sequencing the entire human genome. This enormous initiative was opposed by many scientists and politicians for various reasons; however the project was finally completed in February 2001 with both public and private funding. The successful accomplishments of the HGP resulted in an improved understanding of the role of genetics in human health and disease as genetic factors play a fundamental role in numerous human diseases. Approximately 5.000 mutations are known to cause genetic diseases; this knowledge strengthens the understanding that a person will develop a certain disease if she has the genotype for it. For example, the Huntington's disease gene causes this disease since a person with one copy of this gene will most certainly develop the disease. If it is assumed that a genetic disease is a condition, then approximately 10 percent of the human population has a genetic disease and each person is carrying around five recessive genes being potential cause to a disease. A numerous amount different of genes may predispose people to disease or increase the risk of developing a disease. For instance, BRCA1 and BRCA2 mutations predispose women to develop breast cancer. It has been established that women with these mutations have an increased risk of between

[22] Eileen M. Kane, *Patenting Genes and Genetic Methods: What's at stake?,* 6 Journal of Business and Technology Law 1 2011.

[23] D. B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.17.

40-85 percent of developing the disease compared to the women who do not have this mutation.[24] It is estimated that 60 percent of the human population has diseases with a substantial genetic influence; however, many of the diseases that have a genetic impact are known to also have many other causes.[25] For example, deafness can result from damage to the inner ear caused from diseases or injuries but it can also result from genetic mutations. Most of the vital medical applications of genetic research is achieved through a better understanding of proteins, as genes contain information for producing proteins and proteins control numerous significant cell structures and functions. In any metabolic process, there could be diverse types of proteins involved as basic structures, hormones or enzymes and in order to affect this process it is possible to develop drugs targeting different biochemical trails or reactions. Based on the metabolic process of a disease, it is possible to develop medicines treating the disease by developing a deeper understanding of the proteins involved in the disease. For instance, by using genetic information it is possible to develop medicines to block the formation of blood vessels that supply blood to cancer tumors.[26]

Genes and genetic information do not only have scientific value but also therapeutic and economic value as they are vital to medicine discovery and development.[27] It may also be possible to use genetic information in order to better comprehend how individuals respond in different ways to the same medicines. Researchers and pharmaceutical companies may possibly be able to use genetic information to design medicines, develop treatment combinations or recommend dosages tailored to specific genotypes. In addition to its impact on medicine design and development, genetics has already had substantial application in genetic testing. Scientists have developed tests for varied genetic conditions including breast cancer, heart disease, Huntington's disease and Alzheimer's disease.[28] Information from genetic testing can be useful to prospective parents or adults who want to use the information to prevent diseases or make life plans. For instance, if a woman tests positive for

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[24] E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics Medicine S39-S70 (2010).

[25] Collins F. S, McKusick V. A.*,"Implications of the Human Genome Project for medical science"* 285 Journal of The American Medical Association (2001) pp.540-544.

[26] D. B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.23.

[27] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), pp.303 et sqq.

[28] D. B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.25.

BRCA1 or BRCA2 mutations, she then might decide to take the medicine tamoxofin to lower her chances of developing breast cancer, she could also make certain changes to her diet or she might decide to have a prophylactic mastectomy.[29]

As progress is made in DNA chip technology, it is now possible to test for thousands of different genes. A DNA chip comprises thousands of different strands of single-nucleotide DNAs referred to as DNA probes. These DNA probes can bind with their mirror image strands in the test sample. DNA chips can today test for up to 400.000 unique DNA strands. The information from DNA chips can also be used to examine patterns of SNP's and to analyze gene expressions in tumors and diseased tissues. Developments in genetic testing raise many significant concerns regarding the confidentiality of genetic information and genetic discrimination. As the field of gene therapy is advancing, it may be possible to treat numerous diseases by replacing defective genes, relocating normal genes into the body or by transferring genes to specific targets to trigger immune responses using gene transfer techniques. Genetics have many possible medical applications which still have not been clinically tested, however genetic information may one day have a profound significance in medicine, such as stem cell therapy, therapeutic cloning and organ and tissue engineering as it enables scientists to alter, develop and design cell lines, tissues and organs with specific genetic characteristics.[30] Even though DNA replication and protein synthesis are natural processes, molecular biologists are able to manipulate these processes to reproduce DNA and proteins. Contemporary cloning techniques take advantage of these natural processes. Initially, scientists process a cell with chemical and mechanical practices in order to extract its DNA. Then enzymes are used to break down the DNA into its component parts. When the DNA has been chopped down, scientists are able use to use chemical and electrical processes to sort the DNA into fragments of different lengths. In addition to using the natural processes to clone DNA sequences, they can also be used to modify those sequences.[31] Once a DNA sequence has been extracted from a cell, scientists can treat the sequence with enzymes that cause alterations in the DNA, with techniques of deletion, addition, re-

[29] Ibid.

[30] Ibid, p.26.

[31] Ibid, p.27.

placement, or transposition of DNA sequences.[32] Successively, sequences can then be cloned, isolated, purified or transferred. As a result, it is possible for scientists to produce DNA sequences different from those found in nature. When measuring the degree of similarity between two macromolecules scientists refer to the percent homology: sequences that are 100 percent homologous are identical. The concept of homology is also applied to the correlation between a DNA fragment and a larger sequence. It is possible to use certain significant DNA fragments, known as expressed sequence tags (ESTs) in order to locate a sequence that codes for a protein.[33]

One of the earliest applications of genetic engineering was to use bacteria in order to produce human hormones, such as growth hormone.[34] Scientists are able to design bacteria that produce human growth hormone by taking a human cell, extracting its DNA, finding the genes that code for the hormone, then inserting that sequence in a vector allowing the vector to transfer the DNA to the bacteria which expresses the gene as human growth hormone. Gene transfer techniques can also be applied to transfer genes into livestock and crops for medical and agricultural purposes. It is assumed that one day numerous different animals will be used as medicine factories. Additional potential application of recombinant DNA (rDNA) is to transfer human genes into pigs to enable them to serve as organ donors for humans as pigs are anatomically similar to humans. However, there are several current obstacles to transplantation across species (xenotransplantation) including diseases and tissue rejection. Scientists have also applied genetic engineering to develop animals for use in research. In the 1980's, Harvard University together with DuPont developed a genetically engineered mouse designed to grow specific forms of cancer.[35] The scientists behind the development of the mouse, known as an oncomouse, created it with a predisposition to develop certain types of cancer which consequently provided the researchers with beneficial animal model for cancer treatments[36], the oncomouse saga will be further developed in

[32] Ibid, p.28.

[33] Ibid.

[34] Ibid, p.29.

[35] World Intellectual Proptery Organization Magazine *"Bioethics and Patent Law: The Case of the Oncomouse"* (2006), available at http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html.

[36] Kevles, D., A. Berkowitz, *"The gene patenting controversy: A convergence of law, economic interests, and ethics."* 67 Brooklyn Law Review (2001) pp.233–248.

the next chapter. Since oncomouse, scientists and biotechnology companies have developed genetically engineered mice to model different human diseases, including Alzheimer's dementia, multiple sclerosis and diabetes. Altering the mouse genome is done by either deleting a gene or inserting a gene, in both cases the biochemical and physiological effects of the gene are examined in order to better comprehend the pathways of diseases and possible interventions.[37] These days the laboratory mice industry is valued at $ 200 million a year.[38] Finally, it is of importance to mention that for the past two decades scientists have applied recombinant DNA techniques to produce genetically modified plants, crops and foods. This expansion has raised concerns about the risks to the environment, public health and safety and business strategies applied by biotechnology companies. The advancements in genetic engineering have raised numerous social, political, legal and ethical issues.[39]

Based on the introduction to the subject presented above, one can conclude that the revolutionary speed of innovations in biotechnology has had a significant impact on various stakeholders in society for the past four decades. Furthermore, the traditional understanding and the underlying purpose of intellectual property rights could be challenged as patents on biomaterials are increasingly granted, raising numerous crucial issues. Under conventional patent law in the US and the EU, a patentable innovation must be (i) new, (ii) involve an inventive step and (iii) be useful (industrial application).[40] As it is generally accepted that exploiting something that before now existed in nature is a discovery and consequently is not patent eligible subject matter, the modern system of granting patents on genetic resources appears to challenge one of the most central principles of patent law: the novelty requirement. [41] The legal requirements needed to be satisfied in order for an invention to be considered new are stated in Article 54 of the European Patent Convention.[42] As biotechnology has become a well-established research area and patents are granted on a

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[37] Malakoff, D. *"The rise of the mouse, biomedicine's model animal"* 288 Science (2000), pp.48-53.

[38] Ibid.

[39] D. B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, p.30.

[40] Article 27 TRIPs Agreement, U.S.C. § 101 and Article 52 Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S 199 [Hereinafter EPC].

[41] N. Lucchi, *"Issues and Rights in DNA-based Inventions"* in Bin R., et al. *"Biotech Innovations and Fundamental Rights"* (Springer 2012), p.101.

[42] See Article 54 EPC.

continuous basis, it has been suggested that there is a need for an institutional and legal policy reform in order to ensure the judicial demarcation between human genetics, bioscience and indispensable natural resources. The legal reform has been held to be of immediate relevance because the current absence of legal certainty and predictability on where to draw the line between patentable and non-patentable biotechnological innovations raises issues associated to access to fundamental knowledge, DNA and gene based inventions and individual property rights.[43] As the achievements of genetic engineering and gene sequencing in the field of biotechnology have resulted in a wider range of potentially patentable subject matter, one can conclude that is has also become increasingly difficult to determine the dividing line between an invention and a discovery. As will be shown in the following study, this is not the only challenge impeding the legitimacy of patent eligibility of genetic resources.

[43] Nicola Lucchi, *Governing Control over Human Genetic Resources: Promises and Risks,* 2 The European Journal of Risk Regulation, (2013), pp.245 et seqq.

3 Intellectual Property Rights in Biotechnology

3.1 Patenting Genetic Resources

As it has been established in the previous chapter, even though the advancements in bioscience and biotechnology over the last century has provided new technologies and modern practices beneficial to society, the progress has raised a number of legitimate questions. It has been upheld that the continuous intensification in the scientific and technological manipulation of genetic resources has brought about a dramatic increase of exclusive property rights on genetic resources. At the same time however, it has been claimed among academics, professionals and legislators, that individual rights and fundamental liberties are becoming progressively threatened because the contemporary patent system on genetic materials is challenged by its preventive nature to the accessibility to information and knowledge which is considered to be of fundamental importance for mankind.[44] In conjunction with the development of the patenting system on genetic resources, the role of national courts has been given a central importance in preserving the principal purpose of the legislative acts by clarifying the scope and drawing the line between patentable and non-patentable subject matter. According to the US Patent Act § 101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." The statutory basis explicitly states that a claimed invention must fall within one of these four eligible classifications: (i) a machine, (ii) article of manufacture, (iii) composition of matter or (iv) process. In contrast, Article I, Section 8, Clause 8 of the US Constitution, (the Patent Clause) empowers the Congress "to promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"[45]. As the US Patent Act does not impose any statutory exceptions for subject matter patentability, for the past few decades, numerous case law precedents established by the Supreme Court have created important judicial restrictions to patent eligibility for laws of nature, natural principles, natural phenomena and natural products. This judicially created exception is referred to as the "product of nature"[46] doctrine which is considered by some to play a key role in

[44] N. Lucchi, *"Issues and Rights in DNA-based Inventions"* in Bin R., et al. *"Biotech Innovations and Fundamental Rights"* (Springer), 2012, p.97.

[45] US Constitution Article I, Section 8, Clause 8.

[46] Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

the legal challenge to the patent eligibility of genetic resources.[47] According to this doctrine, anything made by man is eligible for patent protection however; the mere discovery of a natural phenomenon does not constitute an invention and is thus non-patentable subject matter.[48] In the following, a significant landmark case in which the US Supreme Court for the first time established that living subject matter can be eligible for patent will be summarized and certain fundamental principles developed by the Court will be emphasized. Additionally, the distinguished oncomouse saga which was invented by Harvard University and granted patents will also be reviewed. By reason of the EU legislators and the EPO being greatly influenced by the US patent system in identifying and determining the uncertain legal status of genetic materials, the judicial doctrine which has been established in the US in the past decades is considered to be of great relevance for the analysis on the patentability of genetic resources in the EU.

3.1.1 Diamond v Chakrabarty[49]

In this groundbreaking precedent, Dr. Chakrabarty, a microbiologist and also the plaintiff in the case, filed a patent application for three claims for a human-made, genetically engineered oil-eating bacterium. The first two were method claims regarding the method of producing the bacterium and the application of the bacteria to oil. Both were proved. The third claim was for the bacterium as a subject matter and the Patent Trademarks Office, the Defendant, rejected this on the grounds that it was living subject matter and was not included in Title 35. The appellate court reversed, however the Supreme Court granted certiorari. The Court's decision stated that microorganisms produced by genetic engineering are not excluded from patent protection by § 101. The decision further clarified that the question of whether or not an invention consist of living subject matter was irrelevant to the issue of patentability. Relevant was, however, whether the living matter was the result of human intervention. By its way of reasoning, the Court stated that the relevant distinction was between products of nature, whether living or not, and human-made inventions. Furthermore, the Court held that "the laws of nature, physical phenomena and abstract ideas" are not patentable subject matter but that a "non-naturally occurring

[47] N. Lucchi, *Governing Control over Human Genetic Resources: Promises and Risks,* 2 The European Journal of Risk Regulation, (2013), p.247.

[48] John M. Conley, *"Gene Patents and the Product of Nature Doctrine"* 84 Chicago-Kent Law Review (2009), p.113.

[49] Diamond v. Chakrabarty, 447 U.S. 303, 308, 100 S. Ct. 2204, 65 L. Ed. 2 144 (1980).

manufacture or composition of matter - a product of human ingenuity – having a distinctive name, character, [and] use" is patentable subject matter. The Court developed its position on the matter by stating that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter… such discoveries are manifestations of nature, free to all men and reserved exclusively to none". However, in contrast, the Court also established that "the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery" is a manufacture under Title 35 § 101. Due to the fact that four justices dissented, the judgment was a portent of patent litigation for biotechnological inventions to come.

3.1.2 Patenting Animals: The Oncomouse

Among the first transgenic animals to be produced and granted patent protection was the oncomouse in 1985. Researchers at Harvard University produced a genetically modified mouse that was highly susceptible to cancer, by introducing an oncogene that can trigger the growth of tumors. The genetically engineered oncomouse was considered as a valuable means of furthering cancer research. As the University sought patent protection in the United States and several other countries, the case raised general ethical issues regarding transgenic technology in itself. But it also raised a central issue for the patent system: should patents be granted at all for animals or animal varieties, particularly for mammals, even if they do otherwise satisfy patentability criteria (novelty, industrial applicability/usefulness, inventive step). Noteworthy is that the issue of assessing the patentability of the oncomouse was resolved differently by the patent authorities in three important jurisdictions raising the questions of how far patent law should go and how far the harmonization of patent legal policies can go.[50] In 1989, the EPO rejected the patent entirely. This decision was based on two grounds: (i) in claiming animals that were new based on the introduction of oncogenes, the intention of the patent was deemed to be claiming animal varieties, which according to Article 53(b) are not patentable. The second ground referred to insufficiency of disclosure, which was considered not satisfied by the narrowed-down product claims. Although the product claims were narrowed-down in the application from the extended wording "transgenic non-human eukaryotic animals" to "non-human mam-

[50] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), p.306.

malian animals", the patent story of the oncomouse was only in 2004 finally concluded in the EU. The Technical Board of Appeal once again was required to assess the patentability of the patent and after careful consideration, concluded that the patent was valid, although the product claims were confined to "transgenic mouse".[51] Moreover, it has been considered that the divergent approaches applied by the patent offices in the oncomouse case in the US, Canada and the EU marketplaces indicates that in the absence of a distinct and harmonized understanding of the underlying purpose of the patent system and what patents are intended to achieve, it might be rather difficult to argue convincingly that life patents departs from the fundamental principle of patent law and thus, should not be allowed.[52]

3.1.3 Oliver Brüstle v Greenpeace eV[53]

More recently, in October 2011, an important judgment was delivered by the Court of Justice of the European Union (CJEU) in a case where a German patent granted to Dr. Oliver Brüstle covering isolated and purified human embryos was challenged on ethical grounds. Even though the case concerned the moral aspects associated to the patentability of biomaterials, it has been held that this decision resumed an old debate concerning whether moral aspects must effectively be dealt with by decision-makers when granting or invalidating a patent and furthermore, the decision has drawn even more attention to the issue concerning whether there exists a common concept of morality in the field of biotechnology.[54] It is thought-provoking however, that in its reasoning the CJEU stressed that "The context and aim of the [Biotech] Directive thus shows that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of 'human embryo' within the meaning of Article 6(2) of the Directive must be understood in the wider sense."[55] It has been held that the analysis established by the CJEU in this case has raised questions and challenged issues re-

[51] Ibid, pp.310-312.

[52] Ibid.

[53] Oliver Brüstle v Greenpeace eV (C-34/10) [2012] 1 C.M.L.R 41.

[54] E. Bonadio, *"Biotech patents and morality after Brüstle",* 34 European Intellectual Property Review (2012), pp.433 et sqq.

[55] Oliver Brüstle v Greenpeace eV (C-34/10) [2012] 1 C.M.L.R 41 at [34].

garding the complexity of the existing legal structure of the EU. Even more, the reasoning of the CJEU illustrates a cautious awareness of the complicated policy intersection between EU patent law and fundamental human rights. The reasoning of the CJEU in this particular case also highlighted the seriousness of the challenges ahead regarding potential threats to the rule of law shaped by the increasing complexity and extension of intersecting layers of national, supra-national and international laws. As the growth and complexity of EU patent law has resulted in an unprecedented legal uncertainty in the field of biotechnology, it has been argued that this development eventually could constitute a significant risk to the economic competitiveness of the EU as well as the protection of fundamental human rights.[56]

3.2 The Tragedy of the Commons and the Commodification of Biomaterials

So far, this paper in the previous has revealed the complex development of the role of intellectual property rights in biotechnological innovations. However, as will be demonstrated in the following, the challenges associated to the legal uncertainty on the patent eligibility of essential genetic resources has increasingly seen a complex development of further implications concerning access to necessary information, public health, patient rights and personalized medicine.[57] As for the biotechnological industry, concerns have been made that the incoherent legal framework and the uncertain future of the patenting of biomaterials ultimately will force the corporations to change their commercialization strategies and this strategy has been held to be directed to a harmful increase in patent blocks, patent thickets and trade secrets. The metaphor "tragedy of the commons"[58] was introduced as a concept in order to explain overpopulation and species extinction. The foundation of the theory is that people often tend to overuse resources which are owned in common only because there is no incentive to be provident. It has been held that even if the metaphor emphasizes on the cost of overuse when too many are allowed by the state to use a limited resource, the concept also indicates the risks and possibilities of underuse when too many people are granted exclusive property rights. Today, this concept plays a key role in several

[56] Aurora Plomer, *"After Brüstle: EU accession to the ECHR and the future of European patent law"*, 2 Queen Mary Journal of Intellectual Property, (2012), pp.110 et sqq.

[57] Timo Minssen, David Nilsson, *"Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after AMP v USPTO – Part IV",* 3 Queen Mary Journal of Intellectual Property Law 2011, pp.223-247.

[58] Garrett Hardin, *"The Tragedy of the Commons",* 162 Science (1968), pp.1243-1248.

contexts but in particular it has been recognized to be a powerful justification for the privatization of knowledge. The rapid advancements in the field of biotechnology and enormous investments in research and development have resulted in virtually unrestrained competition on the privatization of knowledge. According to academics, over the past few decades, research and development in biotechnology has increasingly focused on privatizing knowledge. DNA sequences have been patentable since the early 1980's; in the year of 2000 over 355.000 genetic sequences had been published, which is a 5000% increase over 1990.[59] The anticommons effect refers to the mirror image of common property: when a resource is subject to fragmented rights, whereby potential owners can exclude one another, however, no one has the effective privilege of use.[60] The benefits and adverse effects that exclusive property rights can have on research and development in DNA- and gene based inventions has been a central issue of debate in this regard. Among supporters and critics to the present patent eligibility of genetic resources, two generally accepted, although contradictory, intellectual doctrines are established.[61] The advocates in this regard claim that DNA or other genetic resources are simply chemical compounds and consequently it should be possible to claim a disclosed DNA sequence in the same way as a newly characterized chemical can be claimed for all known and yet to be discovered uses. In contrast, the opponents consider DNA to be a product of nature with fundamental information-carrying functions which, even if manipulated or isolated still remains a discovery of a work of nature and not a human invention.[62] Current disagreements among academics and legislators in this issue identify a contradictory consequence of privatization of genetic resources: the increase of exclusive property rights in biomedical research may essentially have an undesirable effect on life-saving innovations. It has been argued that the anticommons effect of fragmented and overlapping exclusive property rights, also referred to as patent thickets, in genetic resources is more probable to endure and intensify than in other

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[59] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), p.303.

[60] Michael Heller, Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research",* 280 Science (1998), pp.698 et sqq.

[61] D. B. Resnik, *Owning the Genome: a moral analysis on DNA patenting,* State University of New York, 2004, pp. 73 et sqq. See also Kathryn Garforth, *"Life as Chemistry or Life as Biology? An Ethics of Patents on Genetically Modified Organisms"*, in Johanna Gibson (Ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008) p.46.

[62] John Sulston, *"Biotechnological inventions: patenting of genes and life forms, and the impact of patenting on upstream science"*, available at http://www.wipo.int/export/sites/www/meetings/en/2006/scp_of_ge_06/presentations/scp_of_ge_06_sulston2.pdf.

areas of intellectual property due to high transaction costs and various interests among owners. Simultaneously, it has also been emphasized that exclusive property rights must be cautiously deployed if the aim of biotechnological research and development is to be beneficial to mankind's well-being. In contrast however, it has been stated that the present legal system of patenting biomaterials is only conceivable because life and living beings are utterly simplified in order to fit in the fictional legal context and that this way of reasoning is not acknowledging the complexity of life.[63] The adverse effect of patenting genetic resources has led numerous scholars and professionals requesting policymakers to ensure coherent limitations of patenting biomaterials, as it is believed that the anticommons effect may paradoxically result in scarcer inventions and discoveries of significant value to human health and well-being.[64] Moreover, it has been argued that since practically any human invention is in fact founded on previous inventions it is of great significance to consider patents on biotechnological inventions in the context of 'cumulative innovation'. In other words this refers to a situation in which an inventor uses a previous invention, which holds a valid patent, in order to develop a new invention. The fundamental nature of cumulative innovation has raised additional serious issues concerning the system of accessibility to necessary scientific information.[65]

As a tool for economic advancement, patents have manifestly contributed to the improvement of society through availability of new and beneficial products, services and information. Moreover, the establishment of the modern patent system is commonly understood as a regulatory response to the failure of the free market to optimize resource allocation for innovations.[66] Today, one of the most controversial areas of patenting is that of genetic resources.[67] The uncertain, sparse, yet complex legal policies, the proliferation of patents on biotechnological inventions in combination with the traditionally adopted

[63] K. Garforth, *"Life as Chemistry or Life as Biology? An Ethics of Patents on Genetically Modified Organisms"*, in Johanna Gibson (Ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008) pp.48 et sqq.

[64] M. Heller, R. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research",* 280 Science (1998), pp.698 et sqq.

[65] N. Lucchi, *"Issues and Rights in DNA-based Inventions"* in Bin R., et al. *"Biotech Innovations and Fundamental Rights"* (Springer), 2012, p.103.

[66] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), p.110.

[67] Ibid, p.302.

commercialization strategy of the industry has highlighted serious issues in regard to public health safety, patient rights and personalized medicine.[68] The correlation between exclusive property rights and public health has become increasingly a globally controversial issue as answers are sought to the question: do patents kill? Although patents are considered to be an economic advancement, they are also a fundamental incentive in order to accumulate private investments for research and development. It has been held that the industry has often been criticized for its research priorities as heavy investments are directed to the development of treatments to trivial conditions rather than life-saving ones. Additionally, many of the 'new' products available on the market are considered not to be profoundly new, rather variants of, or insignificant improvements upon existing products. Further criticism of the industry has demonstrated how the contemporary commercial strategy has raised concerns on the issue of 'disease mongering', which refers to the concept of selling of sickness. Although patents are not considered to be the only reason to this competitive development it has could be argued that if the purpose of the patenting system is to serve the public interest then patents should be a greater encouragement to channel research investments where public needs are greatest.[69]

An inventor that determines the function of a gene and isolates it can be granted patent protection, not just on the isolated gene itself, but also on diagnostic tests detecting the presence of the gene. Such a patent allows the owner to block others from offering diagnostic tests for the gene, irrespective of whether the patent owner actually offers the test. Thus, gene patents have been argued to have the potential to prevent patients from learning about their own genetic information and thereby impacting their ability to make informed health care decisions.[70] Furthermore, it has been held that individuals have a fundamental interest in knowledge regarding their own genetic information, to the extent that such information will help them make informed decisions regarding medical treatment. Since gene patents are issued by the government and block individuals from obtaining this necessary information, the legitimacy of patents on genetic resources has been challenged

[68] E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics Medicine S39-S70 (2010).

[69] G. Dutfield, U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, 2008), pp.312 et sqq.

[70] T. Minssen, D. Nilsson, *"Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after AMP v USPTO – Part IV",* 3 Queen Mary Journal of Intellectual Property Law (2011), pp.223-247.

based on the restrictive effect gene patents distinctly has on patients access to genetic information.[71] This disturbing development becomes even more incredible as a recent study on the market for biomaterials has reported that human DNA can raise as much as $ 9.7 million and antibodies which are produced in our body are worth about $ 7.3 million.[72] The enormous economic value of patent eligible genetic resources raises an extremely complicated legal question: who owns the genetic materials excised from the human body? The individual whose body they came from or a third part who owns a patent claiming these materials? The legal issue is held to be founded on the adopted concept that patents on genetic resources are exclusive properties with a significant economic value, and wherever there is a valuable resource, disagreements over its ownership are ultimately inevitable.[73]

3.3 Legal Challenges in DNA-based Innovations

Hitherto, this study has highlighted more than a few serious and legitimate issues and questions raised in relation to the present proliferation of patents on genetic resources. In the previous, it has also been demonstrated how the rapid advancements in the field of genetic engineering has resulted in a confused and complex regulatory framework in which several issues of fundamental importance have not been properly addressed, or not addressed at all. The current approach adopted by the two world leading competitors in the field of biotechnology, the US and the EU, is that an innovation, in order to be eligible for patent protection, must meet three fundamental substantive requisites:[74] (i) it must be new, (ii) it must involve an inventive step (the non-obviousness criteria in the US) and (iii) be capable of industrial application (the utility criteria in the US). Although the statutory requirements provide the basic yet broad requirements that must be satisfied in order for an invention to be eligible for patent protection, the patenting of human DNA and genes raises the fundamental question: where is the line to be drawn between patentable and non-patentable innovations? The unpredictable nature of the patent eligibility doctrine established by case law is rather evident, as judicial inquiries have been developed but consequently explicitly disregarded or rejected. In contrast, it is generally accepted that utilizing something that al-

[71] S. Kumar, *"Gene Patents and Patient Rights",* 35 Whittier Law Review (2014), pp.363-372.

[72] S. Ghosh, *"The Taking of Human Biological Products",* 102 California Law Review 511 (2014), p.529.

[73] Ibid, pp.516-517. See also Angela A. Stanton, *"Forfeited Consent: Body Parts in Eminent Domain"* in Johanna Gibson (ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008) pp.95 et sqq.

[74] Article 27 TRIPs Agreement, U.S.C. § 101 and Article 52 EPC.

ready before existed in nature is a discovery within the judicially created product of nature doctrine and is therefore non-patentable subject matter. In this regard, patenting of genetic resources appears to challenge one of the fundamental principles of patent law: the novelty requirement. Does an innovation satisfy the novelty requirement although this claimed product or law of nature existed in time before it was discovered by man? This is an important question as it is strictly connected to the distinction between discovery and invention. According to Article 52 (2)(a) of the EPC, discoveries are excluded from patentability, however, as the achievements of genetic engineering and gene sequencing have extended the range of potentially patentable subject matter, the demarcation between invention and discovery has become progressively problematic to determine. This legal uncertainty is even more challenging as it has been strongly advocated that the identification and isolation of DNA and genetic sequences from its natural environment does not satisfy the patent eligibility requirement since the material existed in its present state before it became known to man, and thus are discoveries and not inventions eligible for patent protection. Consequently, with the significant economic value derived from exclusive property rights on genetic resources, this raises the question: is the commercialization of a fundamental and common good justified? The investigation so far has demonstrated that the principal cause to the legal challenge of the patent eligibility of human DNA appears to be originated from incorrect applications of the regulations. In the following, this study aims to further demonstrate the complex and incoherent judicial developments established recently under the common law system in the US. With the intent to further validate the previously associated to the legitimacy of exclusive property rights on genetic resources, the following chapter will primarily provide the reader with the contextual facts to what has become a landmark case settled by the US Supreme Court. In this case, the legitimacy and constitutionality of exclusive property rights on human DNA and genetic sequences was challenged. The judgment, delivered in June 2013, has drawn global attention and consequently raised additional issues and questions to the contemporary legal challenge on the patent eligibility of DNA and genetic sequences.[75]

[75] Timothy Caulfield et al., *"Myriad Genetics and the Mass Media: The Coverage of a Gene Patent Controversy",* in 9 Genetics Medicine 850 (2007).

3.4 Possible Alternatives to Exclusive Property Rights

As regards gene patents, it has been established that an isolated genetic sequence of a natural gene or protein becomes the absolute property of the patent owner, provided the claim is concentrated to the isolated genetic sequence as a product in itself. In addition, it has been held that an isolated genetic sequence becomes a conditional property of the patent owner if it is directed to the isolated genetic sequence as a component in a process. In this respect, as an alternative to exclusive property rights, a new, unique and independent system of intellectual property has been proposed to be implemented: the Genetic Sequence Right (GSR). The GSR proposal establishes that the use of genetic sequences or other biomaterials should not come to the ownership or be controlled by any one person or establishment, for whatever purpose. Rather, the purpose of the GSR is to encourage an unrestricted use and that, irrespective of a genetic sequence being an 'invention' or not, the identification of a genetic sequence and its function is beneficial knowledge which must be recognized. Accordingly, a GSR would be granted to the first person to file an application and make known a genetic sequence defining genetic resources of any origin and explaining its function and usefulness. As opposed to the contemporary patenting system's act of exclusion, the GSR proposal suggests that the more use of the GSR, the greater the potential GSR fee revenue will become. [76] Another initiative with the purpose of establishing an alternative to patents is the Medical and Research Development Treaty (the Treaty).[77] In 2005, a combination of Non-Governmental Organizations (NGO's), public health experts, legal academics and economists proposed a new legal framework promoting research and development for the medical industry. The basic principle of the Treaty is that exclusive property rights limits access to essential medicines and directs investments away from neglected diseases into more profitable diseases offering greater potential revenue. For that reason, as a means of implementing fundamental human rights, the Treaty proposes that relevant health-associated goals are to be achieved by setting minimum financial obligations for qualifying research and development based upon each state's gross domestic product. However, the status of the Treaty is at the time of writing this study still unknown.

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[76] Luigi Palombi, *"The Genetic Sequence Right: A Sui Generis Alternative to the Patenting of Biological Materials",* in Johanna Gibson (ed.), *Patenting Lives: Life Patents, Culture and Development*, (Aldershot: Ashgate 2008), pp.92 et sqq.

[77] For the full background and text of the proposed treaty, see http://www.cptech.org./workingdrafts/rndtreaty.html.

4 Patent Litigation in DNA-based Innovations

4.1 The Patenting of Two Genes Linked to Cancer Risk

In the 1980's research establishments committed to breast cancer awareness initiated efforts to draw attention to the progressive development of the breast cancer epidemic. As a response to these efforts, in 1991 the US department of Defense established a program dedicated to breast cancer research. Following this initiative, scientists from the United States, Europe, Japan and other countries aimed to be the first to identify the DNA nucleotide sequences linked to breast cancer. However, already in 1990 a group of scientists led by Dr. Mary-Claire King at the University of California Berkeley published a groundbreaking paper locating for the first time a gene, BRCA1, with an unknown sequence associated to breast and ovarian cancer located on a section of chromosome 17 through a technique called linkage analysis. This landmark discovery intensified the global research and resulted in tougher competition. During the same time period another group of researchers led by Dr. Marc Skolnick at the University of Utah were also committed to identify the gene and in 1991 Dr. Skolnick and his fellow researchers formed Myriad Genetics Inc. as a spin-off aiming to obtain the needed funding to further pursue their research. Following Myriad's achievement obtaining the needed investments and Dr. King's preceding location of the gene, Dr. Skolnick and his team were able to analyze the previously unknown sequence of the DNA in the region resulting in identification of the nucleotides containing the BRCA1 gene and in 1994 Myriad filed a patent application covering the gene sequence and its mutations and in late 1997 the United States Patent and Trademark Office granted Myriad its first patent covering 47 separate mutations in the BRCA1 gene.[78] Subsequently, Myriad was granted five additional patents comprising the BRCA1 gene and related diagnostic tests.[79] In 1995 Myriad applied for two more patents covering the methods of detecting BRCA1 mutations and the entire sequence of the gene and as the patents were granted in 1998 it resulted in Myriad having exclusive rights and control over the BRCA1 gene.[80]

[78] United States Patent and Trademark Office. Available at www.uspto.gov. US 5,693,473.

[79] Ibid. US 5,709,999, US 5,747,282, US 5,710,001, US 5,753,441 and US 6,162,897.

[80] E. R. Gold & J. Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics Medicine S39-S70 (2010).

In late 1994 a UK based research group led by Dr. Michael Stratton announced that they had located another region with an unknown sequence associated to hereditary breast cancer on chromosome 13 comprising the BRCA2 gene. In December 1995 the team published an article comprising the gene's sequence and filed for a patent application covering the gene BRCA2. In the meantime, one day before Dr. Stratton's publication Myriad stated that it too had effectively isolated and sequenced the gene and had deposited the entire gene sequence in a database comprising gene sequences, GenBank. Myriad claimed that Dr. Stratton's article only "reported a partial sequence and six mutations" [81] and not the complete sequence. Consequently Myriad filed for a patent in the United States in 1996 comprising BRCA2 DNA, associated mutations and diagnosis and in 1998 for the method of detecting mutations in the gene.[82]

Once Myriad was gradually granted its patents on the BRCA1 and BRCA2 genes it received exclusive control over the use of diagnostic tests based on them and made use of its competitive advantage by opening a US$30- million laboratory in late 1996 and began marketing three principal diagnostic tests in the United States aiming to become a leading biopharmaceutical diagnostic company linking gene discovery to therapeutics. However, during the same time Myriad announced its tests, other laboratories had already been performing tests on BRCA1 and BRCA2 applying other methods and once Myriad obtained its patents it attempted to eradicate the competing laboratories by sending cease-and-desist letters for patent infringement resulting in a large number of research laboratories and universities to cease with their research on BRCA1 and BRCA2.[83]

As Myriad's commercialization strategy prospered in the US, it pursued for exclusive property rights globally using the submitted applications filed to the USPTO in order to receive priority over any other possible inventor. In early 2001 the EPO granted Myriad its European patent[84] comprising any methods of diagnosing a tendency for breast and ovarian

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[81] Tavtigian SV, Simard J, Rommens J, et al. *The complete BRCA2 gene and its mutations in chromosome 13q-linked kindreds*, 12 Nature Genetics 333-337 (1996).

[82] E. R. Gold & J. Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics Medicine S39-S70 (2010).

[83] Ibid.

[84] European Patent Office. Available at www.epo.org. EP 699,754.

cancer. The same year Myriad obtained two other patents from the EPO, one associated to the mutated BRCA1 gene[85] and one relating to the BRCA1 gene itself[86]. Lastly, in early 2003 the EPO granted Myriad a patent claiming the BRCA2 gene.[87] However, in 2001 a large coalition of scientists and non-governmental organizations launched the first of several of opposition proceedings in which the validity of the patents granted by the EPO were challenged. These proceedings resulted in the patents associated to the claimed genes to become either withdrawn or reduced.[88]

Armed with its patents and its competitive market position, Myriad soon encountered strong opposition and concerns were being raised associated to its commercialization strategy comprising its exclusive rights to isolate an individual's BRCA1 and BRCA2 genes and to synthetically create BRCA composite DNA. The opposition included, among others, the scientific community stating that Myriad's aggressive manner in fact could impede further research due to the inability to access necessary information. The clinical community expressed similar concerns as they were worried that Myriad offered its testing to any person who desired it although there was lack of clinical justification and thereby opposing Myriad's efforts at direct-to-consumer advertising arguing that this insincerely increased demand for testing. Additionally, concerns were voiced regarding patient rights and violation of patient privacy as it was argued that Myriad could establish a database of genetic mutations comprising private health care information but also the risk of discrimination was observed by patients and patients groups since Myriad offered testing to specific ethnic groups. However, Myriad encountered severe difficulties when health care legislators entered the discussion. While Myriad's commercialization approach might have been successful for another type of invention, it failed to cautiously consider the legal policies applied in countries with public health care systems.[89]

[85] Ibid EP 705,903.

[86] Ibid EP 705,902.

[87] Ibid EP 785,216.

[88] E. R. Gold & J. Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 Genetics Medicine S39-S70 (2010).

[89] Ibid.

As the attention increased and the debate thickened concerning the legitimacy and the impact of Myriad's patents on scientific research, patient rights and public health, Association for Molecular Pathology[90] (AMP) and a number of other plaintiffs filed an action on May 12, 2009, claiming violations of 35 U.S.C. § 101. AMP et al. challenged the validity of 15 claims contained in seven patents obtained by Myriad concerning isolated DNA and methods for comparing and analyzing the gene sequences in order to identify a predisposition to breast and ovarian cancer.[91] However, as has been stated in the introduction, this thesis is delimited to the analysis of the patent eligibility of isolated DNA and thus the claims associated to the methods will be disregarded.

4.2 The District Court's Decision

In March 29, 2010 Judge Sweet at the District Court for the southern district of New York (the court) provided the parties with the conclusions of law in a summary judgment regarding the legitimacy of the 15 claims contained in seven of Myriad's patents challenged by the plaintiffs'.

The court initiated the legal assessment by affirming the broad scope of 35 U.S.C. § 101 concluded by the Supreme Court in Diamond v. Chakrabarty stating that "Congress plainly contemplated that the patent laws would be given wide scope"[92].[93] However, the court continued by declaring that the extensive reading of § 101 has its limitations as "the Supreme court has recognized that scientific principles and laws of nature, even when for the first time discovered, have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the subject of exclusive rights to any one person"[94]. Explicitly, the court has acknowledged three classifications of subject matter

[90] Association for Molecular Pathology is a not-for-profit scientific society dedicated to the advancement, practice, science of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics, www.amp.org.

[91] Association for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010).

[92] Diamond v. Chakrabarty, 447 U.S. 303, 308, 100 S. Ct. 2204, 65 L. Ed. 2 144 (1980).

[93] Ass'n for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010) at [12].

[94] In re Meyer, 688 F. 2d 789, 795 (C.C.P.A. 1982) citing Leroy v. Tatham 55 U.S. 155, 175, 14 L. Ed 367 (1852).

which are not covered by § 101: "The laws of nature, physical phenomena and abstract ideas have been held not patentable"[95] explaining that "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discovery' that the statute was enacted to protect[96].[97] The court proceeded by declaring that when assessing whether an invention is subject to patent "the obligation to determine what type of discovery is sought to be patented must precede the determination of whether that discovery is, in fact, new or obvious"[98]. Consequently the courts have excluded patent claims although the alleged invention was highly advantageous or novel.[99] Concluding that "products of nature"[100] are excluded from patent eligibility the court proceeded its inquiry on whether or not the composition claims concentrated to isolated DNA comprising naturally-occurring sequences are covered by the products of nature exception to § 101.

Initially, the court stated that the Supreme Court precedent has recognized that products of nature must result in the making of essentially a new invention in order for it to be eligible patent subject matter. Referring to the application of § 101 to product claims addressed in Diamond v. Chakrabarty, the court stated that "the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own…"[101] This prerequisite, that an invention must hold "markedly different characteristics" from a product of nature constituted the foundation for the legal assessment concerning Myriad's product claims directed to isolated DNA. Although the court did not further elaborate on what specifically constitutes "markedly different characteristics", it stated that the previous

[95] Diamond v. Chakrabarty, 447 U.S. 303, 308, 100 S. Ct. 2204, 65 L. Ed. 2 144 (1980) at [309].

[96] Parker v. Flook, 437 U.S. 584, 593, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (1978).

[97] Ass'n for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010).

[98] Parker v. Flook, 437 U.S. 584, 593, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (1978) at [593].

[99] Ass'n for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010) at [17].

[100] Diamond v. Chakrabarty, 447 U.S. 303, 308, 100 S. Ct. 2204, 65 L. Ed. 2 144 (1980) at [313] stating that the applicable distinction for § 101 patentability is "between products of nature, whether living or not, and man-made inventions".

[101] Ibid at [310].

clear line of the Courts precedent has established that only the purification of a product of nature is not enough to transform the invention into patentable subject matter.[102]

As the court proceeded its inquiry it held that in support of its position Myriad has relied on numerous dissimilarities between the isolated DNA claimed in the patents and the native DNA found in humans. However, as the central premise of Myriad's argument is the statement that "isolated DNA molecules should be treated no differently than other chemical compounds for patent eligibility"[103] and that the assumed "difference in the structural and functional properties of isolated DNA" [104] holds the claimed DNA as patentable subject matter, the court stated that Myriad's emphasis on the chemical structure of DNA failed to recognize the exclusive characteristics of DNA as genes are of double nature: chemical substances and physical carriers of information. The court stated that Myriad's argument failed to acknowledge that the information encoded in DNA is not information about its own molecular structure related to its biological functioning as the information encoded in DNA directs the synthesis of other molecules in the human body as its primary function. Proceeding, the court confirmed that DNA serves as the physical embodiment of laws of nature and thus consideration cannot be made to analogies comparing DNA with other chemical substances, such as adrenaline although this compound is also a carrier of limited information. The structural and functional differences presented by Myriad between BRCA1/2 native DNA and the BRCA1/2 isolated DNA were considered not to render the isolated DNA "markedly different" as the DNA's nucleotide sequence plays a key role to its biological function as well as the application associated with DNA in its isolated form and therefore the preservation of this central characteristic is considered to fall under the products of nature exception. As Myriad argued that the legal assessment of subject matter patentability of isolated DNA ought to focus exclusively on the alleged existing differences between native and isolated DNA, the court rejected this statement and emphasized that "the claims must be considered as a whole"[105]. The court further rejected Myriad's statement that because native DNA contains intron sequences that are absent in the claimed

[102] Ass'n for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010) at [32].

[103] Ass'n for Molecular Pathology v. U.S. PTO, 702F. Supp. 2d 181 (S.D.N.Y. 2010).

[104] Ibid.

[105] Ibid.

isolated DNA this difference should render the isolated DNA "markedly different", holding that the coding sequences is the result of the natural phenomena RNA splicing. The functional differences asserted by Myriad between native DNA and isolated DNA to demonstrate that they are "markedly different" relied on the fact that isolated DNA have applications for which native DNA is inappropriate, for instance in medical treatments as isolated DNA has the ability to target and interact with other DNA molecules. Likewise, the effectiveness of isolated DNA as a sequencing target is dependent on the preservation of native DNA's nucleotide sequence. The court did concur that the absence of introns and other nucleotide sequences is required for DNA to be suitable for the mentioned purposes, however the purification of native DNA does not result in alterations in its nucleotide sequence which is defined by nature and key to its biological function as well as its function as a research tool in the lab. Isolating DNA is thus a technological limitation to the use of DNA and this purification process may not be central in the future for molecular and diagnostic purposes and consequently, the court concluded that Myriad's use of isolated DNA has not established the existence of dissimilarities between native DNA and isolated DNA and consequently the claimed isolated DNA was deemed not "markedly different" from native DNA and thus covered by the product of nature doctrine of non-patentable subject matter.[106]

The inquiry established by Judge Sweet has been held by scholars and commentators to be rather radical.[107] This is due to the fact that since the inception of gene patenting, the USPTO and the courts have uniformly acquiesced that DNA and other genetic resources are just chemical compounds. Their information-carrying function has been irrelevant to their patentability and because genes are chemically different in isolation, in a literal sense at least, they cannot be considered products of nature. Judge Sweet however, decided that the information-carrying function of genes is indeed what makes them distinct from other chemicals and this raises the question of whether genetic exceptionalism has become a principle of law?

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[106] Ibid.

[107] T. Minssen, D. Nilsson, *"Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after AMP v USPTO – Part I",* 3 Queen Mary Journal of Intellectual Property Law 2011, pp.223-247.

4.3 The Court of Appeal's Decision

Myriad appealed the decision arguing that the district court had misread Supreme Court precedent as excluding all products of nature if not markedly different from ones naturally occurring and focusing incorrectly on the one similarity: their informational content. The court of appeal initiated its inquiry by stating that the government, as amicus curiae to this case, has held that it does not defend the USPTO's position that isolated DNA is eligible subject matter, instead it argues for a middle ground. More specifically, the government declared that DNA engineered by man, including complementary DNA, is patent-eligible compositions of matter because they do not occur in nature, however isolated and unmodified DNA is not patentable since their nucleotide sequence is the effect of evolution and not man. The government demonstrated its position by introducing the magic microscope test stating that "if an imaginary microscope could focus in on the claimed DNA molecule as it exists in the human body, the claim covers unpatentable subject matter"[108]. More precisely, the government held that since an imaginary microscope is not able to focus in on a synthetically created complimentary DNA (cDNA) sequence because this sequence is engineered by man, claims covering cDNA's are eligible subject matter.[109] The court however, rejected the government's proposed test explaining that the test misjudged the difference between science and invention and also failed to take into consideration the existence of molecules as separate chemical entities, concluding that "visualization does not cleave and isolate the particular DNA; that is the act of human invention"[110]. The court proceeded its legal assessment by focusing the "markedly different characteristics" test on the differences between isolated DNA and purified DNA establishing that isolated DNA is not purified DNA as BRCA1 and BRCA2 in their isolated forms are not the same molecules as exists in the human body. Stating that, although isolated DNA must be removed from its native cellular, it has also been chemically manipulated in order to produce a molecule that is markedly different from that which exists in the human body, the court considered that the isolated DNA had not been purified by being isolated. Assessing that isolation of DNA is not equivalent to purification of DNA the court held that the claimed isolated DNA molecules must be chemically cleaved from their chemical combination with other genetic materials and thus when cleaved, the isolated DNA molecule constitutes a distinct chemical unit. Es-

[108] Ass'n for Molecular Pathology v. U.S. Pat. &Trademark Off., 653 F.3d 1329, 1334 (Fed.Cir. 2011).

[109] Ibid.

[110] Ibid.

tablishing that the distinctive nature of isolated DNA as compositions of matter is what determines the patent eligibility and not its physiological use or benefit. As genes are materials having a chemical nature, the court held that they should be described in patents not by their functions but rather their structures. Concluding that the challenged claims do cover molecules that are markedly different because they have been found having a distinct chemical identity from molecules existing in nature, the court reversed the district court's decision and rendered isolated DNA to be patentable subject matter under § 101.[111] Noteworthy is that the court delivered its judgment in a 105-page-long split decision where each panel member had included their argumentative opinions. Initially, the judgment appeared to be moderately favorable to the industry; however, the panel members' inquiries which included rather elusive statements indicated a potential threat to present patent practice.[112]

4.4 The Supreme Court's Decision

As the Supreme Court granted certiorari, the court had to decide on whether isolated DNA was patentable subject matter under § 101 and the patent eligibility of cDNA. The court initiated its assessment by stating that Myriad discovered the precise location and sequence of the BRCA1 and BRCA2 genes affirming that it is undisputed that Myriad did not create or alter the genetic structure encoded in the those genes. Locating an essential and valuable gene and separating it from its surrounding genetic material cannot be considered an act of invention. The court proceeded its inquiry applying a different approach from the lower courts, emphasizing that the language used in Myriad's patents descriptions illustrates the problems with the challenged claims. The court established that numerous of Myriad's patent descriptions merely detailed an extensive process of discovery by which Myriad was delimiting the potential locations for the genes sought for. Stating that extensive research efforts even being a groundbreaking, innovative or even brilliant discovery does not alone satisfy the § 101 inquiry. The court proceeded by stating that the challenged claims cannot be saved by the fact that isolating human DNA separates the chemical bonds that compose gene molecules for the reason that Myriad had failed to express its claims in the patents description in terms of chemical composition, not either were the claims dependent on the chemical modifications resulting from the isolation of a specific DNA segment. Myriad had

[111] Ass'n for Molecular Pathology v. U.S. Pat. &Trademark Off., 653 F.3d 1329, 1334 (Fed.Cir. 2011).

[112] T. Minssen, D. Nilsson, *"Standing on shaky ground: US patent-eligibility of isolated DNA and genetic diagnostics after AMP v USPTO – Part I",* 3 Queen Mary Journal of Intellectual Property Law 2011, pp.223-247.

in its patent description instead focused on the genetic information encoded in the two BRCA genes. The court therefore concluded that Myriad's claims to isolated DNA fall within the product of nature exception.[113] In the subsequent assessment concerning the patent eligibility of cDNA, the court held that the creation of a cDNA sequence from mRNA results in the non-coding regions being removed: an exons-only molecule. This creation, the court stated, is the act of human invention as the scientists indisputably creates a new subject matter when making cDNA. Although cDNA preserves the naturally occurring exons of DNA, it is different from the DNA from which it was derived. Based on this way of reasoning, the court came to the conclusion that cDNA is not a product of nature and therefore is patent eligible under § 101, however the court explicitly held that very short sequences of DNA without intervening introns to remove are excluded since a short strand of cDNA may possibly be indistinguishable from native DNA.[114]

4.5 The Implications from the Case

The inquiry established by the Supreme Court held that naturally-occurring DNA is not eligible for patent protection just because it has been isolated from its natural environment, thus stating that naturally-occurring DNA remains a product of nature. Additionally, the decision stated that the human act of isolating naturally-occurring DNA is not enough to be considered made by man. The decision marked a significant change in the law, and reversed the decades-old USPTO practice of granting patents on naturally-occurring substances as long as they are isolated from its natural environment. It has also been held that this landmark case highlighted the unfavorable impact of an indiscreet administration of the patenting system.[115] The decision has raised concerns in regard to the divergent opinions of the courts related to what level of human intervention alters an innovation significantly enough to legitimize patent eligibility.[116] The incoherent and sometimes unsubstantiated reasoning of the courts in the trial has also been subject to discussion as regards whether the lack of scientific expertise among the panel members in this particular field of

[113] Ass'n for Molecular Pathology v. Myriad Genetics,Inc., 132 S. Ct. 1794, 182 L. Ed. 2d 613, 2012 U.S. LEXIS 2356, 80U.S.L.W. 3545 (U.S. 2012).

[114] Ibid.

[115] Bin R., Lorenzon S., Lucchi N. (Eds.): *"Biotech Innovations and Fundamental Rights",* (Springer), 2012, pp.30-31.

[116] E. M. Kane, *Patenting Genes and Genetic Methods: What's at stake?,* 6 Journal of Business and Technology Law 1 2011.

the patenting system identifies a need for judicial specialization?[117] In order to mitigate the legal uncertainties and the unpredictability which resulted from this decision, the USPTO on the 16 of December 2014 issued a new guidance[118] describing an innovative eligibility analysis to be applied by decision-makers at the USPTO in order define whether claimed subject matter satisfies the markedly different characteristics test and hence patent eligible under 35 U.S.C. 101.[119] The markedly different characteristics analysis determines if a nature-based product falls within the product of nature exception which have been held by the courts to fall under the laws of nature or natural phenomena exceptions. From the analysis established by the court, one can conclude that the product of nature doctrine is held to play a key role, particularly in biotechnology, as it creates a fundamental restriction for products and processes which are derived from the duplication of chemical compounds in living organisms or produced naturally in animals or plants. In contrast, the Supreme Court did not further elaborate on what actually defines markedly different characteristics, and consequently in leaving the future task of interpretation to the lower courts, the legal uncertainty and unpredictability is further increased. Nevertheless, scholars and commentators to the case have drawn attention to a potential future concern.[120] From the reasoning established by the Supreme Court, it has been concluded that as long as a claim attempts to patent genetic materials in its natural state, the patent will be invalidated for the foreseeable future however, the validation of isolated DNA patents proposes that even the smallest change to the natural state can suffice for patent eligibility under § 101. In theory at least, this has left the practitioners with the ability to patent genetic materials as long as the claim places emphasis on differences on the invention, method or unique application of process. This recently established approach raises the question: has the legitimacy of exclusive property rights on DNA and genetic sequences become reduced to the practitioners' abilities of drafting the claims?[121]

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[117] A. M. Bakshi, *"Gene patents at the Supreme Court: Association for Molecular Pathology v. Myriad Genetics"* Journal of Law and Biosciences (2014), pp.1-7 at p.7.

[118] 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618 (Dec. 16, 2014)

[119] See Appendix 1, also visit http://gbpatent.com/resources/Patent_Eligible_Subject_Matter/index.html.

[120] Alex Boguniewicz, *"Discovering the Undiscoverable: Patent Eligibility of DNA and the Future of Biotechnological Patent Claims Post-Myriad",* 10 Wash. .L. Tech. & Arts 35 (2014).

[121] Nicola Lucchi, *"Issues and Rights in DNA-based Inventions"* in Bin R., et al. *"Biotech Innovations and Fundamental Rights"* (Springer, 2012), p.101.

5 Conclusion

The purpose of this thesis is to analyze the legal challenge to the patent eligibility of human DNA, delimited to the US and the EU jurisdictions. The investigation has demonstrated transatlantic differences in the legal policies relevant to the patenting of genetic resources and that the legitimacy of the patent eligibility of DNA and genetic sequences has raised several questions. The uncertain, sparse, yet complex legal policies, the proliferation of patents on biotechnological innovations in combination with the traditionally adopted commercialization strategy of the industry has highlighted serious issues in regard to public health safety, patient rights and access to knowledge. As for the biotechnological industry, concerns have been made that the incoherent legal framework and the uncertain future of the patenting of biomaterials ultimately will force the corporations to change their commercialization strategies and this strategy has been held to be directed to a harmful increase in patent blocks, patent thickets and trade secrets. The current approach adopted by the two world leading competitors in the field of biotechnology is that an innovation in order to be eligible for patent protection, must meet three fundamental requisites: (i) it must be new, (ii) it must involve an inventive step and (iii) be capable of industrial application. The statutory requirements provide the basic requirements that must be satisfied in order for an invention to be eligible for patent protection, however, the unpredictable nature of the patent eligibility doctrine established by case law is also rather evident, as judicial inquiries have been developed but consequently explicitly disregarded or rejected. In contrast, important judicial restrictions to patent eligibility for laws of nature, natural principles, natural phenomena and natural products, also referred to as the product of nature doctrine, have been developed from legal practice. According to this doctrine, anything made by man is eligible for patent protection however; the mere discovery of a natural phenomenon or product does not constitute a new invention and is thus non-patentable subject matter. The inquiry established by the Supreme Court in Association for Molecular Pathology v. Myriad Genetics further demonstrates the challenges associated to gene patents. The Supreme Court held that naturally-occurring DNA is not eligible for patent protection just because it has been isolated from its natural environment, thus stating that naturally-occurring DNA remains a product of nature. Additionally, the decision stated that the human act of isolating naturally-occurring DNA is not enough to be considered made by man. The decision marked a significant change in the law and raised concerns associated to the divergent opinions of the courts in regard of what level of human intervention alters an innovation

significantly enough to legitimize patent eligibility and whether the lack of scientific expertise among the judges in this particular field of the patenting system identifies a need for judicial specialization. According to Article 52 (2)(a) of the EPC, discoveries are excluded from patentability, however, as the achievements of genetic engineering and gene sequencing have extended the range of potentially patentable subject matter, the demarcation between invention and discovery has become progressively problematic to determine. In this regard however, patenting of human DNA and genetic sequences appears to challenge one of the fundamental principles of patent law: the novelty requirement and this particular challenge is considered to be originated from incorrect application of the law. In conclusion, this study has established that the proliferation of exclusive property rights on biomaterials has raised several concerns that challenge the underlying purpose of intellectual property protection and consequently identifies a need for institutional and regulatory reform.

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Appendix 1 Analysis for Subject Matter Eligibility