Comparative Legal Review: Reassessing the Social Contract in Europe and the United States for Patenting Human Genetic Materials

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A Comparative Legal Review: Reassessing the Social Contract in Europe and the United States for Patenting Human Genetic Materials

By

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Abstract

In 2013, the US Supreme Court declared isolated gene sequences as 'products of nature' and hence, unpatentable subject matter. Paradoxically, the European Patent Office (EPO), relying on the EU Biotech Directive 98/44/EC, does not perceive a problem with patents on isolated human genetic sequences. However, the EPO excludes human embryonic stem cells (hESCs) from being patentable subject matter on the grounds of morality and *ordre public*.

The controversy arises from an understanding that gene patents create a *de facto* tragedy of the anti-commons. This, in turn, is based on a wider belief that the current statutory regime governing the patent protection of human genetic materials creates expansive property rights, without a proper consideration of the public interest.

This thesis tests this proposition by examining and revealing the contextual genesis of these bifurcated reactions by the United States and European jurists. First, it reframes the historical evolution of patented inventions within the biotechnology sector. By adopting the concept of patents as a social contract between the inventor and society, the research reasserts the fundamental aspects of patent law. Second, the subsequent chapters employ this primary premise in order to map out the theoretical arguments for propertizing genetic materials. Finally, the thesis investigates the possibility of policy guidelines by gathering an empirical dataset through questionnaires and interviews directed at key stakeholders.

This work maintains that the current statutory regimes in Europe and the US governing the patent protection of human genetic materials can create acceptable property rights. But this is only possible if the regime adopts a purpose-bound approach for human genetic materials. Such an enhanced *status quo* approach, as adopted in some European jurisdictions, would entail the consideration of public interest values, as articulated through the empirical research, and which has been set out as a draft manifesto.

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Table of Cases

Consolboard Inc v MacMillan Bloedel (Sask) Ltd, [1981] 1 SCR 504.

Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908).

Diamond, Commissioner of Patents and Trademarks v. Diehr, et al. 450 U.S. 175 (1981)

DeForest Radio Co. v. General Electric Co., 283 U.S. 664 (1931)

Diamond v. Chakrabarty, 447 U.S. 303 (1980)

Eli Lilly & Company v Human Genome Sciences Inc [2008] EWHC 1903 (Pat),

Eli Lilly Canada Inc. v. Novopharm Limited, 2010 FCA 197, [2012] 1 F.C.R. 349

Eli Lilly and Company v. Teva Canada Limited, 2011 FCA 220

Ex parte Allen, 2 U.S.P.Q. 2d (BNA) 1425 (Bd. Pat. App. & Int. 1987), aff'd, 846 F.2d 77 (Fed.Cir.1988)

*Ex Parte Latime*r, March 12, 1889, C.D., 46 O.G. 1638, United States Patent Office, "Decisions of the Commissioner of Patents and the United States Courts in Patent Cases." 1889 (Washington, D.C.: Government Printing Office,1890) Pp.123-127.

Foundation for Taxpayer and Consumer Rights v. WARF. USPTO Board of Appeal and Interferences, (Appeal 2010-001854) Available at: http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf. Accessed May 24, 2012.

Funk Brothers Seed Co. v. Kalo Inoculant Co. 333 U.S. 127 (1948)

Generics (UK) Limited and others (Appellants) v H Lundbeck A/S (Respondents) [2009] UKHL 12

Graham v. John Deere Co., 383 U.S. 1 (1966).

Harvard College v. Canada (Commissioner of Patents) F.C.T.D. April 21, 1998.

Harvard College v. Canada (Commissioner of Patents) [2002]4 S.C.R. 45, 2002 SCC 76

HOWARD FLOREY/Relaxin [1995] E.P.O.R. 388

Human Genome Sciences Inc v Eli Lilly and Company [2011] UKSC 51

Imperial Chemical Industries Ltd. V. Commissioner of Patents (1986), 9 C.P.R. (3d) 289 (F.C.A.).

In re Bell, 991 F.2d 781 (Fed. Cir. 1993).

In re Bilski, 545 F.3d 943, 1013 (Fed. Cir. 2008)

In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990).

In re Duel, 51 F.3d 1552 (Fed. Cir. 1995).

In Re Fisher, 421 F.3d 1365 (Fed. Cir. 2005)

In re Marden 47 F.2d 958 (C.C.P.A. 1931)

In re Roslin Institute (Edinburgh) No. 2013-1407 (Fed. Cir. May 8, 2014)

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

In re Williams 80 U.S.P.Q. 150 (C.C.P.A. 1958)

J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001)

Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd. [2004] UKHL 46 (21 October 2004)

KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)

Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002)

Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc. 566 , 132 S.Ct. 1289, 101 USPQ2d 1961 (2012)

Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005)

Millar v. Taylor (1769) 98 ER 201.

Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902, 2004 SCC 34

Moore v. Regents of the University of California, 793 P.2d 479 (California 1990).

Oliver Brüstle v Greenpeace e.V., Case C-34/10, decision of 18 October 2011.

Parke-Davis and Co. v. H.K. Mulford and Co., 189 Fed. 95 (SDNY 1911) affirmed, 196 Fed. 496 (2nd Cir.1912).

Pioneer Hi-Bred Ltd. v. Commissioner of Patents (1987), 14 C.P.R. (3d) 491

Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents), [1989] 1 S.C.R. 1623

President and Fellows of Harvard College v. Commissioner of Patents, 1998.

President and Fellows of Harvard College v. Canada (Commissioner of Patents) (C.A.) [2000] 4 F.C. 528

Re Application of Abitibi Co. (1982), 62 C.P.R. (2d) 8

Re Application for Patent of Pioneer Hi-Bred Ltd, (1986) 11 C.P.R. (3d) 311

Re Motorola (1998), 86 C.P.R. (3d) 71, 76 (Patent Appeal Board)

Reeves Brothers Inc. v. Toronto Quilting & Embroidery Ltd. (1978), 43 C.P.R. (2d) 145. at 187 (FCTD).

Regents of the University of California v. Eli Lilly & Co. 119 F.3d 1559 (Fed. Cir. 1997).

Scripps Clinic and Res. Found. V. Genentech, Inc.; 666 F.Supp.1379, 3 U.S.P.Q.2d1481,1488 (N.D.Cal.1987)

Scripps Clinic and Res. Found. V. Genentech, Inc; 724 F. Supp. 690, 694 (N.D.Cal.1989)

Tennessee Eastman Co. v. Commissioner of Patents [1974] S.C.R. 111

T 0019/90(Onco-mouse) of 3 October 1990

T 666/05. Decision of the Technical Board of Appeal of the European Patent Office. November 13, 2008

T1213/05-3.3.04, Decision of the Board of Appeal of the European Patent Office. September 27, 2007

T 80/05-3.3.04. Decision of the Technical Board of Appeal of the European Patent Office. November 19 2008.

2 U.S.P.Q., 1427 [Board of Patent Appeals & Interferences 1987]

University of Utah Research Foundation et al. vs. Ambry Genetics Corporation. United States District Court of Utah, Case No.2:13-CV-00640-RJS. March 10, 2014.

Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd., [1985] RPC 59 (CA).

Glossary

This glossary provides the most recent definitions and is intended to provide a reference point for readers who may not be familiar with the following scientific terms.[1]

Deoxyribonucleic acid (DNA)

The genetic material of most living organisms, which is a major constituent of the chromosomes within the cell nucleus and plays a central role in the determination of hereditary characteristics by controlling protein synthesis in cells. It is also found in chloroplasts and mitochondria. DNA is a nucleic acid composed of two chains of nucleotides in which the sugar is deoxyribose and the bases are adenine, cytosine, guanine, and thymine. The two chains are wound round each other and linked together by hydrogen bonds between specific complementary bases to form a spiral ladder-shaped molecule (double helix). When the cell divides, its DNA also replicates in such a way that each of the two daughter molecules is identical to the parent molecule.

Ribonucleic acid (RNA)

A complex organic compound (a nucleic acid) in living cells that is concerned with protein synthesis. In some viruses, RNA is also the hereditary material. Most RNA is synthesized in the nucleus and then distributed to various parts of the cytoplasm. An RNA molecule consists of a long chain of nucleotides in which the sugar is ribose and the bases are adenine, cytosine, guanine, and uracil. RNA can associate with proteins to form complexes called ribonucleoproteins.

Messenger RNA (mRNA)

A type of RNA that carries the information of the genetic code transcribed from DNA to specialized sites within the cell (known as ribosomes), where the information is translated into protein composition.

Transfer RNA (tRNA, soluble RNA, sRNA)

A type of RNA that is involved in the assembly of amino acids in a protein chain being synthesized at a ribosome. Each tRNA is specific for an amino acid and bears a triplet of bases complementary with a triplet on mRNA.

Complementary DNA (cDNA)

A form of DNA prepared in the laboratory using messenger RNA (mRNA) as template, i.e. the reverse of the usual process of transcription in cells; the synthesis is catalysed by reverse transcriptase. cDNA thus has a base sequence that is complementary to that of

[1] The definitions in the glossary are provided by two dictionaries: (1) King, R., P. Mulligan and W. Stansfield. A Dictionary of Genetics (8 ed.) Oxford: Oxford University Press, 2014; and (2) Martin, E. & R. Hine. A Dictionary of Biology (6 ed.) Oxford: Oxford University Press, 2008.

the mRNA template; unlike genomic DNA, it contains no noncoding sequences (introns). cDNA is used in gene cloning for the expression of eukaryote genes in prokaryote host cells, or as a gene probe to locate particular base sequences in genomic DNA. cDNA molecules are inserted into plasmid or phage vectors to create cDNA libraries of expressed genes.

Gene

The definition of a gene has changed as advances in genetic analysis and technology have enhanced our understanding of its structure, function, transcription, and genomic organization. In the classical literature a gene is defined as a hereditary unit that occupies a specific position (locus) on a chromosome; a unit that has a phenotypic effect; a unit that can mutate to various allelic forms and that recombines with other such units in a genetic cross. With the elucidation of the molecular nature of DNA and information gained through the use of molecular biology and sequencing technologies (in the mid to late 1900s), the gene came to be viewed as a hereditary unit composed of nucleotide sequences (including 5′ and 3′ untranslated sequences and introns) that are required for the production of functional protein or RNA product(s). When a function (or phenotype) is unknown, a gene can be identified based on sequence characteristics, transcription, or homology to a known gene. More recently, the use of novel experimental and computational tools have uncovered extensive and overlapping networks of transcription (including noncoding RNA transcription) in humans and other organisms that pose challenges to defining a gene. For example, a gene can overlap another such that the same DNA sequence codes for two different products in different reading frames or on opposite strands; a noncoding RNA can be transcribed from the intron of, or antisense to a protein-coding gene; a gene can have multiple transcription start sites; and a gene can have distant regulatory regions or those it shares with other genes. Taking such findings into account, the following may be added to the evolving definition of a gene: genomic sequences that are required, in sequential or overlapping combinations, to produce one or more functional RNA or protein product(s) that contribute to a particular phenotype.

Gene probe (DNA probe)

A single-stranded DNA or RNA fragment used in genetic engineering to search for a particular gene or other DNA sequence. The probe has a base sequence complementary to the target sequence and will thus attach to it by base pairing. By labelling the probe with a radioactive isotope or fluorescent label it can be identified on subsequent separation and purification. Probes of varying lengths, up to about 100 nucleotides, can be constructed in the laboratory. They are used in the Southern blotting technique to identify particular DNA fragments, for instance in conjunction with restriction mapping to diagnose gene abnormalities or to map certain sequences.

Intron (intervening sequence)

A nucleotide sequence in a gene that does not code for the gene product. Introns, which occur principally in eukaryotes, are transcribed into messenger RNA (mRNA) but are

subsequently removed from the transcript before translation. In certain cases, removal of the introns is an autocatalytic process – self-splicing – whereby the RNA itself has the properties of an enzyme. Self-splicing occurs in primary transcripts of some single-celled organisms, such as Tetrahymena, as well as chloroplasts, mitochondria, and some viruses. However, splicing of primary transcripts produced in the nucleus generally requires the participation of a spliceosome, a complex of proteins and RNAs. The function of introns is still subject to lively debate. They may simply be sequences of selfish DNA, able to move between different loci within the genome with no benefit to the host. On the other hand, introns may act as 'spacers' for exons and facilitate alternative splicing to create distinct mRNAs from the same gene. Moreover, they could enable exon shuffling – recombination or rearrangement of exons encoding functional domains of proteins – which permits rapid evolution of proteins with novel permutations of functional groups. Introns have also been found in certain archaebacteria and cyanobacteria and in some viruses.

Exon

A portion of a split gene that is included in the transcript of a gene and survives processing of the RNA in the cell nucleus to become part of a spliced messenger of a structural RNA in the cell cytoplasm. Exons generally occupy three distinct regions of genes that encode proteins. The first, which is not translated into protein, signals the beginning of RNA transcription and contains sequences that direct the mRNA to the ribosomes for protein synthesis. The exons in the second region contain the information that is translated into the amino acid sequence of the protein. Exons in the third region are transcribed into the part of the mRNA that contains the signals for the termination of translation and for the addition of a polyadenylate tail.

Embryo

A rudimentary animal or plant in the earliest stages of development, produced by zygotic cleavages and dependent upon nutrients stored within the membranes that enclose it (e.g., those covering an egg or a seed). In humans, embryonic development begins with the first zygotic division and lasts until approximately the eighth week of gestation, when an embryo becomes a fetus. Early development in viviparous animals is sometimes divided into two distinct stages, pre-embryonic and embryonic, which are separated by the commencement of organ differentiation or by implantation. In humans, the cell mass resulting from zygotic cell divisions up to about the fourteenth day of gestation is called a pre-embryo, although the use of this term is controversial. The moral status of a human embryo is a major issue area, particularly in embryonic stem cell research and in in vitro fertilization, where surplus embryos may have to be destroyed.

Blastocyst

The mammalian embryo at the time of its implantation into the uterine wall.

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Chapter 1: Introduction

1.1. Background to the research

Patents have been in existence since the 1400s and their acceptance has been largely unquestioned other than in the field of modern biotechnology.[2] However, the issue of patentable subject matter has become a dilemma with the advance of genetic engineering. Queries on what comprises patentable subject matter generate a significant degree of ambiguity for inventors and would-be inventors of original and innovative products and processes. It would appear that in some areas of biotechnology research, the degree of patent protection is doubtful. One primary area of concern is how the law should address patenting human genetic materials. In particular, whether patents should be granted for DNA sequences and inventions derived from human embryonic stem cells (hESCs).

The patent system was primarily developed to accommodate mostly mechanical inventions and their needs during the age of industrialization.[3] Life sciences on the other hand, are inherently different.[4] It can be argued that inserting life science inventions into the traditional patent system that was created for an entirely different type of invention raises concerns about the appropriateness of the protective mechanism.[5] However, this thesis argues that the patent system is, in fact, appropriate in granting

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[2] Venetian Statute of 1474 and 1623 English Statute of Monopolies. Bently, L. & M. Kretschmer (eds.) Venetian Statute on Industrial Brevets, Venice (1474), Primary Sources on Copyright (1450-1900). www.copyrighthistory.org Accessed September 29, 2013. English Statute of Monopolies of 1623, 21 Jac. 1, c. 3, The Original Source of the Anglo-American Patent Law.

[3] "[N]ew technologies and business practices challenge the traditional paradigm of patent protection developed during the industrial revolution. Biotechnology…affects the functioning of the patent system as a regulatory institution." Max Planck Institute for Innovation and Competition. Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm. Accessed on April 15, 2014 at 2. For more information on how biotechnology and software claims have challenged the boundaries of patent law, see: Burk, D. "Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context" in Patent Law in Global Perspective R. Okediji and M. Bagley (eds.). Oxford: Oxford University Press, pp.187-212, 2014.

[4] Lemley, M. & D. Burk. "Policy Levers in Patent Law," in Virginia Law Review. Vol. 89, 2003 at 1581.

[5] Van Overwalle, G. "Patent Protection for Plants: A Comparison of American and European Approaches," in IDEA-Journal of Law and Technology. pp. 143-194, 1999.

protection for biotechnology inventions because it catalyses innovation and the dissemination of knowledge into the public sphere.

In some circumstances, biotechnology encompasses naturally occurring organisms, which if left to their own devices, can naturally develop without human intervention. Research in this area has the ability to benefit humans, animals, food security, and the environment. However, biotechnology also has the capacity to bring negative effects to the same areas as well, which will in turn generate large socio-eco-political transformations. Ethical, legal and social issues coupled with apprehension of the control of the agricultural and pharmaceutical industries raises an essential question: Should it be possible to patent a material that already exists in nature?

In the 1970s, developments in the biotechnological field challenged the patent system, which traditionally granted patents on mechanical inventions. Most international patent regimes were developed with this view in mind, and were not structured with the inclusion of living organisms. In recent years, there has emerged a conservative stance towards patenting life from those in the legal field. Eligibility issues arose, prompting patent office examiners and the judiciary to decide what subject matter qualified for patent protection, and what fell outside the realm of patentable subject matter.

Despite the existence of patent office guidelines regarding biotechnological inventions, issues and debates continue to persist, which raises the question: are they the same as other mechanical inventions?[6] One of the aims of this thesis is to demonstrate

[6] Biotechnology and its relationship with the law has been a controversial topic both in the public sphere and in academia. John Sulston, a Nobel laureate for his work in genetics and noted contributor in the Human Genome Project advocates keeping information accessible for future research and development. Sulston, J. & G. Ferry. The Common Thread: Science, Politics, Ethics and the Human Genome. Great Britain: Bantam Press, 2003.p 108: "It is still permissible to patent a gene sequence as long as you can show how it might be used to diagnose diseases, for example. In the end the issues are being decided not on principled grounds, but according to which side has the most money to spend on lawyers. One of the aims of the Human Genome Project has been to 'raise the bar' by making as much genome information as possible universally available in the public domain and therefore unpatentable."

that although the nature of biotechnological creations is different from that of mechanical ones, they should continue to be accommodated in the patent system.

The protection of products created from biotechnology is a question of intense debate because it challenges traditional property law ideologies.[7] One concern is that granting a patent for human genes permits the possession of human genetic information.[8] Gene patents are granted on the basis of purification and isolation techniques which are considered to qualify as 'inventions' and justify patent protection upon satisfying other patent requirements including utility, non-obviousness and industrial applicability. However, some commentators have argued that isolating and purifying a gene is not as important as the information a gene carries.[9] There are two prevalent views on isolated genes. First, there is the argument that genetic information remains unaltered after the isolation and purification process and as a result, gene patents actually protect discoveries, which contradicts the patent system. Conversely, the opposing view maintains that a genetic change has been made once a gene has been isolated and purified and thus, is different from its naturally occurring counterpart. It appears the gene patent debate ultimately depends on whether human genetic information can be owned and if it can, how the law should construct the qualifications for this ownership.

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[7] Nwabueze, R. Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information. England: Ashgate Publishing Limited 2007. Nwabueze claims biotechnology inventions challenges traditional patent law, as demonstrated by questions over whether human body parts, cell lines and human genes are patentable subject matter and should be categorized as 'property.'

[8] Ontario Report to Premiers, Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare. (Toronto: Ontario Government, 2002).

[9] World Health Organization, Genomics and World Health (Geneva: WHO, 2002) at 136:

> It is argued that a normal or abnormal gene sequence is, in effect, naturally occurring information which cannot therefore be patentable. The counter-argument which has been widely used by patent lawyers, that DNA sequence identification is a form of purification 'outside the body,' and therefore analogous to the purification of naturally occurring pharmacological agents, is specious; the DNA molecule is not, in this context, important as a substance and its value resides in its information content.

Below four initial topics are considered. First, a brief summary will be provided of the significance and scope of the thesis. This will be followed with the hypothesis and research questions. Then the research methodology will be discussed. Finally, this chapter will end with a brief summary of the contents of the remaining five chapters of the thesis.

1.2. Significance and scope of this study

The current discussion over the propertization of human genetic materials advances two mutually exclusive outcomes: (i) one in which the special nature of genetic material means that the existing intellectual property regime is an unsuitable protection mechanism, and as a result, all human genetic materials should be excluded from patent protection and be placed in the public domain and (ii) maintenance of the current status quo, in which any kind of human genetic material is eligible for patent protection. From these two opposing positions, it is generally believed that only one can exist,[10] and until recently, it seems that all human genetic material was considered patentable subject material, bar human embryos in Europe on the basis of morality and *ordre public* considerations.

The significance and originality of this research lies in integrating the normative and empirical scholarship in relation to isolated genes and inventions derived from human embryonic stem cells in order to create policy recommendations in the United States (US) and Europe.[11] The discussion over the protection of human genetic inventions has become a subject of fierce debate among various groups in society, who possess markedly different stances on an appropriate system of intellectual property right (IPR) protection (if at all) for genetic inventions. Over the years, the focus has

[10] Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain Parts 1&2" in Columbia-VLA Journal of Law & the Arts. Vol. 18, pp.1-69, 1993-1994. "How do we decide to treat ideas, inventions and information issues under either an open access policy or, alternatively, a proprietary system?" at 10.

[11] "Europe" refers throughout this thesis to the Contracting States of the Convention on the Grant of European Patents, opened for signature October 5, 1973, 13 I.L.M. 268. The European Patent Convention [hereinafter EPC] was signed on October 5, 1973 and entered into force October 7, 1977.

been on the substantive requirements, resulting in decreasing attention regarding the question of eligibility pertaining to the patenting of modern biotechnology. In bypassing the question of eligibility, two divergent approaches to patenting biotechnology have emerged. Firstly, the US has continued to rely on the biology-chemistry analogy in deciding on questions related to biotech patents. This can be demonstrated in the substantive requirements of patentability, particularly regarding the concepts of inventiveness and enablement.[12] There is a different approach in Europe, where the focus is not on eligibility in regards to biotech subject matter *per se*, but on the patentability requirements.

As biotechnology has progressed, objections have been raised from religious and public interest groups grounded in moral and ethical arguments.[13] However, these concerns have less to do with patent law than with drawing the proper ethical boundaries on scientific advancement. In some instances, the courts, legislators and patent offices have attempted to address some of the issues.[14] Some legislators have developed legal instruments to provide some answers, such as the *Directive 98/44/EC for Biotechnological Inventions* (Directive 98/44/EC). Although there are ethical and moral questions involved in the production of naturally occurring entities, they require further political and social dialogue and it is up to other organizations like the legislature exclusively assigned to address such issues.[15]

It is important to note the limitations of this study, which does not attempt to attend to all issues relating to patents and human genetic materials, of which there are many. The study is limited to an examination of isolated genetic sequences and hESCs.

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[12] See *In re Duel*, 51 F.3d 1552 (Fed. Cir. 1995), *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993), *Amgen Inc. v. Chughai Pharmaceutical Co., Ltd*., 927 F.2d 12000 1203 (Fed. Cir. 1991)

[13] For a discussion on the effects of patents on the related aspects of ethics and justice, see: Evangelischen Kirche in Deutschland (EKD). The Earth is the Lord's and all That is in It: Biopatents and Food Security from a Christian Perspective. April 2013. www.ekd.de. Accessed April 30, 2013.

[14] E.g., see *Oliver Brüstle v Greenpeace e.V*., Case C-34/10, decision of 18 October 2011.

[15] The moral considerations add a further dimension to the complex subject, which are beyond the parameters of this thesis, but the main policy issues will be addressed briefly in the thesis.

It should be noted that there are several other issues related to the discussion of IPRs for biotechnology patents in industrialized countries. As the research will demonstrate, one of the by-products of this thesis is some consideration of morality and ethics. In view of the broad nature of these topics and the need to discuss a number of themes in depth, the thesis does not discuss the morality and ethics of patenting human genetic materials unless they inform public policy.[16]

1.3. Hypothesis and research questions

This thesis sets out to test the proposition that the current statutory regime governing the patent protection of human genetic materials creates property rights without consideration of the public interest. In order to examine this hypothesis, this thesis evaluates the key question:

Does the recognition of genetic sequences as property serve the public interest?

In answering this primary question, the following secondary questions are addressed:

(i) Whether gene patents create a *de facto* tragedy of the anti-commons?

(ii) Can a temporary exclusive right over human genetic materials be justified?

(iii) How have Europe and the US addressed human genetic materials in determining patent eligibility and the scope of protection?

(iv) Do the current statutory regimes in Europe and the US need to be amended in the name of the public interest with regards to human genetic inventions?

1.4. Methodology

The methodology adopted for this research employs both theoretical and empirical data. First, the theoretical framework of the study involves an analysis of relevant legislation, statutes, case law and academic legal literature. Specifically, the study involves an extensive literature review on the legal development of patenting

[16] Ethics is touched upon in 4.4.3 (i.e. the proper scope of Article 53(a) EPC), but an in depth discussion is beyond the scope of the thesis.

human biological materials and underlying policy rationale, as well as considering several key aspects of international agreements such as the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (WTO/TRIPS)[17] and the Directive 98/44/EC.[18] The research also involves data from NGO reports, governmental reports and print sources.

To obtain a greater comprehensive landscape of the complexities and contended underlying problems of applying patent protection for human genetic materials and produce a solution, this thesis employs an empirically-based data set to assess the legal issues. One of the qualitative research techniques employed includes a comparative analyses of relevant case law in Europe and the US to identify the differing substantive legal principles/solutions adopted by the three jurisdictions that provide for the same legal problem.[19] Moreover, a comparative legal analysis is employed to raise awareness of foreign laws, jurisprudence and scholarly views to provide the necessary perspective of significant legal norms and legal settings which occurs external to respective national systems.[20] The data set also consists of interviews with key stakeholders including research entities, intellectual property lawyers, academics, the judiciary, biotechnology companies, religious figures, and key individuals from civil society who were able to provide comment on the range of issues.[21]

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[17] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

[18] 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

[19] These two jurisdictions were chosen on the basis that they are biotechnology-rich and embody most of the relevant case law. "Experience shows that this is best done if the author first lays out the essentials of the relevant foreign law, country by country, and then uses this material as basis for critical comparison, ending up with the conclusion about the proper policy for the law to adopt which may involve a reinterpretation of his own system." Zweigert, K. and H. Kötz. An Introduction to Comparative Law. Oxford: Clarendon Press, 1992 at 6.

[20] Calboli, I. "The Role of Comparative Legal Analysis in Intellectual Property Law: From Good to Great?" in Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, 2013 at 28. The author maintains that intellectual property scholars who do not engage in a minimal level of comparative analysis will likely neglect significant insights and alternative perspectives.

[21] In qualitative samples, there is a point of diminishing return in that more data does not necessarily mean more information. Ritchie, J. et al. Qualitative Research Practice. 2nd edition. Los Angeles, Sage

After receiving the ethics approval from Queen Mary University of London to conduct interviews, a preliminary list of the names of potential participants was made. This list included representatives who possessed knowledge of the issues surrounding patenting isolated genes and hESCs, such as scholars who have written extensively in the subject area, speakers at conferences who have presented on the topic,[22] and experienced practitioners working with patents in the biotechnology and pharmaceutical fields. The participants were invited to take part in interviews via email.

In order to undertake the initial interviews, preliminary contact was made with the stakeholders and formal letters were presented for signatures of consent, along with a copy of the questionnaire about the relevant case study and the list of questions to be asked at the interview. Using two separate case studies and interviews as data sources, the study explores the different dimensions of argument of the stakeholders' approach towards either patenting genes or hESCs. The interviews took place in London, Munich, Edinburgh and Geneva between February and June 2012. In addition, 11 of the 37 interviews took place via email as a face-to-face meeting was not feasible.[23] The interviewees were divided into three groups: (i) inventors, investors and the scientific/research community; (ii) legal actors and (iii) civil society.

In the legal sector, 30 representatives were asked to be interviewed and 20 agreed to participate, while 13 declined. 10 of the participants were from the United Kingdom, 4 of them were with patent attorneys, 1 with an experienced solicitor, 2 with barristers, 1 with a retired senior judge and 2 with law professors. 3 interviews took place in Germany composed of 2 experienced lawyers and 1 judge from the European Patent Office Enlarged Board of Appeal. 3 interviews took place with international

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Publications Inc., 2014. "There is therefore a point of diminishing return where increasing the sample size no longer contributes new evidence." P.117.

[22] For instance, after attending the panel discussion which took place at the University College London's Law Faculty entitled "Brüstle v Greenpeace: Has the European Court seriously damaged stem cell research?" February 1, 2012 the three panelists were invited to take part in the study: Dr. Justin Turner, Professor Pete Coffey, and Professor Jo Wolff. All three individuals accepted the invitation.

[23] Interviews are on file with the author and bound by confidential terms.

policy makers in Geneva from WIPO and the WTO. From the United States, 3 interviews took place with experienced patent attorneys and solicitors. Finally, 1 law professor from the Netherlands also participated.

From the biotechnology and research sector, 30 individuals were invited for an interview, but only 7 accepted. These participants were all based in the UK. This included 1 interview with a large pharmaceutical company and 1 interview with a biotechnology firm, both of which are particularly engaged with the patenting isolated genes and hESCs discussion. 5 interviews were with scientists from research institutes. From the civil society sector, 30 representatives were invited for an interview and 10 agreed to participate in the study. 2 interviews were conducted in Germany with representatives from 2 different NGOs. In the UK, 6 interviews took place with 3 professors with expertise in law and ethics, 2 council members from the Nuffield Council on Bioethics, and a director of an ethics consultancy firm. 2 interviews took place in Geneva with representatives from 2 separate NGOs.

There were a total of 37 interviews, 20 from the legal community, 7 from the biotech and research community, and 10 from civil society.[24] The interviewees who agreed to participate had the option of speaking under the condition of anonymity or be attributed. Whilst efforts to ensure that a balanced number of representatives from all three of these groups took place, it is important to note that many more representatives from the legal sector positively agreed to an interview than from the biotechnology and civil society sector. The reason for the prominence of the legal sector in terms of the number of interviewees is that invitees from this sector of society tended to reply more positively and quickly to the invitation than invitees in the other two sectors.

90 invitations were sent out via email to individuals requesting their participation in this study, but as there were only 37 acceptances, this means that 53

[24] See Annex V for a table of interviewed stakeholders.

individuals declined the invitation to be interviewed. The most common explanation provided was that an individual was too busy and did not have time to spare for an interview. In addition, whilst some individuals expressed interest in participating, they explained that they were in positions of power which did not permit them to express their personal opinions on the issues at hand. For example, one judge tentatively agreed in preliminary email exchanges to an interview, but regrettably declined in the end explaining that he was unable to obtain approval from his chambers.

It is also worth noting the limits of the methodology. It is acknowledged that there are many stakeholders throughout the developed world including Canada,[25] Australia[26] and Japan.[27] However, due to the necessity of undertaking empirical research within the jurisdictions featured in the study within a reasonable time frame, the study is expressly limited to the jurisdictions of Europe and the US.[28] Furthermore, given the diversity of views on the issue of patents and human genetic materials, the qualitative study cannot claim to construct a definitive declaration on the topic. There are significantly more legal stakeholders represented in the study compared to industry stakeholders. It is arguable that only those scientists and researchers who had an interest in patent law would have been willing to take time out to complete the questionnaire or agree to an interview.

Moreover, there were significantly less US participants than UK and EU participants. Unfortunately, due to time and financial restrictions, it was not possible to travel to the US. It was suggested to the list of US individuals that a Skype interview

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[25] Canadian Biotechnology Advisory Committee. Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee. June 2002. www.publications.gc.ca/collections/Collection/C2-598-2001-2E.pdf. Accessed May 27, 2012.

[26] Australia Government. Genes and Ingenuity Report: Gene Patenting and Human Health. Australia Law Reform Commission. Report 99, June 2004.

[27] Penner-Hahn, J. & J. Shaver. "Does international research and development increase patent output? An analysis of Japanese pharmaceutical firms" in Strategic Management Journal. Vol. 26, no. 2, pp.121-140, 2005.

[28] "Here sober self-restraint is in order, not so much because it is hard to take account of everything as because experience shows that as soon as one tries to cover a wide range of legal systems, the law of diminishing returns operates." Zweigert, K. and H. Kötz at 39-40.

could take place. While some participants agreed to a Skype interview, many individuals in the US declined. In contrast, most of the interviews conducted in the UK and Europe involved a personal visit to the participant's choice of venue, which usually involved his or her place of work. This may account for why there were more positive responses from the European stakeholders than from the US.

The inventors, investors, scientific/research community and the legal stakeholders were asked questions regarding the US Federal Circuit decision in *Association for Molecular Pathology vs. United States Patent and Trademark Office et al.* [29] (see Annex I). The questionnaire consisted of:

- A general set of introductory questions regarding patents
- Technical questions pertaining to isolated genes
- Questions on their view on the impact of gene patents on innovation

The civil society interviewees were given a separate questionnaire in response to the Court of Justice of the European Union (CJEU) decision in *Oliver Brüstle v Greenpeace e.V*[30] (see Annex II). The questionnaire consisted of:

- A set of introductory questions pertaining to their views on the patentability of inventions derived from human embryonic stem cells
- Questions requesting their views on patenting genetic information and genetically modified organisms[31]
- Policy-decision making questions

[29] *Association for Molecular Pathology v United States Patent and Trademark Office et al*. 2010-1406. United States Court of Appeals for the Federal Circuit. Decided August 16, 2012.
[30] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011.
[31] The questionnaire for the civil society stakeholders featured questions pertaining to genetically modified organisms, but this was deemed to be beyond the scope of the thesis.

1.5. Structure of the thesis

This thesis proceeds by way of five steps to sustain the hypothesis, which correspond with the five main chapters.

Chapter 2

Chapter 2 provides the context to the thesis by focusing on the relationship between patents and biotechnology inventions. It analyses the development of biotechnology and noteworthy inventions in the field. This is followed by an introductory explanation of the relevant science followed by a discussion of the anti-commons theory, its main tenets, implications on innovation in respect to gene-related research tools, and some practical limitations of the theory.

Chapter 3

Chapter 3 explores the concept of patents as a social contract between the inventor and society. In particular, it emphasizes the social function of intellectual property and how on balance, the temporary propertization of genetic resources is socially beneficial to the public. It also considers the nature of patent protection and argues that it forms an essential part of societal infrastructure that underpins research and development. Theoretical arguments are examined for patenting genetic materials by analysing the concept of property and the relevant justification theories of granting patents. It also places the current debate about the appropriate scope of protection within a broader discussion of how innovation can promote societal good.

Chapter 4

Chapter 4 undertakes a comparative legal analysis of the current status of isolated DNA sequences and human embryonic stem cell patents in Europe and the US as reflected in case law. The main part of this chapter focus on the legal development of doctrines used to differentiate between a ‘discovery’ and an ‘invention,’ particular that of the ‘product of nature’ doctrine in the US and the meaning of ‘technical effect’ in

Europe. The chapter also undertakes a comparative analysis of how Europe and the US have addressed Myriad Genetics' BRCA1 and BRCA2 patents in the context of patent eligibility vs. patentability requirements.

Chapter 5

Chapter 5 presents the empirical data gathered from stakeholder interviews to gather a practical perspective on whether the current status quo in patenting human genetic materials is satisfactory and if not, what can be done to maintain the social contract.

Chapter 6

Chapter 6 concludes the thesis delivers a draft manifesto of policy recommendations that are applicable to Europe and the US. The policy recommendations entail the consideration of public interest values as articulated through the empirical research.

Chapter 2: Patent Protection of Biotechnology Inventions

2.1. Introduction

In recent years, the argument that patents act as incentives to stimulate innovation in biotechnology has been criticized. In particular, there is the notion that gene patents create a *de facto* tragedy of the anti-commons. This, in turn, is based on a wider belief that the current statutory regime governing the patent protection of human genetic materials creates expansive property rights,

> "[B]asic genetic information in the human genome is simultaneously so commonplace and extraordinarily important that the question of patentability is just that, an open and unanswered policy question which should not be automatically answered by recourse to the doctrinal structures of patent law (which contain a strong bias in favor of rewarding entrepreneurial inventors with exclusive rights)…The idea of inventorship needs to be re-examined through a much more 'informationally-egalitarian' lens."[32]

How biotechnology research should be protected is a major concern due to its increasing economic value[33] and the extent to which biological materials should be protected by the patent system raises ethical, legal, religious and policy questions.[34] In Europe, patents for monoclonal antibodies, cells lines, isolated genes and human embryonic stem cells have been challenged in court and encounter tremendous opposition from society.[35]

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[32] Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain- Part II" in Columbia-VLA Journal of Law & the Arts. Vol. 18, Issues 3 & 4, 1993-1994 at 234.

[33] OECD. Future Prospects for Industrial Biotechnology. OECD Publishing, (2011). The European Commission maintains biotechnology significantly contributes to the modernization of European industry. "Its broad range of high-tech applications is increasingly playing a role in enhancing our competitiveness, raising economic growth and improving the welfare of European citizens." European Commission. The Contribution of Biotechnology to Europe's Industry Sectors. May 2, 2013. http://ec.europa.eu/enterprise/sectors/biotechnology/what-is-biotechnology/contribution/. Accessed June 14, 2013.

[34] See for example, the Canadian Supreme Court decision invalidating Harvard College's oncomouse patent, declaring 'higher life' organisms ineligible subject matter for patent protection. Harvard College v. Canada (Commissioner of Patents) [2002] 4 S.C.R. 45, 2002 SCC 76

[35] In 2011, the CJEU proclaimed that all inventions where the use of human embryos which involves their destruction at some point in the past cannot be patentable on the basis of immorality in *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011. "Accordingly, even inventions using 'off the shelf' stem cells derived, at some point, from the destruction of a human embryo, are unpatentable. The chilling effect of this decision on stem cell research remains to be seen, but is likely to be significant." Jacob, R., D. Alexander and M Fisher. Guidebook to Intellectual Property-6th edition. Oregon: Hart Publishing, 2013 at 37.

One of the most challenging dilemmas facing the proprietors and would be inventors of biological inventions is the incapacity of the law to react quickly enough to match the stride of technological developments.[36] The capacity to secure a property interest for an invention and to safeguard the claimed expertise is recognized as offering an important incentive for the private sector to invest time and financial resources to perform the necessary research and development and bring the product or process to market. Lacking this power to prevent third parties from appropriating the products of the previous research and development (R&D), numerous new endeavours which could spearhead other significant products would not be commenced.[37]

This chapter of the theses explores the development of biotechnology. It then briefly discusses the scientific background of DNA, RNA, cDNA, and how genes are both chemicals and carriers of information. The chapter then explores the theory of the anti-commons, its main assertions, potential implications on the biotechnology field, and practical limitations of the theory.

[36] The field of biotechnology has expanded and developed at a swift rate, where a combination of technologies including genetics, microbiology, engineering, biochemistry and bioinformatics has emerged. Through the creation of new living organisms, biotechnology can have a significant impact on numerous fields including the pharmaceutical industry, agriculture, the environment, and the food and beverage industry. In 2009, the U.S. Food and Drug Administration allowed the first human biological drug ATryn, which was created from a goat. The drug was developed from goat's milk, and acts as an anticoagulant, which reduces the likelihood of blood clots. Modified animals are also suitable for research on genes linked to diseases. There are also a number of proteins that have come on the market in the last 30 years, one of which is insulin. These are called biopharmaceuticals (protein-based drugs) and are manufactured by genetic engineering processes, inserting the gene into bacteria, which mass produces the protein for which it codes. Biotechnology also has an extraordinarily powerful market. The amount of money spent on investment in biotechnology research and development (R&D) by the corporate sector within a jurisdiction is a reflection of its research emphasis on biotechnology. The United States is the highest-spending country on biotechnology BERD (business enterprise research and development), totalling USD 22 030 million in PPP (purchasing power parity), accounting for 7.6% of the total US BERD. Comparatively, some European countries spent more in BERD than the US. For instance, Ireland spent the most as a percentage at 15.1%, and Switzerland and Belgium tied for second place at 12.6%. OECD. OECD Fact book 2011-2012: Economic, Environmental and Social Statistics. OECD Publishing. 2011 at 184-185.

[37] Commercial Biotechnology: An International Analysis (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984) at 383.

2.2. What is biotechnology?

Biotechnology is one of the fastest growing technical disciplines even though it is the youngest of the sciences.[38] It is an amalgamation of a number of fields in the broader subject of biology and is known as a revolutionary science because of the rapid pace of information gain which surpasses human ability to keep up with the understanding of functional products and processes in society.[39] In 1919, Károly Ereky, a Hungarian engineer first used the term[40] to express the industrial production of pigs, whereby sugar beets were fed to the pigs as an affordable major source of nutrients. Ereky then applied the term to other industrial fields where raw materials combined with the use of organisms are used to create commercial products.[41]

There are various definitions of "biotechnology" today. Robert Bud[42] maintains that the best-known definition today is that of the Organization for Economic Co-operation and Development (OECD), which defines biotechnology as:

> The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.[43]

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[38] Between 2006-2010, the number of worldwide biotechnology patent applications experienced a growth rate of 3%. In 2010, 36,362 patent applications were filed. World Intellectual Property Organization. World Intellectual Property Indicators, 2012 Edition. WIPO Economics & Statistics Series. Section A: Patents, Utility Models and Microorganisms at 72. http://www.wipo.int/ipstats/en/wipi/. Accessed July 24, 2013.

[39] Shmaefsky, B. Biotechnology 101. London: Greenwood Press, 200 at 1.

[40] Ereky, K. Biotechnologie der fleisch, fett und milcherzeugung im landwirtschaft- lichen grossbetriebe Biotechnology of Meat, Fat and Milk Production in an Agricultural Large-Scale Farm (English translation) Berlin, 1919.

[41] Fiechter, A. (Ed.) History of Modern Biotechnology I. Berlin, Springer, 2000 at 153.

[42] Bud, R. The Uses of Life: A History of Biotechnology. Cambridge: Cambridge University Press, 1993 on the OECD's definition of biotechnology at 1: "This may be all-encompassing, yet despite many attempts at refinement, all such short expressions inadequate."

[43] The Organization for Economic Co-operation and Development (OECD) provides two definitions of biotechnology: a single definition and a list-based definition. The OECD's single definition of biotechnology is deliberately broad, encompassing all aspects of modern biotechnology which also includes traditional activities. The OECD's list-based definition includes a catalogue of biotechnology techniques that functions as an interpretive guide to the single definition which includes: DNA/RNA, proteins and other molecules, cell and tissue culture and engineering, process biotechnology techniques, gene and RNA vectors, bioinformatics and nanotechnology The list-based definition of biotechnology techniques include:
DNA/RNA: Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.
Proteins and other molecules: Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signalling, identification of cell receptors.

Other definitions include:

> "The exploitation of biological processes for industrial and other purposes, especially the genetic manipulation of microorganisms for the production of antibiotics, hormones, etc."[44]

> "Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.[45]
> The use of living things to make products."[46]

> "The use of living organisms or parts of living organisms to provide new methods of production and the making of new products."[47]

> "Any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or develop micro-organisms for specific purposes."[48]

> "The application of molecular and cellular processes to solve problems, conduct research, and create goods and services."[49]

There seems to be a shared feature with all the definitions, and that is the idea of applying scientific or technical knowledge to living material to create a new product. Therefore, one could define biotechnology as the application of a technical process to living matter to provide a new method or to make a new product. This definition is the one that will be used in the thesis.

2.2.1. Development of Biotechnology

During the ancient and classical biotechnology period, traditional methods such as fermentation and the domestication of plants and animals emerged.[50]

Cell and tissue culture and engineering: Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.
Process biotechnology techniques: Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation.
Gene and RNA vectors: Gene therapy, viral vectors.
Bioinformatics: Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology.
Nanobiotechnology: Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.
OECD. "Biotechnology" in OECD Fact book 2011-2012: Economic, Environmental and Social Statistics. OECD Publishing. 2011.

[44] Stevenson, A. (Ed.). "Biotechnology." Oxford Dictionary of English. www.oxfordreference.com. Accessed July 9, 2013.

[45] United Nations. Convention on Biological Diversity (1992) Article 2, p 3. www.cbd.int/convention/articles.shtml?a=cbd-02. Accessed July 9, 2013.

[46] The American Association for the Advancement of Science. http://ehrweb.aaas.org/ehr/books/glossary.html#biotechnology. Accessed July 22, 2013.

[47] Health Canada. Biotechnology.www.hc-sc.gc.ca. Accessed July 22, 2013.

[48] Commercial Biotechnology: An International Analysis (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984) at 33.

[49] The U.S. Commerce Department, A Survey of the Use of Biotechnology in U.S. Industry. November 2003 at 3. http://www.bis.doc.gov/. Accessed July 22, 2013.

"Modern biotechnology" refers to newer developments arising from biotechnology like genetic engineering.[51] There appears to be a common denominator amongst the various periods of biotechnology, which is the use of living or biological material to create new products. The earliest forms of biotechnology involved using microorganisms to make food like cheese and yoghurt, and alcoholic beverages like beer and wine through the process of fermentation. Before modern genetic engineering emerged, biological matter and processes were already recognized as patentable in the 19th century. The first patent for a living organism was granted on November 8, 1843 in Finland for a new method for producing yeast cultures.[52] Thirty years later, Louis Pasteur's isolated yeast was granted US Patent No. 141,072. The claim included a "[y]east, free from organic germs of disease, as an article of manufacture."[53] Pasteur's yeast brought biotechnology into the sphere of patenting. It was also the first patent on a microorganism. It would take over a hundred years for the second microorganism to be awarded a U.S. patent, due to the prominence of the 'product of nature' doctrine as determined in 1889 in *Ex Parte Latimer*.[54]

2.2.2. Biotechnology today

The term "biotechnology" is used interchangeably with "modern biotechnology," specifically pertaining to: genetics, vaccines and antibiotics, recombinant DNA, transgenics, the Human Genome Project, cloning and monoclonal antibodies. In the last fifty years, there have been many strides in the field of biotechnology, from James Watson and Francis Crick's discovery of the DNA

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[50] For a brief introduction of the history of biotechnology, see Ashish, S. et al. "Biotechnology in the Realm of History," in Journal of Pharmacy &Bioallied Sciences. Vol. 3, Iss.3, pp. 321–323. Jul-Sep 2011 and Bud, R. The Uses of Life: A History of Biotechnology. Cambridge: Cambridge University Press, 1993.
[51] Canadian Food Inspection Agency. http://www.inspection.gc.ca. Accessed July 22, 2013.
[52] Wilkinson, S. Bodies for Sale: Ethics and Exploitation in the Human Body Trade. London: Routledge, 2003 at 192.
[53]US Patent 141,072, claim 2 (July 22, 1873)
[54] Refer to section 4.3.3 for further discussion on 23 *Ex parte Latimer*, 1889 Dec. Com. Pat. 123.

structure in 1953,[55] Stanley Cohen and Herbert Boyer's discovery of recombinant DNA in 1973,[56] sheep cloning,[57] to discovering genes related to breast cancer.[58] Most notably, genetic engineering comes to mind, which encompasses changing the genetic code of cells by purposely altering individual genes through insertion or removal activities.[59] These techniques allow scientists to create organisms which are specifically designed with unique genes and physical traits, like the production of human insulin by Genentech in 1978.[60] The following illustrates some key inventions in modern biotechnology.

A. Cloning of genetically engineered molecules

When Herb Boyer and Stanley Cohen developed the recombinant DNA technique in 1973, it paved the way for scientists to alter the genetic makeup of animals and humans in the lab.[61] Their technique allowed foreign genes to be inserted into microorganisms, creating new organisms with unique genes. Patents for Boyer and Cohen's method of gene cloning and expression were granted to Stanford University. [62] Cohen and Boyer's invention formed a foundational tool for genetic engineering but became a topic of public debate in the 1970s as recombinant DNA stirred up controversy amongst many groups. One of the main criticisms was that genetic

[55] Pray, L. "Discovery of DNA structure and function: Watson and Crick" in Nature Education. Vol. 1, Iss. 1, 2008.
[56] Russo, E. "Special Report: The Birth of Biotechnology" in Nature. Volume 421. pp. 456-457, January 2003.
[57] Park, A. "The Perils of Cloning" in Time Magazine. July 5, 2006. www.time.com. Accessed July 23, 2013.
[58] Angier, N. "Fierce Competition Marked Fervid Race for Cancer Gene" in New York Times. September 20, 1994. www.nytimes.com. Accessed July 23, 2013.
[59] Karp, L. Genetic Engineering: Threat or Promise? Chicago: Nelson-Hall, Inc., 1976.
[60] Goeddel, D. et al. "Expression in Escherichia coli of chemically synthesized genes for human insulin" in Proceedings of the National Academy of Sciences. Vol. 76, No. 1, pp. 106-110, January 1979.
[61] Hughes, S. Genentech: The Beginnings of Biotech. Chicago: The University of Chicago Press, 2011.
[62] Prior to the expiration of the patents in 1997, Stanford granted 468 licenses to use the technique for commercial purposes. These licenses generated more than US$255 million in licensing revenues for the university and led to the development of over 2400 commercial products with cumulative sales above $25 billion. See Feldman, M., A. Colaianni and C. Liu. "Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program" in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices. A. Krattiger et al (eds.) MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. 2007. Available online at www.ipHandbook.org. Accessed March 21, 2014.

engineers could speed up evolution and alter the makeup of humanity.[63] However, the debate was metaphorically decided in 1980 with the US Supreme Court ruling in *Diamond v. Chakrabarty,*[64] which opened the floodgates to patenting living organisms by holding an oil-eating bacterium as patentable subject matter.[65] The decision paved the road for the Cohen-Boyer patent which claimed a fundamental research technique with a tremendous capacity to develop into a platform technology that effectively developed a new standard in biotechnology.

B. Chakrabarty's oil-eating bacterium

The US Supreme Court was faced with the question of granting patents on living matter in *Diamond v. Chakrabarty* and ultimately held that patentable subject matter includes "anything under the sun that is made by man."[66] But the Court added that this statement did not include every type of discovery, which included "the laws of nature, physical phenomena and abstract ideas."[67] The decision essentially reversed an extended custom of legal decisions in holding products of nature ineligible subject matter for patent protection and had a large impact on patent policy and thought around the world.[68] As a result, the patenting in all areas of technology increased, including the patentability of products created from recombinant DNA: "By virtually every measurable factor, the biotechnology industry has literally exploded in the 25 years since Chakrabarty."[69] Even though Chakrabarty had not used recombinant DNA techniques in making his bacteria, some scientists who created hybrids from recombinant DNA techniques had applied for patents before a decision on Chakrabarty

[63] Hughes, S. Genentech: The Beginnings of Biotech. Chicago: The University of Chicago Press, 2011.
[64] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
[65] Ibid.
[66] Ibid.
[67] Ibid.
[68] Drahos, P. "Biotechnology Patents, Markets and Morality," in E.I.P.R. Iss. 9, 1999 at 442.
[69] Robinson, D. and N. Medlock "Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents" in Intellectual Property & Technology Law Journal. Vol. 17, No. 10, October 2005 at 13.

had been made.[70] Companies and research programs working with recombinant DNA were looking towards the outcome in *Chakrabarty*, which would set the precedent for the patentability of their own work. "[T]he patentability of living organisms-spoke directly to the rapidly increasing stake in biotechnology patents."[71] With the advent of recombinant DNA, scientists began to manipulate living organisms, and the patent system responded by granting patents. [72]

C. The Harvard oncomouse

In 1984, Harvard University filed a patent application on behalf of Philip Leder of Harvard University, and Timothy A. Stewart of Genentech, the inventors of the oncomouse.[73] DuPont owned the patent rights until recently as the US patent expired in 2005. In 1988, the United States Patent and Trademark Office (USPTO) granted Harvard the patent.[74] The patent claim included:

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[70] Wilson, J. "Patenting Organisms: Intellectual Property Law Meets Biology," in Who Owns Life? D. Magnus, A. Caplan & G. McGee (eds.). New York: Prometheus Books, 2002 at 25.

[71] Kevles, D. "Of Mice & Money: The Story of the World's First Animal Patent" in Daedalus. Spring 2002 at 80.

[72] Data assembled by the Biotechnology Industry Organization showed that in 1989, the USPTO granted 2,160 biotechnology patents compared to the significant rise to 7,763 in 2002. "Biotechnology Industry Facts." June 9, 2005 available at www.bio.org/speeches.pubs/er/statistics.asp. Accessed November 3, 2013.

[73] The oncomouse is a genetically modified mouse that carries an activated 'oncogene' and had the potential to be useful for testing new drugs for cancer research. Mice have very short life spans, and contain many of the same genes as humans. Leder and Stewart inserted the oncogene sequence into a fertilized mouse egg, and then implanted the mouse egg into a female mouse. Once the gene was activated, the mouse's vulnerability to cancer in the mammary glands increased. The offspring carrying the oncogene sequence would then be susceptible to developing cancer. See Crespi, S. "Biotechnology Patenting: The Wicked Animal Must Defend Itself," in European Intellectual Property Review. Vol. 17, Iss.9, pp. 431-441. 1995 and Kevles, D. "Of Mice & Money: The Story of the World's First Animal Patent" in Daedalus, pp. 78-88, Spring 2002. Schneider, K. "Harvard Gets Mouse Patent, A World First" in New York Times. April 13, 1988.

[74] A year before the oncomouse was granted a patent in the US, it had already been established that a living animal was patentable subject matter. 'Manufacture' and 'composition of matter' were expanded to include 'higher life forms.' In 1987, the Board of Patent Appeals and Interferences renounced a US patent policy, maintaining that multicellular organisms were eligible for patenting in *Ex parte Allen, 2 U.S.P.Q. 2d (BNA) 1425 (Bd. Pat. App. & Int. 1987), aff'd, 846 F.2d 77 (Fed.Cir.1988)*. In this case, a patent application was filed for an improved version of the Pacific oyster that made it more edible. Although the claim failed on meeting the 'obviousness' requirement, the case established the principle that patents could be granted for living animals. See generally: Rimmer, M. Intellectual Property and Biotechnology. Cheltenham: Edward Elgar, 2008 at 84-86. After *Ex parte Allen*, USPTO Commissioner Donald Quigg issued a notice reversing the office's prior policy of rejecting patent applications claiming animals: "The Patent and Trademark Office now considers nonnaturally occurring on-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101." Quigg D., (USPTO), Statement, Policy Statement on Patentability of Animals, 1077 Off. Gaz. Pat. Office 24 (April 7, 1987).

> A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said animal, at an embryonic stage.[75]

The US patent claim filed by Harvard was exceptionally broad, claiming a 'non-human mammal,' although it narrowed down its claims to that of a 'mouse' or 'rodent' in its final two claims.[76] In other words, the patent could cover other mammals even though Leder and Stewart only showed the patent office that it worked in a mouse. Because of the way the claims were written, it could cover the whole class of Mammalia except humans.

In addition, Harvard claimed the ancestors of the animal at the embryonic stage, which meant that the patent would not only cover the first generation of oncomice, but each successive generation of mice, which carried the oncogene up until the date of patent expiry. In life patenting, the crucial concern is that rights can be extended to products of self-reproducing things, which can be covered by reach-through claims.[77]

One should note that there is no mention of human beings in the claim, reflecting the attitude towards patenting human beings and the moral ramifications of altering the human genome. However, moral concerns regarding human patents were addressed in *Ex Parte Allen*.[78] In this case, the Board of Patent Appeals and Interferences overturned another policy by stating that multicellular organisms were eligible for patentability. Aside from being the first animal patent, the patentability of the oncomouse invention is interesting as it was assessed by three biotechnology rich nations, who differed in their interpretation of the oncomouse but ultimately granted Harvard a patent for its invention.

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[75] See U.S. Patent No. 4, 736, 866, 1089 Off. Gaz. Pat. Off. 703 (April 12, 1988), claim 1.
[76] Ibid, Claim 11: The mammal of claim 1, said mammal being a rodent.
Claim 12: The mammal of claim 11, said rodent being a mouse.
[77] Dutfield, G. and U. Suthersanen. Global Intellectual Property Law. United Kingdom: Edward Elgar Publishing Limited, 2008 at 307.
[78] *Ex parte Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (Bd. Pat. App. & Int. 1987), aff'd, 846 F.2d 77 (Fed.Cir.1988)

In 2002, the Canadian Supreme Court addressed whether the words 'manufacture' and 'composition of matter' within the framework of the *Patent Act* included higher life forms. The court maintained that although the *Patent Act* does not explicitly refer to the patentability of life forms, the status quo in the country was that lower life forms were patentable and higher life forms were not. In addition, the court rejected the claim that a higher life form met the requirements of 'manufacture' and 'composition of matter.' "The best reading of the words of the Act supports the conclusion that higher life forms are not patentable."[79]

The majority differentiated between a microorganism and higher life forms. It reasoned that bacteria have been used in industrial processes for a long time, and possess uniform properties that make them more straightforward to characterize as chemicals. However, this is not the case with higher life forms like animals. In addition, the majority highlighted the fact that until there is clear guidance from the legislature to indicate that Parliament intended an expansive interpretation of the term 'manufacture,' and 'composition of matter,' the Courts must make decisions by the ordinary meaning of 'invention.'[80]

The dissent held that Harvard should be granted a patent for the oncomouse because the inventors had attained a substantial achievement by transforming every single cell in the mouse's body.[81] Furthermore, they held that a line should not be drawn between a single cellular life form and a higher life form, stressing that it was illogical to grant patents for genes and germ cells, but not the mouse that develops from those cells.[82] Finally, the dissent highlighted the importance of the harmonization of patent

[79] *Harvard College v. Canada* [2002] at 122.
[80] Ibid at 106.
[81] Dissenting Justice Binnie wrote: "I believe that the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of "the genetic material of which it is composed", is an inventive "composition of matter" within the meaning of s. 2 of the Patent Act." Ibid at 62.
[82] Many scientists and academics adopt this position. Graham Dutfield maintains "the legal line drawn…between lower and higher life forms is a dubious one. No legal distinction is scientifically

law with respect to living organisms. By not allowing patents for higher life forms, it directly goes against what is accepted in the U.S. and other biotechnology-rich countries, which may have an effect on attracting investment.[83] In effect, Canada adopted a more conservative approach than the US, granting only a patent for the process of creating the oncomouse.[84] However, this decision by the Canadian Supreme Court was essentially overturned in a case following soon after in *Monsanto Canada Inc. v. Schmeiser*,[85] which seemed to offset for the earlier, apparently wrong turn the courts took in the oncomouse case.[86]

The oncomouse patent application was the first case the EPO managed in regards to the patentability of animals. The EPO was initially hesitant in granting a patent for a living organism, but eventually adopted a similar approach to the US at the appeal level. The European Patent Office Technical Board of Appeal asked the examiners of the patent to reconsider the case after the examiners rejected Harvard's claim.[87] The EPO approach to patenting considers moral and ethical considerations in deciding what is eligible for a patent: namely, under Article 53 of the EPC which excludes two types of inventions from patentability:

> (a) inventions the commercial exploitation of which would be contrary to "ordre public" or

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trustworthy. If higher life forms are unpatentable, the same should probably go for lower ones." (Dutfield, Graham, "Who Invents Life: Intelligent Designers, Blind Watchmakers, or Genetic Engineers?" in Journal of Intellectual Property Law & Practice. Vol. 5.No. 7, 2010 at 539-540)

[83] Ibid at 59.

[84] Canadian patent 1341442 was granted for the method of creating the oncomouse, although the Canadian Supreme Court held that the oncomouse was not patentable as it was a higher life form. The patent claimed:
"A method of testing a material suspected of being a carcinogen, comprising: exposing a transgenic non-human mammal to said material and detecting neoplasms as an indication of carcinogenicity; said transgenic non-human mammal being a transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage."

[85] Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902, 2004 SCC 34

[86] "While *Harvard Onco-Mouse* appeared to alienate the country's biotechnology sector, the subsequent *Schmeiser* case cemented the country's place in the league of biotechnology nations." Onwuekwe, 155-156.

[87] At the patent examination level, the EPO found that the oncomouse did not violate Article 53(a), but failed to satisfy Article 53(b) of the European Patent Convention because the oncomouse was a new variety of animal, a product of natural biological processes, and therefore was ineligible for a patent. Harvard appealed the decision, arguing that the oncomouse was a not a new variety of animal, but an entirely new type of animal. Like *Chakrabarty*, Harvard maintained the oncomouse did not arise from natural biological processes, but was made by man. See T 0019/90(Onco-mouse) of 3 October 1990.

> morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
>
> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof [88]

The EPO maintained that the oncomouse did not violate Article 53(b), but had to be assessed under Article 53(a) because of morality and *ordre public* considerations.[89] In assessing the *ordre public* or morality exception, the EPO developed a morality balancing test which involved weighing the potential benefits (anticipated medical benefits to mankind) of a claimed invention against its costs (suffering of the oncomouse). Other factors that could be considered in the test include potential environmental risks. Harvard responded that the mice would ultimately benefit humanity in the fight against cancer. Since mice were prone to picking up cancer, only a few of them would be required to suffer. The benefit to human beings outweighed the suffering of a few mice. In response to the environmental concerns, they reasoned that the mice posed only a small risk to the normal mouse population as the oncomice were held safely in the laboratory.[90] The EPO decided that the benefit of the oncomice for cancer research was likely to be substantial and offset the moral matters about the suffering brought to the affected mice. [91]

The same practical line to the morality question was utilized by the EPO in the Upjohn case, but with different result. The Upjohn pharmaceutical company created a transgenic mouse in which a gene was inserted into its genome so that the mouse would lose its hair. The purpose of inserting this 'bald' gene was to use it as a tester for

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[88] For a discussion on TRIPS flexibilities for plants, plant varieties and essentially biological processes for the production of plants, see: WIPO Secretariat. CDIP/13/10. Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels- Part III. March 27, 2014.

[89] Kevles, D. A History of Patenting Life in the United States with Comparative Attention to Europe and Canada: A Report to the European Group on Ethics in New Science and Technology. January 12, 2002. http://ec.europa.eu/bepa/european-group-ethics/docs/publications/study_kevles_en.pdf. Accessed June 8, 2013 at 59.

[90] European Patent Application No. 863044907, President and Fellows of Harvard College, Response to the Official Letter of 11th December 1990

[91] In 1991, the European Patent Office ruled that Harvard would be granted a patent on the oncomouse. European Patent Office, Press Release 3/92, European Patent for Harvard's Transgenic Mouse

products to cure human baldness. The EPO evaluated the benefits (useful in research to treat hair loss) and the harm (suffered by the bald mice) and concluded that the harm to the mouse was not outweighed by the benefit to human beings. As such, the commercial exploitation of the invention was declared contrary to morality and the transgenic mouse was not patentable.[92]

D. Pluripotent Embryonic Stem Cells

The WARF patents, commonly known as US Patent No. 5,843,780[93], US Patent No. 6,200,806[94] and US Patent No. 7,029,913[95] are directed to pluripotent primate embryonic stem cells, which also encompass hESCs. The patent claims covered the methods for obtaining stem cells from fertilized embryos and the embryonic stem cells themselves. WARF had an active licensing program in place based on these three patents, requiring all researchers working with hESCs in the US to pay a license fee. However, WARF came under extensive criticism from the stem cell community for its insistence on license terms that many claimed were sufficiently onerous and slowed the progress of embryonic stem cell research.[96] In response, WARF established a reduced royalty rate for non-profit organizations and offered licensee scientists training in embryonic stem cell work. Even so, a number of organizations are choosing to conduct their embryonic stem cell research programs outside the US, a decision attributed by some to a desire to avoid the reach of the WARF patents.

The Foundation for Taxpayer & Consumer Rights challenged WARF's '913 patent on the grounds of lacking novelty and nonobviousness in 2006 by filing a Request for Inter Parties Reexamination. In 2010, the USPTO Board of Appeal and

[92] *R v. Leland Stanford/ Modified Animal Opposition Division*. 16 August 2001 [2002] EPOR 16.
[93] Filed January 18, 1996, issued December 1, 1998 claiming a purified preparation of primate embryonic stem cells.
[94] Filed June 26, 1998, issued March 13, 2001, claiming primate embryonic stem cells.
[95] Filed October 19, 2001, issued April 18, 2006, claiming a culture of human embryonic stem cells for use as tools in the treatment and prevention of nervous system, blood and developmental disorders.
[96] "[T[he so-called WARF patent on primate embryonic stem cells issued in the US virtually wreaked havoc in the biotechnology research community and in the related industry." Plomer, A and P. Torremans. Embryonic Stem Cell Patents: European Law and Ethics. Oxford: Oxford University Press, 2009 at 388.

Interferences (BPAI) decided that the WARF'913 patent which claimed pluripotent hESCs on the basis that it was obvious in light of the prior art.[97]

E. Dolly the Sheep

In the 1980s and 1990s, genetic engineering techniques became increasingly advanced and genes began being inserted in plants and animals. One such technique was used in the cloning of Dolly the sheep. In 1996, Ian Wilmut and Keith Campbell successfully took a cell from a mature sheep, removed its nucleus and inserted it into an embryo with its nucleus removed.[98] US biotech company Geron Bio-Med acquired the first UK patent rights for cloning, covering the nuclear transfer technology that was used to create Dolly. Geron Bio-Med was also granted a UK patent for compositions of matter, claiming non-human animal embryos and cloned non-human animals produced from nuclear transfer. UK patent No. 2318578 claimed methods of nuclear transfer in which the nucleus of a quiescent donor cell was transferred to a recipient cell.[99]

2.2.3. International instruments

The international legal framework on the issue under examination is constituted mainly by the Universal Declaration on the Human Genome,[100] the Convention on Biological Diversity[101] and TRIPS.[102]

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[97] Foundation for Taxpayer and Consumer Rights v. WARF. USPTO Board of Appeal and Interferences, (Appeal 2010-001854) Available at: http://www.consumerwatchdog.org/resources/WARFDecision042910.pdf. Accessed May 24, 2012 at 36-38. The prior art included a patent granted to an Australian inventor Robert Williams, who was granted US Patent No. 5,166,065 which was issued in November 1992 and would have anticipated the WARF patents. Rimmer, M. Intellectual Property and Biotechnology. Cheltenham: Edward Elgar, 2008 at 261.

[98] Krauthammer, C. "A Special Report on Cloning" in Time. March 10, 2007. Print.

[99] The claim was broad, covering occurrences where somatic cells were used as the nuclear donor. The patent claimed methods of producing animal cells by nuclear transfer and methods of producing cloned animals. The patent also covered both human and non-human cell lines produced from the technology. Mayor, S. "First UK patents for cloning issued to creators of Dolly the sheep" in BMJ. Vol. 320, January 29, 2000 at 270.

[100] The Declaration was adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) at its twenty-ninth session on11 November 1997 and endorsed by General Assembly resolution 53/152 of 9 December 1998.

[101] The Convention on Biological Diversity was adopted in 1992 at the United Nations Conference on Environment and Development and entered into force in 1993.

[102] The TRIPS agreement came into effect on January 1st, 1995 and is a comprehensive multilateral agreement on intellectual property administered by the World Trade Organization.

A. Universal Declaration on the Human Genome and Human Rights

UNESCO's Universal Declaration on the Human Genome and Human Rights claims the human genome belongs to the "heritage of humanity"[103] and its natural state "shall not give rise to financial gains."[104] Moreover, any financial benefits which do arise from research involving the human genome should be "shared with society as a whole and the international community."[105] At first glance, these articles suggest that patenting of the human genome is forbidden since the essence of the patent system is linked with commercialization. Conversely, the patenting of the human genome is challenged by the business and technological sector, and there has been no approved international policy in response.[106]

B. Convention on Biological Diversity

According to the Convention on Biological Diversity, states have sovereignty over their genetic resources, which entitle them to determine how genetic resources are accessed and utilized.[107] National legislation indicates whether human genetic materials are patentable subject matter, and what is required to shift a genetic source from being a discovery into one that is considered an invention. In fact, there is a divergence even amongst the most technology advanced jurisdictions: the Europe and the US have different positions on the patent eligibility of human genetic materials, which illustrate the controversy which persists. It is therefore up to states to determine how this social contract between society and biotechnology is arranged.

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[103] Article 1, UNESCO 1997. For more on the human genome as common heritage, see Ossario, P. "The Human Genome as Common Heritage: Common Sense or Legal Nonsense?" in Genetics and Group Rights. Pp. 425-439, Fall 2007.
[104] Ibid, Article 4.
[105] Article 15 of Universal Declaration on Bioethics and Human Rights, UNESCO, 2005.
[106] Rhodes, C. Governance of Genetic Resources: A Guide to Navigating the Complex Global Landscape. Cheltenham: Edward Elgar, 2013 at 88.
[107] Convention on Biological Diversity (1992), Article 15.

C. Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement

Under TRIPS, patents shall be made available for inventions in all fields of technology, which is known as the doctrine of non-discrimination and is codified in Article 27(1):

> [P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (...) patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

The TRIPS Agreement does not provide for a definition of an 'invention' and has left it to its Member States to determine what is patentable. Conversely, this discretionary space is limited by the doctrine of non-discrimination which means Member States cannot exclude a field of technology.[108] In the context of this thesis, this means that the TRIPS Agreement advocates for a technology-neutral patenting approach. However, this has to be balanced against certain established doctrines in Member States' patent jurisprudence, such as Europe's distinction between a patentable invention and a non-patentable discovery[109] and the US 'product of nature' principle which distinguishes patentable and non-patentable subject matter.[110] This balancing between principles is a necessary and beneficial aspect to the social contract, because the patent system alone is a social contract which reflects broader contracts between the government and society.

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[108] However, WTO Member States may exclude inventions from patent protection in Article 27.3(b), which refers to the exclusion of plants and animals from patentability and essentially biological processes for the production of plants and animals. Article 27.3(b) of TRIPS states:
"Members may also exclude from patentability: (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by a combination thereof."
Therefore, the provision distinguishes between the level of protection afforded to microorganisms to that of plants and animals. Currently, Member States must provide patent protection for: (i) microorganisms and (ii) non-biological and microbiological processes used in the production of plants and animals. This means that the doctrine of non-discrimination cannot be used to sustain a technology that would invalidate Article 27.3(b).

[109] See 4.4.1 for a discussion on Article 52(2) EPC.

[110] See 4.3.3 for a discussion on the product of nature doctrine in the US.

2.3. DNA and genes

One of the most controversial areas in patent law and policy is that of DNA sequences and genes. In the 1980s and 1990s, several branches of the US federal government promoted patenting, particularly of genes.[111] As of 2010, there have been approximately 40,000 US patents granted related to 2,000 human genes.[112] These patents include isolated genes, methods of using the isolated genes and methods of diagnosis.[113] There is the argument that the USPTO and Federal Circuit have surrendered too much terrain to the wellbeing of the biotechnology industry. In an endeavour to support this industrial field, a collection of peculiar and startling decisions have been rendered.[114]

Since many terms have been used in discussion pertaining to the patenting of human DNA, genes and genetic information, it will be useful for the purposes of this thesis to first develop a basic understanding of the science. This will lay the foundation for further discussion in how the idea of propriety and the common development of scientific understanding may come into conflict.

Deoxyribonucleic acid (DNA) is a chemical molecule made up of four complementary nucleic acid base pairs: adenine (A) with thymine (T), and cytosine (C) with guanine (G).[115] The physical structure of DNA is a double-stranded helix composed of the four complementary base pairs and the entire sequence is a code for genetic information.[116] The human genome consists of a sequence of these four bases

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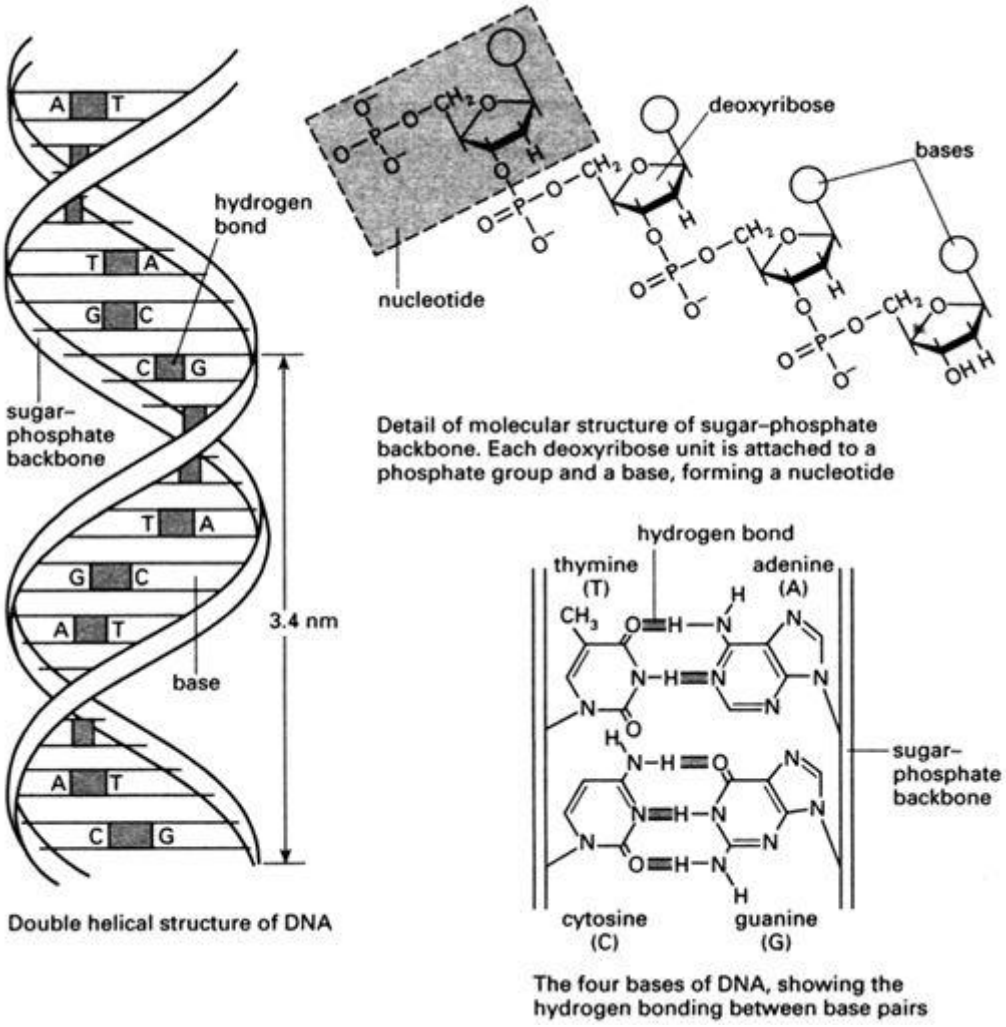
[111] Rai notes that the implementation of the Bayh-Dole Act in 1980 by Congress strongly favoured patenting in universities. See Rai, A. "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science," in Northwestern University Law Review. Vol. 94, No.1, 1999 at 94-108.
[112] Jensen, K. and F. Murray. "Intellectual Property Landscape of the Human Genome," in Science. Vol. 310 no. 5746, pp. 239-240. October 14, 2005.
[113] Ibid.
[114] Jackson, M. "How Gene Patents are Challenging Intellectual Property Law: The History of the CCR5 Gene Patent" in Perspectives on Science. Vol. 22, No. 3, Fall 2014. Jackson argues that the USPTO erroneously granted a patent on the CCR5 gene, even though the patent holder incorrectly claimed the sequence in the specification and did not know the most important characteristic of the gene product.
[115] Lodish, H. et al. Molecular Cell Biology, 7th edition. New York: W.H. Freeman and Company, 2012 at 8.
[116] Ibid.

which carries information and determines the function of an organism. Only some parts of the human genome possess functional roles; these "useful" regions are known as genes.[117]



Source from: Martin, E. & R. Hine. A Dictionary of Biology (6th edition). Oxford: Oxford University Press, 2008. http://www.oxfordreference.com/view/10.1093/acref/9780199204625.001.0001/acref_9780199204625_graphic_042-full.jpg. Accessed January 4, 2014.

[117] Ibid, 1.

A gene is a "locatable region of genomic sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions and/or other functional sequence regions."[118] A gene is composed of many DNA base pairs, ranging from 1000 to thousands, depending on the length of the gene.[119] There is no consensus amongst the scientific community as to how many genes human beings possess. The numbers range from between 13,000-23,000[120] to 30,000 genes.[121] Other coding parts of DNA include single nucleotide polymorphisms (SNPs) and expressed sequence tags (ESTs). A SNP consists of an area on the genome where humans display genetic disparity.[122] An EST is a small fragment of a gene which acts as a marker for a gene.[123]

Genes provide an instructional template for the manufacture of proteins.[124] Accordingly, the manner in which proteins are created is called gene expression.[125] Most genes contain two sections: (i) the coding region which identifies the amino acid sequence of a protein and (ii) the regulatory region which fixes particular proteins and controls when and in which cells the protein is made.[126] During the first step of gene expression, transcription, the DNA strand unzips into two separate strands in the regions which code for the protein to be made. An enzyme called RNA polymerase copies the coding region of DNA into a single strand known as ribonucleic acid (RNA). The RNA nucleotides are then matched up with the template strand of DNA, and RNA polymerase catalyzes the combination of nucleotides into an RNA chain. The result is a strand of RNA complementary to a strand of DNA, where uracil replaces thymine. This

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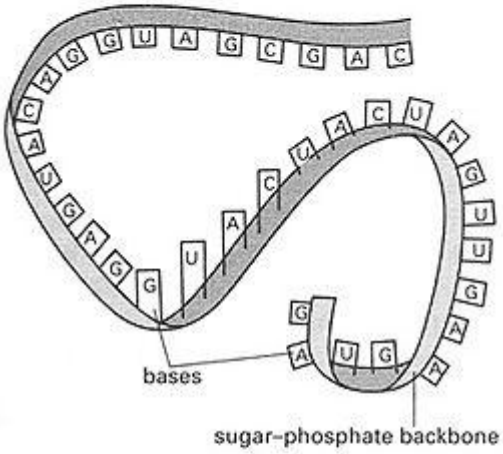
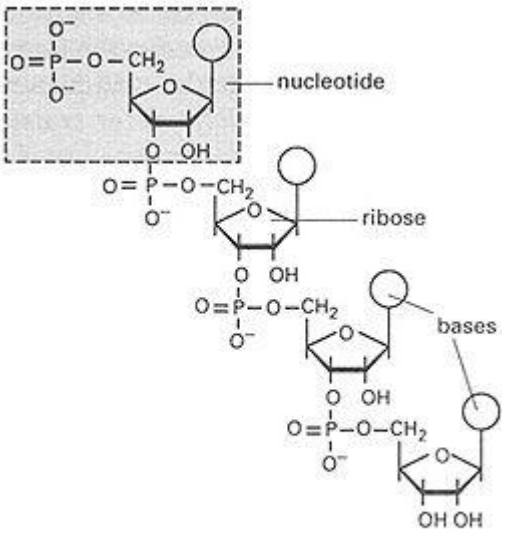
[118] Pearson, H. "Genetics: What is a Gene?" in Nature. Vol. 441. 2006 at 401.
[119] Supra note 115, Lodish at 208.
[120] Ibid, 9.
[121] National Institutes of Health. National Human Genome Research Institute.www.genome.gov. Accessed June 27, 2013.
[122] Supra note 115, Lodish at 8.
[123] Human Genome Organisation. HUGO Intellectual Property Statement on Patenting of DNA Sequences. May 1997. http://www.hugo-international.org/img/ip_sequencedata_1997.pdf. Accessed November 14, 2013.
[124] Supra note 115, Lodish at 1.
[125] Ibid, 279.
[126] Ibid, 9.

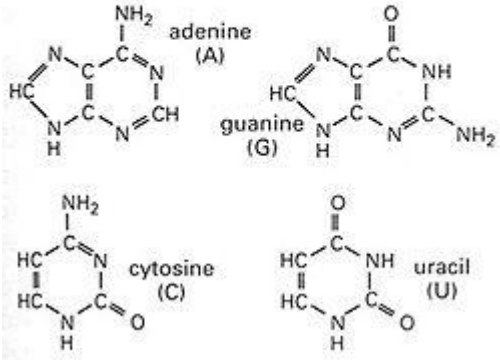
RNA chain is processed into messenger RNA (mRNA) which leaves the nucleus for the cytoplasm.[127] In the cytoplasm, the mRNA fastens to the cellular ribosomes and the next step of gene synthesis begins. The ribosomes decode mRNA to create an amino acid chain which then folds into a protein with the assistance of transfer RNA.[128]



Single-stranded structure of RNA



Detail of molecular structure of sugar–phosphate backbone. Each ribose unit is attached to a phosphate group and a base, forming a nucleotide.



The four bases of RNA

Source from: Martin, E. & R. Hine. A Dictionary of Biology (6th edition). Oxford: Oxford University Press, 2008. http://www.oxfordreference.com/view/10.1093/acref/9780199204625.001.0001/acref_9780199204625_graphic_118-full.jpg. Accessed January 4, 2014.

[127] Ibid, 9.
[128] Ibid, 116.

2.3.1. The DNA/cDNA distinction

The emergence of automated sequencing technologies which allow for the speedy detection of nucleotide sequences has contributed to tremendous progress in the identification of the coding regions of human genomes.[129] This means that the synthesis of DNA has become a routine production. A vital technique for discovering coding regions is to synthesis complementary DNA (cDNA). The difference between naturally occurring DNA and cDNA is that cDNA does not contain introns. cDNA can be synthesized using reverse transcriptase, which enables for transcription to happen in reverse.[130] The product is a single strand of cDNA which encompasses only the coding area as mRNA does not contain any introns. As a result, cDNA can be valuable in identifying genes.[131]

For the purposes of this thesis, it is important to identify the similarities and differences between genomic DNA and cDNA. Genomic DNA exists within the body, whilst cDNA is created outside the body. In addition, the exact nucleotide sequence of cDNA does not exist naturally within the human body. Yet, genomic DNA possesses both exons and introns, the coding and non-coding sequences. But the sequence of the first single strand of cDNA is complementary to the mRNA, whilst the second strand of cDNA possesses the precise mRNA sequence.[132]

Patent claims to genetic sequences usually entail a claim to the sequence that is in its isolated and or purified form. The query is whether these claiming methods provide sufficiency to differentiate the claimed sequences from their naturally occurring equivalents.

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[129] Hunkapiller, T., R. Kaiser, B. Koop and L. Hood. "Large-scale and automated DNA sequence determination" in Science. Vol.254 no. 5028, pp. 59-67, October 4, 1991.
[130] Supra note 115, Lodish at 186-188.
[131] Ibid.
[132] Ibid.

2.3.2 Chemical-analogy metaphor

The analogy between genes and chemical compounds was advantageous because patent law had reached a point at which isolated and purified naturally occurring chemicals could be patented.[133] It advocated a view where DNA is no more than a chemical and DNA sequences should be claimed in the same way as a recently typified chemical can be claimed for known and new uses.[134]

One important patent in the US was for adrenaline, a naturally occurring hormone. It was granted in 1906 and challenged and upheld in *Parke-Davis v. Mulfor*d ("*Parke-Davis*").[135] Judge Learned Hand maintained that purified adrenaline was more useful than its naturally occurring counterpart: "it became for every practical purpose a new thing commercially and therapeutically."[136] When patent claims for DNA sequences began, the isolation and purification principle was well already deep-rooted in chemical patents and carried over into DNA patents, which led to the assumption that DNA is eligible for patent protection provided it is isolated and purified from its natural chemical state.[137] Regarding DNA sequences as chemical combinations can give rise to an absolute right, meaning that the patent holder can exclude any third party commercial use of the patented product even if the use has not been disclosed in the original patent claim.[138] This means if a patent applicant claims a gene as a product, the patent scope is extremely broad and covers all and any future commercial uses of a gene. Therefore, it is due to the reduction of a gene to a chemical entity that DNA sequences entered the

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[133] See Conley, J. & R. Makowski. "Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents," in Journal of the Patent and Trademark Office Society. Vol.85, pp.301-334, 2004; Demaine, Linda and Aaron Fellmeth. "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent" in Stanford Law Review. Vol.55, 2002 and Calvert, J. and P-B. Joly. "How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA" in Social Science Information. Vol. 50, Iss.2, pp. 1-21. 2011.
[134] Ibid.
[135] *Parke-Davis and Co. v. H.K. Mulford and Co.*, 189 Fed. 95 (SDNY 1911) affirmed, 196 Fed. 496 (2nd Cir.1912).
[136] Ibid, 1092.
[137] See supra note 133, Conley & Makowski.
[138] See Beier, F-K, R. Crespi & J. Straus. Biotechnology and Patent Protection: An International Review. Paris: OECD, 1985.

realm of patentable subject matter and no longer deemed a 'product of nature,' provided they are isolated and purified and meet the other patentability requirements.

However, not everyone accepts this view of DNA as merely a chemical.[139] In the last decade, there has been great debate over how to define the gene. For instance, Graham Dutfield maintains that this analogy is misleading and that language used by scientists and lawyers to structure their patent claims encouraged the expansion of patent law. He notes that a metaphor like "life is largely chemical" is deceptive in persuading judges to think that things are inventions when in fact, they are merely discoveries.[140]

Even the esteemed Joseph Straus who previously endorsed the "gene as a chemical" metaphor has altered his argument:

> Any simple equation of a gene sequence (identical to the natural one) with (absolutely) new synthetic molecules, or 'ordinary' chemical substances found in nature, disregards the, by now, known and substantial differences between these categories of products. In view of the consensus concerning the present state of technology, the technical problem (object) solved by such an invention cannot be seen in isolation or chemical synthesis or a new chemical compound of a more closely defined structure, but only in conjunction with the discovery of one or several functions of a product that exist in nature and whose discovery and structure clarification are not based on any inventive activity. Under such circumstances limiting the scope of protection to the function(s) disclosed seems necessary. [141]

Straus indicates that the scientific fact that most genes have more than one function has a significant effect on gene patents because new functions can be discovered which were not previously known when the patent for the gene was granted.

Despite the fact that questions about the nature of the gene and its understanding in patent law have been raised, in practise, genes continued to be treated as merely chemical compounds, which can be considered the basis for why there are now

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[139] Human Genome Organisation. HUGO Intellectual Property Committee Statement on Patenting of DNA Sequences in Particular Response to the European Biotechnology Directive. April 2000. www.hugo-international.org/img/ip_dna_2000.pdf. Accessed November 14, 2013.

[140] Dutfield, G. "'The Genetic Code is 3.6 Billion Years Old: It's Time for a Rewrite' Questioning the Metaphors and Analogies of Synthetic Biology and Life Science Patenting" in A. Lever (ed.) New Frontiers in the Philosophy of Intellectual Property. Cambridge: Cambridge University Press, 2011. At page 4, Dutfield claims there are limitations to metaphors and analogies used by scientists, particularly in the field of synthetic biology, a new branch of biology that has created minimal genomes, standardized parts, devices and systems, and metabolic engineering.

[141] Straus, J. "An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patent Genes-An Academic Point of View" in Official Journal of the European Patent Office Special Issue, 2003 at 186.

problems pertaining to gene patents. A 2003 report for the French Prime Minister questions the notion that genes are merely chemical compounds, holding them to be centres of information and 'essential facilities' economically speaking:

> For the economist, it constitutes then a fundamental/essential infrastructure-essential, as it is fundamental to pursue activities social essential (here affecting health) whose access is refused by whom control it; it is a kind of abuse of dominant position particularly damaging/harmful.[142]

Another figure advancing the notion that genes are essential facilities is Nobel laureate Joseph Stiglitz:

> Regarding such elements, which incidentally are discovered and not invented…from the viewpoint of economic efficiency, it might be necessary to reduce a patent's breadth further, even below what might seem the inventor's marginal contribution in expanding the frontier of knowledge. In antitrust terms, these elements are 'essential facilities'. In addition, there is an argument that today the process of isolating, sequencing and characterizing has become almost routinized, with costs contained. Perhaps not even the 'obviousness' criterion is satisfied.[143]

The dominant assumption that a gene is merely a chemical compound was a solution to the problem of patenting naturally occurring entities by applying the dogma of isolation and purification which were applied to patents on chemicals. Another consequence of this chemical analogy is that the conception of genes became a non-issue in the context of patents, and there was no major dispute for gene patents until the last decade. In the past, genes were not treated as chemical compounds.[144] US case law illustrates the flawed acceptance of the viewpoint that the difference between the naturally occurring and the artificial is clear and distinct. In contrast, Europe took a legislative decision and implemented Directive 98/44/EC, acknowledging that the variable outlook of human genes was trounced by a discrepancy made between the gene *per se* (which naturally exists in the human body) and the gene as an invention (when it is isolated and purified and commercially useful to the market). However, in a recent

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[142] Henry, C., M. Trommetter and L. Tubiana. "Innovations et droits de propriété intellectuelle: quels enjeux pour les biotechnologies." Rapport du Conseil d'Analyse Economique. Paris: La Documentation Français, 2003 at 61.

[143]Henry, C. & J. Stiglitz. Intellectual Property, Dissemination of Innovation and Sustainable Development" in Global Policy. Volume 3, Iss.3, October 2010 at 241.

[144] See Calvert, J. & P-B. Joly. "How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA" in Social Science Information. Vol. 50, Iss.2, pp. 1-21, 2011. Calvert and Joly explain that the earliest gene patents in the USPTO are patents for Mendelian genes: patent claims for genes which were defined by their phenotype rather than in molecular terms.

decision in June 2013, the US Supreme Court challenged this conception of genes, maintaining that the value of Myriad' claims was directed to the information contained within the claimed nucleotides rather than the chemical composition itself.

Prior to 2013, the USPTO treated DNA sequences similarly to other isolated and purified chemical compounds, like hormones.[145] The USPTO made the artificial distinction between isolated and purified DNA sequences which are patent eligible, and naturally occurring DNA sequences (non-isolated and non-purified) which are not patent eligible. This is because one of the principles of patent law is that products of nature cannot be patented, and it is assumed that an isolated and purified DNA sequence is a product of human ingenuity. Patents on genes and DNA sequences were first granted in the 1980s. The first patents for DNA sequences claimed in US patent application were in 1978.[146] The early gene patents usually comprised an isolated DNA sequence which coded for a specific protein. By the end of the year, 25,000 DNA-based patents had been issued in the US.[147] The companies with the highest number of applications for human gene sequence patents were Genset, Ribozyme, Genetics Institute, Genzyme, Hyseq, and Human Genome Sciences.[148] But in the 1990s, the sequencing of DNA became a standard and routine practice, and leading scientists began to challenge gene patent applications at the USPTO, claiming that DNA sequences were being claimed whose sole function was as a molecular probe in identifying the location of certain genes, and whose function was classified speculatively through a search in a DNA database.[149] "HUGO [Human Genome Organisation] does not oppose patenting of useful benefits derived from genetic

[145] Dutfield, G. "Patents on Steroids: What Hormones tell us about the Evolution of Patent Law and the Pharmaceutical Industry" in Intellectual Property Law Journal. Vol. 23, pp. 249-66. 2011.
[146] Dutfield, G. Intellectual Property Rights and the Life Science Industries: Past, Present and Future 2nd edition. London: World Scientific Publishing Co. Pte. Ltd., 2009 at 194.
[147] Ibid.
[148] Ibid.
[149] Human Genome Organisation. HUGO Intellectual Property Statement on Patenting of DNA Sequences. May 1997. http://www.hugo-international.org/img/ip_sequencedata_1997.pdf. Accessed November 14, 2013.

information, but does explicitly oppose the patenting of short sequences from randomly isolated portions of genes encoding proteins of uncertain functions."[150] As a response to these criticisms, the USPTO and EPO issued patent examination guidelines pertaining specifically to gene related inventions. The USPTO issued Revised Guidelines which stated that 'utility' attributed to a DNA patent had to be "specific, substantial and credible".[151] It is noted that one way of meeting this requirement is to disclose the function for the claimed gene.[152]

2.3.3. DNA sequences: information content within the chemical compound

> *"[H]ow can genomic information be owned, when genomic information exists in every gene of every chromosome of every cell of every human being?"*[153]

The information/chemical debate is one that persists for patents directed at any DNA sequence. This is because the value of DNA lies in the genetic information rather than the molecular structure. It is no longer suitable to use the "DNA as a chemical"[154] analogy because over time, it has been found that DNA sequences are encoded with new information. Most genes encode for more than one function and the genetic sequence itself can operate in several variations. "The DNA sequences identified by high-throughput sequencing look less like new chemical entities than they do like new scientific information...the chemical analogy is of little value as a strategic guide to exploiting this information as intellectual property."[155] Thus, a DNA sequence is no longer just a chemical sequence of As, Ts, Gs, and Cs, but also the information it yields.

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[150] Ibid.
[151] United States Patent and Trademark Office. "Utility Examination Guidelines" in Federal Register. Vol. 66, No.4, Friday, January 5, 2001. Pp.1092-1099. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.Accessed October 18, 2012.
[152] Calvert, J. "Patenting Genomic Objects: Genes, Genomes, Function and Information" in Science as Culture. Vol. 16, No. 2, pp. 207-223, 2007.
[153] Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain- Part II" in Columbia-VLA Journal of Law & the Arts. Vol. 18, Issues 3 & 4, 1993-1994 at 232.
[154] Eisenberg, R. "Re-examining the Role of Patents in Appropriating the Value of DNA Sequences" in Emory Law Journal. Vol. 49, 2000.
[155] Ibid, 785.

This means that the human genome is not merely a chemical compound, but information.[156]

> Human genes - quintessential products of nature – are useful because they convey vital information. The human genome's ability to be our instruction book on life distinguishes human DNA from all other chemicals covered by patent laws.[157]

Therefore, the dual nature of DNA as both a chemical substance and information carrier differentiates it from other chemical compounds like hormones.[158]

As discussed in the above section, one of the main issues directed at gene patents is whether the focus should be on the structural (or chemical) difference between the isolated genes and their naturally occurring counterparts. Until *AMP v. Myriad*, US patent attorneys have succeeded in convincing the patent offices and courts that the chemical structure of genes is the key focus of the patentable subject matter inquiry. Three particular words: 'isolated,' 'purified' and or 'synthesized' are believed to somehow render genes patentable subject matter.[159] The argument is that claims of isolated DNA or synthesized cDNA are not products of nature or discoveries because RNA, rather than DNA, is the chemical which undergoes splicing, when the introns are removed.[160] This means that although one of the cDNA strands will contain the same information as the mature RNA from which it was derived, it is chemically different. And the other cDNA strand, although chemically the same as the naturally occurring DNA, does not include the introns.[161]

Meanwhile, the Opposition Division of the EPO in *Howard Florey v. Relaxin* held that DNA is not life, but a chemical:

> Finally, the allegation that human life is being patented is unfounded. It is worth pointing out that DNA is not "life", but a chemical substance which carries genetic information and can be

[156] The Nuffield Council on Bioethics. The Ethics of Patenting DNA. London: Nuffield Council, 2002 at 27.
[157] Brief of James D. Watson, Ph.D. as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 12.
[158] Dickenson, D. Property in the Body: Feminist Perspectives. Cambridge: Cambridge University Press, 2007 at 116.
[159] See supra note 133, Conley & Makowski at 393.
[160] See supra note 115, Lodish at 9.
[161] See supra note 133, Conley & Makowski at 393.

> used as an intermediate in the production of proteins which may be medically useful. The patenting of a single human gene has nothing to do with the patenting of human life. Even if every gene in the human genome were cloned (and possibly patented), it would be impossible to reconstitute a human being from the sum of its genes.[162]

In the case, the EPO allowed a patent for the genetic engineering of DNA from a pregnant woman's body to create human H-2 relaxin. The patent was opposed on morality grounds, that it involved patenting human life. However, the court held that extracted DNA that was treated does not constitute life, but rather holds genetic information that can be useful in creating proteins. Directive 98/44/EC has increased the threshold requirements for gene patents where it is now required for the patent applicant to include two things in the written description: (i) a particular function and (ii) specific industrial applicability.[163] The purpose is to minimize speculative and broad patents from being granted.[164]

Moreover, genes are complex, as they may have several biological pathways. Treating a gene solely as a chemical entity in the patent framework fails to take into account the complexity of biological materials.

> "Everything holds information in a way. It may mean that perhaps the basis for the inventive step analysis is different. It may mean that you need to claim things functionally. But I don't see that just because something has an information rich quality that you should have some sort of miraculous effect in and of itself. The early days of DNA patenting, like EPO, or the HGS type of patenting, people are not actually concerned with protecting the DNA itself even though they claim the DNA. They claim the DNA because of the information inherent to those claims as a way of seeking to monopolize the proteins to which those sequences code it. Thus, you have DNA claims in the EPO patent, DNA claims in the HGS patent. But the interest was not in the DNA, the interest was that it was a good way of claiming the protein itself, or claiming the protein when produced by recombinant DNA technologies. Because the protein itself was already isolated and thus lacked novelty."[165]

Despite some chemical divergences, the thing that is patented is the information it contains. While the patent claims a chemical, the thing that is of value is the information rather than the chemical formula. Moreover, the patented isolated DNA and RNA "contains exactly the same genetic information as its natural counterpart. It can do

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[162] HOWARD FLOREY/Relaxin [1995] E.P.O.R. 388 at 400.
[163] See Articles 5(1) and 5(2) of Directive 98/44/EC
[164] For instance, the US National Health Institute attempted to patent expressed sequence tags (ESTS), short fragments of DNA whose function is unknown.
[165] Interview with Trevor Cook, April 20, 2012.

precisely the same work as a naturally occurring gene-protein synthesis - and it employs precisely the same processes to do it, whether in the body or in the laboratory."[166] As a result, the claimed 'invention' is merely something that does the work of a naturally occurring gene, albeit without the non-coding regions. The non-coding introns do not do any of the functional work. Therefore, in assessing the relevant differences between naturally occurring DNA sequences and the isolated claimed sequences, the chemical differences may not be as significant as the informational character of the claimed sequences, which is identical to that of its naturally occurring counterpart. "Critically, it is these informational functional properties that are the whole reason for seeking DNA patents."[167] Thus, it can be argued that the differences between isolated sequences and their naturally occurring counterparts are not substantial enough to remove them from the "product of nature" or "discovery" category.[168]

2.3.4. Purpose bound protection

One central area of conflict is when an inventor attempts to claim all the potential uses of a gene on the basis of a limited understanding of the gene's function. DNA sequencing at the present time yields information, but it is unclear whether the information has a concrete value because the resultant biological functions of the sequence are not yet understood.[169] Moreover, newly found human genomic information is valuable both to businesses and the scientific community, which raises issues of whether it should be protected.[170]

> Because genetic information itself is both valuable as basic scientific research and is also potentially patentable, human genomic research presents the question of whether newly discovered scientific information will be treated as widely available and free-flowing, or as a 'propertized' scarce product.[171]

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[166] See supra note 133, Conley & Makowski at 394.
[167] Ibid, 395.
[168] See 4.3.3. for a discussion on the product of nature doctrine in the US.
[169] Eisenberg, R. "Re-examining the Role of Patents in Appropriating the Value of DNA Sequences" in Emory Law Journal .Vol. 49, 2000 at 788.
[170] The scientific community works under the norm of open access where information is freely shared, which contrasts with the very essence of property.
[171] Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain- Part II," at 220.

One major concern for product-based patents for DNA sequences is that it encompasses all uses/applications of the claimed product, regardless of whether those applications were claimed in the original application. This would mean that if someone else finds another use or application of the claimed DNA sequence, a license would be necessary to not infringe the original product patent on the sequence. For instance, in 1995, Human Genome Sciences (HGS) applied and was granted a patent for a gene that produced a receptor protein called CCR5. At that time, HGS did not realize that the receptor is the point of contact of the AIDS virus and identified only one function in the patent application for the CCR5 receptor. Even though the patent application did not state a connection between the gene and HIV, it claimed rights to the gene under the umbrella of AIDS research. HGS's attorney maintained, "Whoever is first to patent a DNA sequence -for any use - can lock up subsequent uses."[172] This incident gave rise to concerns about whether the patent owner may aggressively assert patent rights and block future research.[173]

There has been considerable opposition to these types of product-based DNA sequence patents, mainly because it can block further research from taking place, as competitors are not able to invent around the sequence. In response to arguments that product patent protection of DNA sequences is detrimental, Germany and France have chosen to implement "purpose-bound" protection for human DNA sequences, where a specific use must be stated in the patent application.[174] Indeed, advocates of this position could emphasize some coherent scientific and economic reasons.

2.4. DNA and the public domain

There are three main arguments for keeping the human genome in the public domain. First, the conception that information in the human genome is a common

[172] Marshall, E. "HIV Experts vs. Sequencers in Patent Race," in Science. Vol. 275. 28.2. 1997 at 1263.
[173] For a discussion on HGS's patent on the CCR5 receptor, see: McGloughlin, M. The Evolution of Biotechnology: From Natufians to Nanotechnology. Dordrecht: Springer, 2010 at 104-105.
[174] See §1a (4) of the German Patent Act and Article L. 613-2-1 (Loi no 2004-800 du 6 août 2004, art. 17) (English translation: Art. L. 613-2-1 (Act No. 2004-800 of August 6, 2004, art. 17)

resource owned by all of humanity is an argument against the patenting of human genetic material. Second, granting patents for DNA sequences can inhibit downstream research.[175] And third, the fact that genes are complex and needs to be better understood and patenting genes will slow down man's understanding of the human genome.[176]

2.4.1. Common heritage of mankind

The argument that genes are the common heritage of mankind is rooted in the argument that there are resources which are owned and shared in common internationally and should be used only for the common benefit of all. "Are we to commodify such information and turn unowned but abundant genetic information into something scarce, in the name of encouraging inventive subjects to go out and transform more such 'raw materials' into proprietary objects?"[177] This position suggests alternatives to such ownership of genetic information.

According to the Convention on Biological Diversity (1992),[178] genetic resources fall under state sovereignty which means states are entitled to regulate their access and use.[179] Under the *res nullious* approach, objects remain in the commons until they are appropriated by someone.[180] Consequently, one can argue that the human body is a part of the commons, but states have the authority to carve out a small area of property rights for those who invent something using the commons because it benefits society. For instance, Merges argues that human genetic information is not 'raw material,' but an "unowned biological 'fact' to be 'transformed' into an inventor's property".[181] Moreover, he notes that open access is not the single goal of IP law,

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[175] Heller, M. & R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science. Vol. 280, 1998 at 698-701.
[176] For a general discussion, see Keller, E. Making Sense of Life: Explaining Biological Development with Models, Metaphors and Machines. Cambridge: Harvard University Press, 2003.
[177] Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain- Part II" at 229.
[178] United Nations 1992
[179] Ibid, Article 15.1.
[180] Joyner, C. "Legal Implications of the Concept of the Common Heritage of Mankind," in International and Comparative Law Quarterly. Vol. 35, Iss. 1. 1986 at 193-194
[181] Merges, R. Justifying Intellectual Property. Cambridge: Harvard University Press, 2011 at 230.

maintaining that new material is constantly being created which is why there is a lesser need to conserve what already exists:

> In a dynamic context where new material is constantly being added, maintaining access to the largest possible set of works (via an expansive legal public domain) is only one aspect of policy. Encouraging the next round of new additions is even more important.[182]

It is worth noting here that members of the biotech industry and some select research institutes advance pro-patent arguments, maintaining that human biological materials should be treated like any other invention and that a "no patents" approach would seriously harm the industry.[183] Specifically, biotech industry members are in favour of a sturdy and effective IP regiment to provide future investors with the confidence necessary to invest in life science innovations.[184] Echoing this sentiment, Professor Sir Leszek Borysiewicz, the vice-chancellor of Cambridge, has deemed patent protection so absolutely essential to the continued development of science that he asserted the Cambridge laboratories will bypass the European Court of Justice ruling that banned embryonic stem cells from being patentable subject matter.

> I believe embryonic stem cells have to be the way forward. We do have a problem in the European area, but I've been very clear, both to ministers and others about how Cambridge is

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[182] Ibid, 301.

[183] The UK Intellectual Property Office also issued guidelines relating to patent applications relating to biotechnology inventions. The UK Intellectual Property Office states at the outset of the report that biotech inventions are regarded as the same as other technical inventions. See UK Intellectual Property Office, "Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the Intellectual Property Office" (April 2011).

[184] BIOTECanada represents 250 biotechnology firms across Canada and stressed the necessity of a strong intellectual property system: "A strong intellectual property regime is essential to the success of Canada's biotechnology industry." See: BIOTECanada. Intellectual Property. http://www.biotech.ca/en/policy-matters/intellectual-property.aspx Accessed July 22, 2013. Furthermore, a statement provided by BIOTECanada President Andre Casey emphasized that Canada's biotechnology sector would benefit from the nation's proposed changes to strengthen its IP regime, which would encourage further innovation by attracting greater investment. "We need to be as good as, if not better, than all those other jurisdictions when it comes to protecting intellectual property…This deal will raise Canada to that level…If capital sees some certainty here in terms of protection of the property, then they're more likely to come here. If it looks like we're disadvantaged compared to other countries, then the capital is going to migrate to those sectors elsewhere and we're going to lose out… That's important to the large companies, but it's [even] more important for the smaller ones who have a bigger challenge accessing capital." The proposed changes Casey is referring to in the Canadian-EU free trade agreement includes strengthening the patent data protection term from eight years to ten years, giving patent holders the right to appeal an revoked patent, and also the introduction of a patent term restitution structure to reimburse patent applicants for the time exhausted during the patent grant process. The Canadian biotech industry deems that these proposed amendments in intellectual property protection would provide investors with the assurance required for investment in research and development in biotech inventions in Canada. See: Plecash, C. "Canada's Life Sciences Industry Split on Canada-EU Free Trade Agreement" in The Hill Times. September 10, 2012.

> going to tackle that. We will continue to do a lot of research here, we will engage with whatever development we can locally and further forward, but the university itself will look at ways of ensuring that patenting can actually occur, and, if necessary, be run through the US, and, if necessary, the Indian sub-continent.[185]

Borysiewicz's stance emphasizes the importance of patent protection for embryonic stem cell research and the necessary means the university will undergo to ensure that the research will continue by means of looking to patent protection outside Europe.

2.4.2. Impediment to downstream innovation

The second argument for keeping human DNA in the public domain is that DNA sequences influences the development of drugs and vaccines that are largely reliant on protein technologies. The fact that many different patent owners own different gene sequences can give rise to the threat of royalty stacking, which can impede research and development. There is the view that patents can impede commercialization because patent holders can opt to restrict their rights, which could result in diminishing further innovations.[186] Nuno Carvalho maintains: "Genes and their functions are scientific facts, not inventions. The patent system was not devised to permit gains from revealing and understanding those facts. To do so otherwise is to distort the patent system and diminish its value as a social and economic tool."[187] Once a patent is granted, the patent holder has the ability to permit others to use, develop or commercialize the invention through a license, where the licensee gives the patent holder a fee or a percentage of the royalties. But if a patent holder adopts a restrictive attitude, it can result in greater transaction costs and restrain the transfer of patented goods onto the market as

[185] Seymour, E. "Cambridge Academics Will Bypass European Stem Cells Ruling" in The Huffington Post. December 1, 2012. http://www.huffingtonpost.co.uk Accessed June 5, 2013.
[186] Holman, M. & S. Munzer. "Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags" in Iowa Law Review. Vol. 85, No.3, Pp. 735-848, March 2000.
[187] Pires de Carvalho, N. "The Problem of Gene Patents" in Washington University Global Studies Law Review.Vol.3, No. 3, 2004, at 751-752.

researchers need to obtain many licenses from patent holders before a product can be developed.[188]

DNA sequencing is the first step in providing an information source for future breakthroughs. This is because patent claims for information depart from the traditional theories of the patent system, which is based on disclosing information to the public in return for exclusive rights. Since patents to DNA sequences could potentially restrict mere analysis of the information as described in the patent disclosure, it could hamper access to the disclosed information once the patent has been granted.

2.4.3. Genes are complex biological phenomena

Despite the completion of the Human Genome Project, there are still many questions about how genes function. James Watson, co-founder of DNA, maintains:

> To this day, we continue to learn how human genes function. We estimate that humans have approximately 21,000 genes. We have yet to fully understand the functions of all human genes, but this lack of understanding is further reason that scientists should be permitted to experiment on human genes free from any threat of patent infringement.[189]

Relatively simple life forms like bacteria have genes that are much closer together. On the other hand, human beings have long regions where nothing seems to be happening. Today, scientists do not refer to these regions as 'junk DNA' anymore; rather they are believed to be the key to human complexity. In other words, scientists still understand a lot less than they thought they did. They are still unable to explain how genes function and the way they interact with one another. It is inadequate to divide the genome into little blocks, because genes work together. Patenting assumes that each particular gene performs a certain function. However, this is not the case.

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[188] See Merges, R. & J. Duffy. Patent Law and Policy: Cases and Materials, 5th Ed. Lexis Nexis, 2011. Merges and Duff maintain at page 141: "Fundamental inventions with a very wide range of applications might perhaps be the most valuable types of inventions; providing incentives to make such discoveries is a logical goal of the patent system. On the other hand, patenting the fundamental tools of science does decrease the incentives for improvers and also creates difficult problems for negotiations where future improvements are all covered under a single early pioneer patent."

[189] Brief of James D. Watson. as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 8.

Genes actually work together in a harmonious system, and granting patents because someone discovers a function in a gene is erroneous, since a gene may have more than one function. Granting a patent for a gene in which only one function has been declared but covers all future yet-to-be discovered functions is unsuitable.

2.5. The tragedy of the "anticommons"

One major contention against the patenting of human biological materials is problems associated from patent holders hampering the flow of information, such as difficulties stemming from licensing of patented inventions that could obstruct further innovation in medicines and would result in an "anticommons."[190] An anticommons arises when too many patents are granted which exclude the use of an product or process.[191]

In 1998, Michael Heller and Rebecca Eisenberg wrote an article asking whether patent protection could discourage biomedical research.[192] They explored the double-edged sword of patent protection. On the one, they could facilitate incentives by securing protection through a patent right, whilst simultaneously creating an enormous thicket and act as a barrier to innovation. As a result, a user needs access to multiple patented inputs to create a single useful product. Heller and Eisenberg used the term "tragedy of the anticommons" to describe the underuse of scarce resources as a result of too many rights holders in one area:

> The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.[193]

[190] See Heller, M. "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," in Harvard Law Review. Vol. 111, 1998 at 670-672.
[191] Ibid. Employing the example of empty Moscow storefronts, Michael Heller explains how multiple property rights over a scarce resource can lead to the underuse of a product.
[192] Heller, M. & R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science.Vol.280, 1998, Pp. 698-701, 1998.
[193] Ibid at 699: Heller and Eisenberg use the term "anticommons" to differentiate this situation from the "commons," which described the public land in England before the industrial revolution took place. The commons was destroyed when people built fences around their own private property.

The problem of the anticommons has been applied to the biotechnology sector.[194] Innovation in the field of biotechnology is cumulative and built on existing knowledge. As a result, patent rights can hinder development rather than encouraging it.[195] The grant of patent rights entitles the right holder to exclude others from the commercial use of the patented invention. This contains an intrinsic dilemma. Can patents be granted for inventions that are so rudimentary and central to future developments that patenting them will excessively encumber subsequent inventors? If too many patent owners block one another from accessing the technical and scientific information in biological products to develop further innovative products, a biological anticommons could arise due to the existence of a simultaneous fragmented system of intellectual property rights.[196]

2.5.1. Patent thickets

In the field of biotechnology, where research is cumulative and is based on previous work, the common complaint is that the growing number of overlapping patents can lead to the development of a 'patent thicket,' which economist Carl Shapiro defines as:

> [A]dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology. With cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging, innovation.[197]

In other words, a patent thicket is a illustrative term which refers to the obstacles researchers may encounter when attempting to innovate in a field of technology that is inundated with overlapping upstream patent rights that are held by several competing

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[194] For more on the anticommons in the biotechnology field, see Report of the National Institutes of Health (NIH) Working Group on Research Tools, June 4, 1998. http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm. Accessed Sep 23, 2013.
[195] See supra note 192, Heller & Eisenberg at 699.
[196] This is why there is the argument that commercialisation should not occur through absolute privatization, but there should be room for the public domain. See Boyle, J. The Public Domain: Enclosing the Commons of the Mind. New Haven: Yale University Press, 2008.
[197] Shapiro, C. "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting," in Jaffe, A., J. Lerner, and S. Stern (eds.) Innovation Policy and the Economy. Cambridge: The MIT Press. 2001 at 122.

entities.[198] It is maintained that a thicket can arise due to an increase in the number of patents filed and increased technological complexity and interdependence.[199] To navigate through this thicket of patents, one needs to pay license fees, which could make it costly to conduct research and may delay further innovation. However, one possible interpretation is that the patent thicket issue is merely an a natural effect and price of the patent system, and will be a persisting problem.[200]

2.5.2. Biotechnology Research Tools

The problems associated with a patent thicket with respect to human genetic materials is that a proliferation of patent rights could slow down or hinder the development of essential health processes and products.

> [T]here is concern that the extent of patent protection of biological research tools may be such as to impede biotechnological progress. For example, the existence of separate patents on gene fragments may make the transaction costs of assembling genetic material needed for research very high.[201]

Patents on genes could claim research tools, which are essential materials used by researchers in the laboratory to further develop new products.[202] They are often referred to as 'upstream' products because they involve primary-stage inventions that are exercised to develop final products. [203] Correspondingly, final end products are referred to as 'downstream' inventions because they are developed based on the use of

[198] UK Intellectual Property Office. A Study of Patent Thickets. July 30, 2013 at 59. The report investigated the effect of patent thickets on small firm behaviour.
[199] Ibid.
[200] Jacob, R. "Patent Thickets: A Paper for the European Patent Office Economic and Scientific Advisory Board Meeting," in Journal of Intellectual Property Law & Practice. Vol. 8, No.3, 2013 at 4.
[201] Landes, W. & R. Posner. The Economic Structure of Intellectual Property Law. Cambridge: Belknap Press, 2003 at 316.
[202] See supra note 200, Jacob, R., at 2. Sir Robin Jacob states that gene patents are a sort of essential patent by reason of the natural world as it is not possible to design around them..
[203]An upstream patent is a patent that is essential to the development of other inventions. For example, a patent on a gene sequence would be an upstream patent and a genetic test for the gene would be the downstream invention, since the genetic sequence is essential to the development of the test. For more on upstream patents, see: Wang, R. "Biomedical Upstream Patenting and Scientific Research: The Case For Compulsory Licenses Bearing Reach-Through Royalties" in Yale Journal of Law and Technology.Vol.10, Iss.1, Article 7, 2008.

upstream research tools.[204] The issue of 'upstream' patenting is particularly substantial in the context of biotechnology because they become 'blocking patents.'[205]

"Blocking patents" refer to a situation where an upstream patent can affect future downstream inventions. In the United States, there is no legal obligation for a patent holder to grant a license. If a company owns an upstream patent, it can stifle downstream inventions by refusing to license. Companies who possess upstream patents may only grant licenses if they can obtain a share of the profits from future downstream inventions.[206] An accumulation of fragmented patent rights requires high transaction costs in obtaining permission from the various patent owners before wider development can be completed.[207] For instance, the University of Washington developed corresponding gene sequencing methods for detecting inherited mutations in ovarian and breast cancer genes. Rather than using the BRCA1 and BRCA2 genes, the test used multiple genes to detect cancer risk. [208] It is suggested that gene patents can hinder innovation in genetic technologies that require the evaluation of multiple genes.
In this respect, if each gene is patented by a different company, and if any one of the patent holders refuses to license his or her property right, then the cost of a project could rise significantly as the 'holdout' may request a bribe that is near to the cost of the project.[209] Therefore, too many obstructive patents result could result in a loss of

[204] Ramirez, H. "Defending the Privatization of Research Tools: An Examination of the Tragedy of the Anticommons in Biotechnology Research and Development" in Emory Law Journal. Vol. 53, pp.359-389, 2004 (Providing instances of where technology covered by research tool patents was broadly disseminated); Epstein, R. & B. Kuhlik, "Is There a Biomedical Anticommons?" in Regulation. Vol. 27, No. 2, 2004 at 54, questioning the assumption of an anti-commons in the field of biotechnology.
[205] See supra note 4, Burk & Lemley at 1646.
[206] Heller, M. & R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science.Vol.280, 1998.
[207] See supra note 4, Burk & Lemley at 1611.
[208] See Walsh, T. et al. Detection of Inherited Mutations for Breast and Ovarian Cancer Using Genomic Capture and Massively Parallel Sequencing. Proceedings of the National Academy of Science. Vol. 107, No. 28, 12629–12633, 2010.
[209] For a discussion concerning the holdout question, see: Cohen, L. "Holdouts and Free Riders," in Journal of Legal Studies. Vol. 20. 1991 at 361.

welfare, as the entire value of the resources under patents would diminish as industrious possibilities for research could not be continued by would-be innovators.[210]

2.5.3. Impact on sequential innovation

Some scholars have suggested that the solution to preventing an anticommons from development is to grant fewer patents to DNA sequences.[211] There is the possibility that an anticommons can be prevented by precluding DNA patents given if the cost of DNA sequencing is low, and provided that non-proprietary incentives are abundant.[212] This line or argument now seems to apply to isolated gene sequences in the US.[213]

However, there are already thousands of patents on DNA sequences.[214] In addition to patents covering DNA, genes and fragments of genes, patents have also been granted for the methods of sequencing and other various research tools. The issue centres on the quantity of rights with various owners that must be combined. For instance, if a company wants to develop a therapeutic protein that requires several gene fragments, that company will be required to obtain licenses on all the patented gene fragments to avoid patent infringement. If each gene fragment is owned by different owners, then the transaction costs will be very high before an organization can acquire the right to create the product. Heller and Eisenberg maintain that issuing patents on

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[210] Brief of James D. Watson as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 19: "For a new assay using hundreds of human genes, the sea of patents and patent applications would create hundreds, if not thousands, of individual obstacles to developing and commercializing the assay. The best way, in my view, to resolve this problem is to eliminate the unnecessary patenting of human genes."

[211] Jacobs, P. & G. Van Overwalle. "Gene Patents: A Different Approach" in European Intellectual Property Review. Vol. 23, Iss. 11, 2001 at 505. Jacobs and Van Overwalle advance the argument that patents should not be granted for DNA sequences themselves, but only for downstream products.

[212] See supra note 4, Burk & Lemley at 1626.

[213] For instance, Rebecca Eisenberg and Robert Merges wrote a legal opinion letter advancing the argument that the National Institutes of Health (NIH) patent applications on expressed sequence tags are not patent eligible. See: Eisenberg, R. & R. Merges. "Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of the Partial cDNA Sequences," in American Intellectual Property Law Association Quarterly Journal. Vol.23, pp.1-52, Winter 1995.

[214] Thomas, S. et al. "Ownership of the Human Genome" in Nature. Vol. 380. 1996 at 387.

gene fragments "makes little sense,"[215] because many genes are required to make a therapeutic protein or a genetic diagnostic test.

> A proliferation of patents on individual fragments held by different owners seems inevitably to require costly future transactions to bundle licenses together before a firm can have an effective right to develop these products.[216]

The problem could be intensified with reach through license agreements (RTLA), which gives the patent owner of the patented invention rights to subsequent downstream discoveries through royalties in exclusive or non-exclusive licenses. "RTLAs may lead to an anti-commons as upstream owners stack over-lapping and inconsistent claims on potential downstream products."[217] This may create complex obstacles when a user needs access to multiple patented inputs to create a single useful product. For example, if an company wants to develop a genetic testing kit for hereditary colon cancer, it could run into licensing issues.[218]

2.5.4. Is there an anti-commons in biotechnology?

Despite the argument that patent protection creates a vast thicket and could lead to an anticommons, there are several limitations to the argument when it is applied to the patent system. First, patent rights are intangible in nature, which differ from traditional tangible property rights.[219] An inherent part of the anti-commons line of reasoning is that like land scarcity, there is a scarcity to the biological commons.[220] On

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[215] See supra note 192, Heller & Eisenberg at 699.
[216] Ibid.
[217] Ibid.
[218] A commonly inherited condition that could increase an individual's risk of colon cancer is a disorder known as hereditary non-polyposis colorectal cancer (HNPCC), which occurs when there is a mutation in one of the DNA repair enzyme genes MLHI, MSH2, MSH6, PMSI, or PMS2. However, each of these genes code for different types of proteins and RNA (See Stadler, W. (Ed). Cancer Biology Review: A Case-Based Approach. New York: Demos Medical Publishing, 2014 at 14). The genetic test created to test for the five DNA repair enzyme genes may actually need to test for many more combinations of proteins, RNA and DNA. If the various components of proteins, RNA and DNA are patented by several companies, then it would mean the company developing the test would need to obtain licenses for the various parts that would be included in the test to avoid infringement. In this situation, patents cause a blockage in the form of a 'patent thicket' which can be problematic for innovators wishing to enter the market.
[219] Leung, S. "The Commons and Anticommons in Intellectual Property" in UCL Jurisprudence Review. Vol. 16, pp.16-28, 2010.
[220] Buchanan, J. & Y. Yoon. "Symmetric Tragedies: Commons and Anticommons" in Journal of Law & Economics. Vol. 43, 2000 at 1.

the contrary, the intangible commons is very different from physical land in that it does not depreciate with multiple usage. What is unique to genetic research is that there are various pathways with multiple starting points that can lead to the development of an innovative product or process.[221]

In addition, patent rights are temporal.[222] The very concept of the anti-commons exists as a reactionary entity to the problems arising from when ownership is accepted to be absolute.[223] It is submitted that a property right resulting from a patent grant is temporary and not absolute:

> Even the full-blooded owner in theory does not have absolute rights over a resource…the range of excludability that an owner may have can be limited: the range of excludability that an owner may have others in the governance of a particular resource may vary.[224]

Thus, due to the temporal nature of patents, patent holders are restricted in exercising their exclusionary rights for twenty years, and the negative effects that can arise from an anti-commons will fade.

Third, patents do not necessarily mean that resources are under exploited. Patent owners have the option to both use their invention and exclude others from the usage of the invention. What is clear is that the patent holder intends to make money from the utilization of the invention.[225] Since the patent is temporal, it becomes a 'wasting' asset because the holder faces the possibility of new and old patents during the duration of the right, and new techniques that fall into the public domain will erode their dominance.[226] Therefore, if patent holders do not exercise their inventions or license them to other parties, they will miss out on income opportunities.

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[221] Buckley, T. The Myth of the Anticommons. Biotechnology Industry Organization, May 21, 2007, http://www.bio.org. Accessed February 24, 2012.
[222] 35 U.S.C. § 154(a)(2) and Article 63(1) of the EPC (1973)
[223] Lametti, D. "The Morality of James Harris's Theory of Property" in The Properties of Law: Essays in Honour of James Harris. T. Endicott, J. Getzler and E. Peel, (eds.). Oxford: Oxford University Press, 2006.
[224] Lametti, D. "The Concept of Anticommons: Useful, or Ubiquitous and Unnecessary?" in Concepts of Property in Intellectual Property Law. Howe, H. and J. Griffiths (eds.). Cambridge: Cambridge University Press, 2013 at 248.
[225] Epstein, R. & B. Kuhlik, "Is There a Biomedical Anticommons?" in Regulation. Vol. 27, No. 2, Summer 2004 at 55.
[226] Ibid.

Moreover, patents can help facilitate further investment and development into biotechnology sectors that are uncertain and risky, and thus, costly. As such, the exclusive rights granted to patent owners have a positive effect in that it directs resources into areas of industry that may otherwise not be developed.[227]

Fifth, there is a lack of empirical evidence over the probable negative effects connected with patent thickets. Rather, a US study which consisted of a survey of 70 attorneys, scientists and managers in the biotechnology and pharmaceutical industries over whether there was a patent blockade revealed that almost none of the participants believed the current patent regime posed unbeatable impediments that prevented the effective use of research tools.[228] Similarly, a study conducted by the UK's Intellectual Property Office revealed that the thicket problem does not deter innovation, particularly for small companies.[229] Finally, a 2013 study conducted by the EPO's Economic and Scientific Advisory Board concluded that a patent thicket is not a problem in itself, but maintains that procedures to improve patent quality can assist in reducing the intricacy of the system and address patent thickets indirectly.[230]

Although this thesis does not deny the existence of the theoretical problem of the anti-commons in biotechnology, it suggests that it can be overcome in practice. In fact, the data gathered from interview participants from the biotechnology/research sector

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[227] Mireles, M. "An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation," in University of Michigan Journal of Law Reform. Vol. 38, 2004, at 155 & 163.

[228] Walsh, P. et al. "Effects of Research Tool Patenting and Licensing and Biomedical Innovation" in Patents in the Knowledge-Based Economy. Cohen, W. and S. Merill (eds.) Washington: National Academies Press, 2002 at 285.

[229] The UK IPO emphasized that even a finding of a barrier to entry created by patent thickets is not proof that reducing that barrier would lead to increased innovation. See UK Intellectual Property Office. A Study of Patent Thickets. July 30, 2013. www.ipo.gov.uk/ipresearch-thickets.pdf. Accessed November 19, 2013 at 60.

[230] European Patent Office Economic and Scientific Advisory Board. Report of Workshop on Patent Thickets. March 2013. Available at: http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/workshop_patent_thickets_en.pdf. Accessed October 3, 2013. The report proposed 6 possible solutions (at 18): (1) improving the granting process (pricing, quality); (2) improving dispute resolution (specialized court, better opposition); (3) improving standards related to IP management (streamlined licensing); (4) improving transparency (registry); (5) market-based incentives (encouraging better applications, patent pools) and (6) compulsory licensing.

suggests that they have not encountered any 'patent thickets', and, when necessary, license with other parties.[231] Moreover, there has been a lack of empirical data for the assertion that a patent blockade governs patent innovation.[232] Nevertheless, there has been a persistent call for the diminishing of patent protection for biotechnology inventions. In the UK, for instance, the Nuffield Council on Bioethics considered whether granting patents for DNA sequences achieved the patent system's goal of stimulating innovation for the public good and rewarded innovators for useful new inventions and ultimately maintained that patents should be the exception and not the norm.[233] In Germany, the Protestant Church of Germany denounced patents on DNA sequences and genes as they already exist in nature and are not inventions. [234] In the US, a 2006 study by the National Research Council (NRC) acknowledged the possibility of an anticommons pertaining to biotechnology patents, and advocated that the standard for patenting should be strengthened.[235]

2.5.5. Practical realities

One explanation for the lack of empirical evidence of an anti-commons problem is because of the competitors' willingness to reasonably license with one another. For instance, Herbert Boyer and Stanley Cohen's recombinant DNA invention gave rise to genetic engineering in the 1970s. Their patented invention of DNA cloning techniques enabled genes to be relocated amongst different biological species.

> One of the very broadest patents in genetic engineering was one of the first ones. It more or less covered the principle of genetic engineering, and they got a very broad claim in the States. And

[231] See Chapter 5 for stakeholder interviewee responses.
[232] Epstein & Kuhlik, 54.
[233] The Nuffield Council on Bioethics. The Ethics of Patenting DNA. London: Nuffield Council, 2002.
[234] Evangelischen Kirche in Deutschland (EKD). The Earth is the Lord's and all That is in It: Biopatents and Food Security from a Christian Perspective. April 2013. www.ekd.de. Accessed April 30, 2013.
[235] National Research Council (US) Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. Reaping the Benefits of Genomic and Proteomic Research. S. Merrill & A. Mazza (eds.). Washington (DC): National Academies Press (US), 2006. Other two previous US reports suggesting increasing the patent threshold include: Federal Trade Commission. To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy. www.ftc.gov.os/2003/1110/innovationrpt.pdf. October 2003. Accessed January 4, 2014; National Academy of Sciences, Committee on Intellectual Property Rights in the Knowledge-Based Economy. A Patent System for the 21st Century. www.nap.edu/catalog.php?record_id=10976. 2004. Accessed January 4, 2014.

> everybody became very agitated about this as you might reasonably expect, but they made a license available for $10,000, which is not nothing. But it was probably less than it would've cost anyone to investigate the situation seriously. And it clearly was a ground-breaking invention. And in consequence, they had no trouble licensing it, and people had no trouble getting access to the technology. It's more or less the opposite of trolls, if you like. If you are in that position, you need to consider really rather carefully what it is sensible to do.[236]

Had Cohen and Boyer refused to license their technique, it would have delayed the development of the biotech industry. Luckily, they decided to license their technique, which contributed to the rapid growth of the field.[237] Cohen and Boyer's licensing experience reflects the practical realities between patent holders and those non-right holders. Economically speaking, companies are likely to negotiate licensing agreements provided they can afford the transaction costs. The confidential processes of negotiation which occurs when a rights-holder realizes a potential infringement and sends a letter to the alleged offending party. If resolved, these instances do not have to go to court. The majority of the biotechnology stakeholders maintained that negotiated settlements are the most common result of any assertion of patent rights. [238] Therefore, although blocking patents could come in the form of patented processes or methods, most likely, patent holders will find it is more profitable to license inventions rather than hoard them.[239]

2.6. Potential solutions

Although there is a lack of empirical evidence concerning the presence of patent thickets in biotechnology, there remains a possibility that too many patents could encumber access to important technologies.[240] As such, one could look towards potential solutions to prevent the development of a patent thicket. There are three

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[236] Interview with Tim Roberts (British chartered patent attorney) on February 7, 2012.
[237] Kevles, D. & A. Berkowitz. "The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics," in Brooklyn Law Review.Vol.67, pp. 233-248, 2001.
[238] See Chapter 5 for interview responses.
[239] Feldman, M., A. Colaianni & C. Liu. "Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program" in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices. A. Krattiger et al. (eds.) MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. 2007. Available online at www.ipHandbook.org. Accessed March 21, 2014.
[240] Gallini, N. "The Economics of Patents: Lessons from Recent U.S. Patent Reform" in Journal of Economic Perspectives. Vol. 16, No. 2, pp. 121-154. Spring 2002. Gallini maintains that patents have the ability to incentivize research but at the social cost of restricted access to the claimed invention during the duration of the patent.

popular solutions found within patent law discourse: (i) patent pools; (ii) the research exemption and (iii) compulsory licensing.

2.6.1. Patent pools

Patent pools have been suggested to be a promising solution to patent thickets, which are essentially agreements between two or more patent holders to license one or more of their patents to each other, or to combine their patents into one package and license it to third parties.[241] One clear advantage of a patent pool is licensing problems are easily overcome, provided the key players agree to pool their IPR assets together. However, in order for a patent pool in biotechnology to work, it would need to encompass a variety of rights, particularly essential products and processes like DNA and RNA sequences, proteins, recombinant DNA techniques, etc.

Nevertheless, due to the nature of biotechnology inventions, holders of the key inventions may be reluctant to join as there is no apparent benefit:

> Indeed, many private companies with valuable patents on key technologies may decide that joining a patent pool would be a financial blunder. Why would any company allow an outside organization to control its golden egg laying goose?[242]

While in theory, patent pools can be regarded as a potential solution to the problem of a patent thicket, it relies on the voluntary participation of patent holders, particularly those with valuable patents on fundamental technologies. Therefore, not all patentees will participate.

2.6.2. Research exemption

Since the landmark case *Madey v. Duke University*,[243] the research exemption in the US has all but ceased to exist in practice:

> Regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strict philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.[244]

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[241] For a discussion on the virtues of a patent pool, see: Resnik, D. "A Biotechnology Patent Pool: An Idea Whose Time Has Come?" in The Journal of Philosophy, Science & Law. Vol.3, 2003.
[242] Ibid, 12.
[243] *Madey v. Duke University*, 307 F.3d 1351 (Federal Circuit 2002).
[244] Ibid at 1362.

In Europe, the research exemption exists within patent law. Even though the EPC and the regulation on the unitary patent does not make any reference to it,[245] EU Member States tend to include a provision within national patent legislation declaring that patent rights shall not extend to experimental acts that are directed to the subject matter of the patented invention.[246] However, different EU Member States national legislation and courts interpret the scope of the exemption differently. Moreover, the line between a commercial and non-commercial use is blurry in biotechnology, which is why the wording of research exemption clauses needs to be written and implemented carefully.[247]

2.6.3. Compulsory licensing

A compulsory license is a tool that the state or court can employ to compel a patent holder to license the patented invention. Article 31 of TRIPS [248] asserts that it is up to WTO Member States to determine the grounds upon which to grant compulsory licenses. It has been suggested that a compulsory license can be used as a balancing mechanism between the biotechnology industry and access to healthcare. Former Canadian Supreme Court Justice Ian Binnie argued that the Canadian government should implement a compulsory licensing scheme in 'high-outlay, high-reward areas" like biotechnology.[249] For instance, one can argue that a complete monopoly over a gene is inappropriate, and Sir Robin Jacob suggests that a well-designed compulsory license provisions would be helpful in the area:

[245] Article 63(1) of the Convention on the Grant of European Patents of 5 October 1973; Regulation (EU) No. 1257/2012 of the European Parliament and the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ EU, 31.12.2012, L 361/1.
[246] For instance, in Germany, Section 11 Nr. 2 of the German Patent Act states: "The effects of the patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention". In the UK, section 60(5)(b) of the Patents Act exempts from patent infringement acts "done for experimental purposes relating to the subject matter of the invention".
[247] Resnik, D. "A Biotechnology Patent Pool: An Idea Whose Time Has Come?" at 9.
[248] The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.
[249] Young, C. "Law is Lagging Genetic Research, Warns Former SCC Judge Binnie," in The Lawyers Weekly. Vol. 33, No.40, March 7, 2014.

> There are many who say that a complete monopoly over a gene is inappropriate, just because you were first to isolate it, or even if you are first to isolate it and know what it is for. It may be that well-designed compulsory license provisions would be helpful in this area…A lot depends on the nature of the invention – one that is not only high risk but involves billions in research and years in time to bring to market stands in a different economic category than an isolated gene, especially one isolated by more or less standard techniques.[250]

However, compulsory licenses are granted only under extraordinary circumstances, like a national emergency.[251] Moreover, the state may be hesitant to use it regularly as it is contrary to the essence of a patent right.

2.7. Conclusion

With the arrival of growing levels of patenting activity in biotechnology, the idea of the formation of a possible thicket that could obstruct access to essential technologies and create an anticommons has drawn certain consideration. The anticommons theory advances the argument that the over-fragmentation of patent rights can lead to additional costs and the potential underuse of a product or process. There are three main arguments that emphasize the existence of an anti-commons in biotechnology. First, institutions and companies who require access to many different types of technical knowledge to develop new inventions may encounter a thicket of patents. Second, blocking patents can exacerbate a patent thicket, referring to upstream patents that can affect future downstream inventions. Third, researchers and companies may have to pay high licensing fees because they will have to negotiate with several different companies who hold the relevant patents in the field. Moreover, proposed measures to control the negative effects of patent thickets include: patent pools, a research exemption, and compulsory licensing.

This thesis acknowledges that due to the nature of gene patents, there is no way to invent around them. As a result, conditions conducive to the development of an

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[250] Jacob, R. "One Size Fits All?" in Perspectives on Properties of the Human Genome Project. S. Kieff (ed.) San Diego: Elsevier Academic Press, 2003 at 453.

[251] For a discussion on compulsory licenses, see Van Zimmeren, E. & G. Van Overwalle. "A Paper Tiger? Compulsory License Regimes for Public Health in Europe" in International Review of Intellectual Property and Competition Law. Vol. 4, pp. 4-40, 2011.

anticommons exist. Nevertheless, there is a lack of empirical evidence that proves the presence and negative consequences of patent thickets in biotechnology. Even so, the importance of biotechnology innovation encourages patent policy makers to take into account this issue when considering any potential patent law reforms.

Chapter 3: The Justifications of Patents for Human Genetic Materials

"It is evident then that it is best to have property private, but to make the use of it common; but how the citizens are to be brought to it is the particular business of the legislator."

-Aristotle, *The Politics*, II.v.

3.1. Introduction

Aristotle's quote above sets the tone for this chapter and overall thesis, maintaining that private property performs a social function, in the way that it serves the common good of society. The quote emphasizes that private property should be used in a way which increases the overall good of humanity. This social aspect of property is a noticeable theme in academic property discourse.[252] This chapter provides a definition of property, followed by an inquiry into the concept of property as a social and legal construct. Next, the focus will return to a discussion of the patent system as a social contract between the state and patent holder with a focus on the right to exclude. It emphasizes that patents perform a social function, such as protecting business interests and the temporary nature of the right. The weaknesses of a natural law approach to the propertization of human biological materials will be addressed and an explanation for why it is limited in its application to patenting human biological materials. Instead, a social construction of property is appropriate for the justification of patenting genetic material, as the patent system is a social legal construction designed to increase societal welfare. The economic justifications of patenting human biological materials will follow. The primary question is what type and extent of rights an inventor should have in human genetic materials that could meet the objectives of the patent system whilst also advancing societal interests.

[252]See Lametti, D. "The Concept of Property: Relations Through Objects of Social Wealth," in University of Toronto Law Journal. Vol. 53, pp.325-378.2003, Penner, J. The Idea of Property in Law. Oxford: Clarendon Press, 1997, Davies, M. & N. Naffine. Are Persons Property?: Legal Debates about Property and Personality. Aldershot: Ashgate, 2001. Chapter 1; Honoré, A.M. "Ownership" in Oxford Essays in Jurisprudence. Guest, A. (ed.). Oxford: Oxford University Press, 1961 at 174.

3.2. Defining Property

Advances in the medical and biotechnological fields have resulted in a perception of how human genetic materials are valued economically, becoming increasingly valuable in parallel with the rising advancement of therapies and diagnostics, which compels the courts and legislators to re-examine granting property rights to the human biological materials. Before the arguments for and against the recognition of property rights on human biological material are examined, the definition of "property" will be clarified below.

Black's Law Dictionary defines property as: "The right to possess, use, and enjoy a determinate thing...the right of ownership...Any external thing over which the rights of possession, use, and enjoyment are exercised."[253] The right of ownership results in a variety of property interests: including "the rights to use, transfer, exclude; or-property protects the fruits of human labour, or activities in which human beings flourish."[254] From this definition, characteristics of ownership include: possession, ability to exclude, and transferability. Under this description of property, genetic information can qualify as property. An individual has rights and powers in one's genetic information, including protection from third party interference. An individual's right of control over one's body, and right to exclude others from infringing on the body suggest that there is a property right to the human body, including one's genetic material.

Similarly, the Shorter Oxford English Dictionary defines property as: "The condition of being owned by or belonging to some person or persons; hence, the fact of owning a thing; the holding of something as one's own; the right (*esp*. the exclusive

[253] "Property" Black's Law Dictionary (8th ed.). Bryan A. Garner (Editor in Chief). Minnesota: Thomson West, 2004 at 1252

[254] Underkuffler, L. The Idea of Property: Its Meaning and Power. Oxford: Oxford University Press, 2003 at 14.

right) to the possession, use, or disposal of anything; ownership, proprietorship."[255] The emphasis is on ownership and the right to possess, use, and dispose something.

Along the same lines, the Law of the Twelve Tables, c.450 B.C., the first occasion of codified Roman law states: "When one makes a bond and a conveyance of property, as he has made formal declaration so let it be binding."[256] Two characteristics can be derived from this law: possession and the right to transfer. As long as one has formally declared one's ties to the property, (in this case, it would be an oral announcement), one has legally acquired or possessed the assumed property. In addition, transferability rights can be established from the phrase "conveyance of property," which means transferring ownership from one party to another. Table VI, Law 3 states: "A beam that is built into a house or a vineyard trellis one may not take from its place." From this law, a right of exclusion can be extracted from the phrase.

Three common characteristics of property can be derived from these definitions of property: possession, exclusive use, and transferability. Thus, it is apparent that the concept of property in law is based on a comprehension of legal rights.

3.3. An inquiry into the concept of property and ownership

The categorical application of property theory to intellectual property law is a somewhat modern development in IP scholarship, in which there has been increased interest in studying the concept of intellectual property rights as property rights,[257] possibly due to a reappearance of property principles triggered by the innovative developments in the biotechnology field.[258] For instance, one can argue that DNA sequences should not be patentable because no one should 'own' an aspect of the human genome. This argument is based on ideas about ownership.

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[255]"Property". The Shorter Oxford English Dictionary on Historical Principles Part II 3rd edition.C.T. Onions (Editor). Oxford: Clarendon Press, 1987 at 1687

[256] The Law of the Twelve Tables, Table VI, Law I .c.450 B.C. Project Gutenberg. www.gutenberg.org. Accessed Aug 29, 2013.

[257]Mossoff, A (ed.). Intellectual Property and Property Rights. Cheltenham: Edward Elgar, 2013.pp.1-5.

[258]Merges, R. The Concept of Property in the Digital Age. UC Berkeley, 2008. Retrieved from www.escholarship.org/uc/item/142112hd. Accessed October 23, 2013.

> It is fallacious, I would argue, to say that human DNA is 'special' because it is uniquely human. Firefly DNA is uniquely firefly-ish, but that does not in itself make it any more special than any other organism's genetic material, that of homo sapiens [sic] included. But what about the larger claim that all DNA is inherently unsuitable as an object of property? If there can be rights of ownership over animals and plants, which our legal system clearly allows, then that claim is obviously untenable…As embodied in individual plants and animals, DNA is 'ownable,' however.[259]

It might be considered that those who are against genetic patenting are so because they incorrectly perceive patents as complete ownership - granting the patent owner the entirety of the bundle of rights, instead of a temporary exclusive right to the granted patent claims in exchange for disclosure of valuable knowledge to the public. It must be emphasized that patent rights are not complete ownership rights.[260] Ownership is a legal right a person(s) is granted which grants them a high degree of control over a scarce resource.[261] In a patent context, a patent holder can own a temporary exclusive property right.[262]

As a result of the different questions introduced in acquiring property rights to isolated DNA sequences and cDNA, some academics have considered conceptual property theory in an attempt to articulate the nature of intellectual property rights and the way in which legal principles outline and protect those rights.[263] Although the fundamental queries in policy debates pertaining to intellectual property law are prescriptive and concerned with the establishment of norms, the arguments are based on the structure of legal doctrines. A conceptual analysis of intellectual property rights as property rights uncovers how intellectual property law either sustains or undercuts the normative policy disputes by revealing how legal doctrines are assembled to attain a

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[259] Dickenson, D. Property in the Body: Feminist Perspectives. Cambridge: Cambridge University Press, 2007 at 114-115. This thesis will not enter the disputed discussion over the distinction between the concepts of 'ownership' and 'property,' but uses the terms interchangeably.
[260] Ibid, 118.
[261] Mattei, U. Basic Principles of Property Law: A Comparative Legal and Economic Introduction. London: Greenwood Press, 2000 at 77.
[262] It can be argued that a patent right does not amount to full ownership as it can be undermined through measures like compulsory licensing.
[263] See Barrad, C. "Genetic Information and Property Theory" in Northwestern University Law Review. Vol. 87. Pp. 1037-1086, 1992-1993 and Feldman, R. "Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law" in Stanford Law Review. Vol. 63, pp.1377-1402, 2010-2011.

normative standard. Therefore, understanding property as a concept provides the structure of intellectual property as a property right.

3.3.1. Legal construction of social relations

There are many major contributions to the debate over property and its justifications.[264] In the broadest sense, property is an institution governing the allocation of control of valuable resources to individuals.[265] It is also understood as a set of legal relations composed of several rights and duties: "Property concerns the relationships between human beings and all things - physical or conceptual - which can be made into resources. It therefore also intimately concerns the structure of the social relationships between people."[266] Property also possesses a social aspect, in that it is a form of power, because property consists of social relations amongst people. This idea of individual power in private property is described by Jeremy Waldron: "In a system of private property, the rules governing access to and control of material resources are organized around the idea that resources are on the whole separable objects each assigned and therefore belonging to some particular individual."[267] This means that the quintessence of private property is that individuals are granted some degree of power over the command and use of a resource. Therefore, property is a concept shared by a range of academic fields.[268] Presenting an explanation of the legal institution of property is not to

[264]Wesley Hohfeld's Fundamental Legal Conceptions as Applied in Judicial Reasoning, Anthony Honoré's Ownership, James Harris' Property and Justice, James Penner's The Idea of Property in Law, Daniel Lametti's The Concept of Property: Relations Through Objects of Social Wealth, Laura Underkuffler's The Idea of Property: Its Meaning and Power, Stephen Munzer's A Theory of Property, Jeremy Waldron's The Right to Private Property and Morris Cohen's Property and Sovereignty. Although these works do not address intellectual property specifically, they offer a tremendous foundation for the primary principles of property. In a pluralist setting, no established set of property standards rule. Still, there are some common elements amongst all property justifications, and they identify essential constraints on the scope and structure of private property.

[265]Lametti, D. "The Concept of Property: Relations Through Objects of Social Wealth," in University of Toronto Law Journal. Vol. 53, 2003 at 334.

[266]Davies, M. and N. Naffine. Are Persons Property?: Legal Debates about Property and Personality. Aldershot: Ashgate, 2001. Chapter 1.

[267]Waldron, Jeremy. The Right to Private Property. Oxford: Clarendon Press, 1988 at 38.

[268] See Björkman, B. and S. Hansson. Bodily Rights and Property Rights" in Law, Ethics and Medicine.Vol.32, pp. 209-214, 2006.

discredit other accounts of property, but to highlight the fact that property rights must be legally assembled.[269]

As a legally constructed institution, property is typically referred to as a 'bundle of rights.'[270] The bundle of rights metaphor has become the dominant paradigm in which property is considered,[271] often being reflected in major jurisprudence writings.[272] In addition, Anthony Honoré offers his eleven incidents of ownership, which form the sticks in the bundle of rights: "right to possess, the right to use, the right to manage, the right to the income of the thing, the right to the capital, the right to security, the rights or incidents of transmissibility and absence of term, the prohibition of harmful use, liability to execution and the incident of residuarity."[273] If there are an abundance of these qualities present, Honoré maintains that the conditions are rightfully set and an 'owner' is present. This approach is a follow-up to Hohfeld's concept of property as it defines ownership from the perspective of a property owner and the ensuing entitled rights that may be claimed in respect to an object. Rather than emphasizing the duties non-property owners have, Honoré focuses on the range of the property owner's permitted actions. Honoré claims that these incidents of ownership can extend to intangible goods:

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[269] Barnes, R. Property Rights and Natural Resources. Oxford: Hart Publishing, 2009 at 22.

[270] Wesley Hohfeld maintained that private property was a bundle of rights and differentiated between rights *in rem* and rights *in personam*, which he respectively referred to as "paucital" and "multital" rights: "A paucital right, or claim (right *in personam*), is either a unique right residing in a person (or group of persons) and availing against a single person (or single group of persons); or else it is one of a *few* fundamentally similar, yet separate, rights availing respectively against a few definite persons. A multital right, or claim (right *in rem*), is always *one* of a large *class of fundamentally similar* yet separate rights, actual and potential, residing in a *single* person (or single group of persons) but availing *respectively* against persons constituting a very large and indefinite class of people." (72) Hohfeld, W. Fundamental Legal Conceptions as Applied in Judicial Reasoning. David Campbell and Philip Thomas (eds). Aldershot: Ashgate Publishing Limited, 2001.

[271] "The bundle of rights analysis of property can serve as a "dominant paradigm" under the aegis of which working lawyers and academic theorists may attend to particular problems in the law of property." Penner, J. "The Bundle of Rights Picture of Property" in UCLA Law Review. Volume 43, 1995-1996 at 713.

[272] "The legal definition of property most often refers not to a particular physical object, but which bundle of rights includes the rights to possess, use, and dispose of a particular article." American Jurisprudence 2nd edition.Volume 63C, 2009 revision at §1.

[273] Honoré, A. "Ownership" in Oxford Essays in Jurisprudence. Guest, A.G. (ed.). Oxford: Oxford University Press, 1961 at 113.

> In the law we find the following position. As regards external material objects, it is natural to speak of ownership. A person 'owns' a book, house or car. The terminology of ownership is also extended to some things other than material objects. A person may 'own' a copyright, leasehold property, goodwill, a business, patent rights. In these cases, the analogy with the incidents of the ownership of external material objects is a close one.[274]

The bundle of rights perspective is not without criticism.[275] The key accusation is, to quote Remigius Nwabueze, that "the 'bundle of rights' perspective entails a complete abstraction and disaggregation of property."[276] In other words, this account fragments the concept of property into a compilation of segregated legal interactions, which results in a disconnection of property rights and the object to which those rights pertain. Despite the critiques, however, the Hohfeld/Honoré approach persists as a central model for property, as reflected in the recent application of Honoré and Hohfeld's "bundle of rights" property theory in discussions concerning the relationship between property and the human body.[277] What can be taken from this demonstration of property is that it is a set of legal relations between a property right owner and a non-right holder in reference to something. Absent from the Hohfeld/Honoré depiction of property is the role of the objects of property, which will be discussed in section 3.4.3.

While the Hohfeld/ Honoré approach to property focused on the collection of legal relations designed by humans, legal realist Morris Cohen stressed that these social relationships are essential power relations and that property is a form of power over others. The power of property owners has been compared to sovereign power, an analogy famously made by Cohen, whose formulation of the property concept is found

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[274] Ibid, 129.

[275] See Penner, J. "Hohfeldian Use-Rights in Property" in Property Problems: From Genes to Pension Funds. J. Harris (ed.) London: Kluwer Law International, 1997. Pp.164-174, Duncan, Myrl L. "Reconceiving the Bundle of Sticks: Land as a Community-Based Resource" in Environmental Law. Vol. 32, Pp. 773-807, 2002 and Kohler, P. "The Death of Ownership and the Demise of Property" in Current Legal Problems. Vol. 53, Iss. 1, pp.237-282, 2000 for an assessment of the criticisms against the bundle of rights approach to property.

[276] Nwabueze, R. Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information. England: Ashgate Publishing Limited 2007 at 67.

[277] See Quigley, M. "Property and the Body: Applying Honoré" in Journal of Medical Ethics. Vol.33, 2006. Pp.631-634. Björkman, B. & S. Hansson. "Bodily Rights and Property Rights" in Journal of Medical Ethics.Vol.32, pp. 209-214, 2006.

in his classic essay, *Property and Sovereignty.*[278] The sovereign metaphor is used to explain how the power of property owners is equivalent to a sovereign's power over his or her subjects, submitting that property owners are like sovereigns because they have power over others due to their influence over scarce resources. "Property ownership thus comprises the power to command the services of people who are not economically independent and the power to tax the future social product-both of which also constitute the essence of sovereignty."[279] Cohen maintains that due to sovereign authority granted through exclusive property rights, the minority who acquire property ownership can exercise authority over the majority.[280] As a result, property laws "confer sovereign power on our captains of industry and even more so on our captains of finance."[281] Thus, Cohen emphasized the governance value of property, which institutes the property owner with qualities resembling those of the sovereign. Cohen suggested that the difference between property ownership and sovereignty is exaggerated, that they are closely related terms, and that property is merely another type of power over others.[282]

3.3.2. Power to exclude

A property right could be understood in terms of excludability: the right not to have one's property violated regardless of the economic value.[283] Cohen stated that "the

[278] Morris, C. "Property and Sovereignty" in Cornell Law Quarterly.Vol.13, 1927. Pp.8-30. Like Hohfeld and Honoré, Cohen maintains that property consists of a social relationship. But where the Hohfeld/ Honoré approach to property focused solely on the collection of legal relations designed by humans, Cohen stressed that these social relationships were essentially power relations and that property is a form of power over others.

[279] Martinez, J. "Reconstructing the Takings Doctrine by Redefining Property and Sovereignty" in Fordham Urban Law Journal.Vol.16, p189.

[280] This was the case of Myriad Genetics, a diagnostic company who acquired the patents to the BRCA1 and BRCA2 genes, which in women, could increase the likelihood of having breast and ovarian cancer. Myriad aggressively asserted their patents to prevent their competitors from developing their own breast cancer tests. The result was that one diagnostic company controlled the rest of the field, and other diagnostic firms were unable to provide potentially better and lower priced tests, which would ultimately benefit women. The power dynamics between biotech companies, especially diagnostic companies, and society (people who could benefit from diagnostic tests) can be challenging and a balancing exercise should be undertaken to decide whether the property right should continue to exist in such cases.

[281] See supra note 278, Morris, C. at 29.

[282] Ibid, 13.

[283] Several commentators maintain that property has significant characteristics other than the right to exclude. See, e.g., Hohfeld, Wesley Newcomb. Fundamental Legal Conceptions as Applied in Judicial Reasoning. David Campbell and Philip Thomas (Eds). Aldershot: Ashgate Publishing Limited, 2001;

essence of private property is always the right to exclude others."[284] This conception of property as an exclusionary mechanism aligns with the Hohfeld/ Honoré approach that legal relationships are the basis for property rights, but Cohen goes one step further in emphasizing that the outcome of a property right holder possessing power over non-right holders in relation to something is the right to exclude. The right to exclusion requires an obligation that is implementable by state pressure to submit to the property owner's will. This is what Laura Underkuffler terms the common conception of property, the notion that property recognizes and safeguards individual interests against collective forces.[285] David Lametti maintains that the most evident demonstration of assigning control to individuals is considered to be the ability to exclude others from access to or use of that claimed resource.[286] If a property right is not given, this can result in the claimant being susceptible to the will of others, who may infringe on the claimant's interests that have been deprived of protection.[287] Not only is there a relationship between the property owner and the object of social wealth, but there is also a relationship between the owner and others with respect to the claimed object. This ability to exclude others and the *de facto* duty of others not to interfere is considered to be the most significant facet of the institution of property.[288] This approach holds the view that property is best perceived as social relations between individuals with respect to things.[289]

Honoré, A.M. "Ownership" in Oxford Essays in Jurisprudence. A. Guest (Ed.). Oxford: Oxford University Press, Pp. 107-147, 1961.

[284] See supra note 278, Morris, C. 12. Cohen maintained that there must be a group which wields power over others, because granting a property right to someone causes vulnerability for those who do not hold the property right. Cohen maintains there are two implications resulting from the right to exclude. First, it gives the property right holder the authority to force someone to do what he wants in return for the use of the property. Second, it gives the property right holder the authority to compel others into handing over more property rights in the manner of fees or taxes.

[285] Underkuffler, L. The Idea of Property: Its Meaning and Power. Oxford: Oxford University Press, 2003 at 40.

[286] See supra note 265, Lametti, D. at 335.

[287] Singer, J. "Legal Theory: Sovereignty and Property" in Northwestern University Law Review. Vol.86, No.1 1991-1992 at 41.

[288] See supra note 265, Lametti, D. at 335.

[289] See, e.g., Harris, J. Property & Justice. Oxford: Oxford University Press, 1996 and Waldron, J. The Right to Private Property. Oxford: Clarendon Press, 1988.

The legal exclusion of property is grounded in the interest human beings have in the use of things.[290] James Penner notes "the right to property is a right to exclude others from things which is grounded by the interest we have in the use of things."[291] This power to exclude is the foundation for maintaining that private property is worthwhile, and it is ultimately a right *in rem*.[292] Penner does not classify intellectual property rights as rights *in personam*[293], but refers to them as "rights to monopolies" which correlate to duties *in rem* because everyone has a duty not to infringe the right holder's monopoly.[294] Penner maintains that a patent is a property right to a monopoly that is defined in the claimed idea, rather than a property right to the idea itself.[295] Furthermore, he notes that intellectual property rights "are rights directly to a practise of exclusion…correlating to duties *in rem* by which all subjects of the legal system have a negative duty not to do something. The duty is not one to refrain from interfering with material objects, but to refrain from working an invention."[296] However, excludability

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[290] A slightly different approach to the structure of ownership in property law is of Larissa Katz, who believes that the right to exclude is essential to property, but its main concern is not with the exclusion of all non-owners from the claimed object, but rather with the maintenance of the owner's situation as the exclusive agenda-setter for the owned thing:

> The exclusivity of ownership refers not to the right that others exclude themselves from the object owned, but rather, to the owner's special agenda-setting authority, a position that is neither derived from nor subordinate to the positions of others with respect to that resource. The function of much of property law…is to preserve the exclusivity of the position of the owner by ensuring its supremacy in relation to the rights and privileges of others and by ensuring that non-owners fall in line with the owner's agenda. Exclusion is simply a special case of a more general strategy of deference to the owner's agenda.

Katz, L. "Exclusion and Exclusivity in Property Law," in University of Toronto Law Journal. Vol. 58, No.3, 2008 at 297.

[291] Penner, J. The Idea of Property in Law. Oxford: Clarendon Press, 1997 at 71. Penner defines the objects of property based on the criterion of separability, which gives rise to transferability. "To be conceived of as an object of property a thing must first be considered as separable and distinct from any person who might hold it, and is for that reason rightly regarded as alienable." (113)

[292] A right *in rem* is a right to a thing, which is understood to apply to the world. Hohfeld maintained that property rights consisted of a collection of *in personam* rights and duties. Thus, when an individual is accepted as owning something, then a property right automatically gives rise to a correlative duty which the non-owners owe to the property right owner. In other words, the concept of property is based on the relationship between a property right holder and non-rights holders, rather than the relation between a rights holder and the claimed object.

[293] A right *in personam* is a personal right which only applies to a person or group of people.

[294] See supra note 291, Penner, J. at 109.

[295] Ibid, 120. Penner compares a patent to a 'lease,' which he maintains is not really a property right. As a result, Penner holds that patents are not property rights to the idea or the invention.

[296] Ibid at 119. Along the same lines or argument, Keith Aoki argues: "Instead of defining property relative to an owner's power to exclude others from its physical boundaries, intellectual property law focuses on reinforcing a proprietor's right to exclude others from subsequent uncompensated uses of an

does not encompass the complete spirit of property, as private property is both an idea *and* an institution which is composed of social relationships.

3.3.3. Social-obligation

The objective of this chapter is to recognize property rights as socially constructed relational concepts that are dependent on social institutions for their value and operation. Gregory Alexander articulates that property was always connected with proprietary customs in addition to self-interest.[297]

> [P]roperty is the material foundation for creating and maintaining the proper social order, the private basis for the public good. The proprietarian tradition, whose roots can be traced back to Aristotle, takes seriously the idea that the common good can be defined in substantive terms. That is, it presumes that not all forms of social order are normatively equal but that some are morally superior to others.[298]

This means that property not only serves individual interests, but social functions as well. Alexander proposes the social-obligation theory of the concept of property, holding that human beings have an obligation to their community to promote the capabilities that are indispensable to human flourishing.[299] For property owners, this means that there is an obligation for them to share property to enhance the abilities of others to flourish. Alexander makes the following remarks on how the social-obligation theory can be applied to patent law, emphasizing that patents restrict public access to certain resources that may be necessary for human flourishing:

> From the perspective of promoting essential capabilities, notably health, those who own these intellectual property rights may owe members of their communities, including the global community, an obligation to facilitate access to these resources for those who cannot afford them.[300]

Alexander argues that multinational companies, like large pharmaceutical firms are often the patent holders of essential inventions. Despite their magnitude and the

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intellectual work." Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain Parts 1&2" in Columbia-VLA Journal of Law & the Arts.Vol.18, 1993-1994 at 24.

[297] See Alexander, G. Commodity & Propriety: Competing Visions of Property in American Legal Thought 1776-1970. Chicago: The University of Chicago Press, 1997.

[298] Alexander, G. "Property as Propriety" in Nebraska Law Review. Vol. 77, 1998 at 668.

[299] Alexander, G. "The Social-Obligation Norm in American Property Law" in Cornell Law Review. Vol. 94, 2008-2009 at 745. He advocates some version of a commons-based regime in which this obligation can be realized. There are two possible approaches: compulsory licensing and open licensing for university inventions.

[300] Ibid, 812.

nature of their configuration, like individuals, they are able to engage in practical reasoning and are dependent on others for their development, and it is this dependency which embodies the human condition.

> The sets of relationships within which these firms develop and engage in practical reasoning are often much broader than those of individuals. This is especially true of the multinational companies and elite universities that are the most likely holders of patents or licenses…The world literally *is* their community. They would not be who they are without the world. Their dependence on the rest of the world creates obligations for them.[301]

If one begins from the position of property rights as a social institution that is receptive to societal needs, then it can be argued that it is society that will determine the scope and thresholds of that institution.

> Private property is a social institution that comprises a variety of contextual relationships among individuals through objects of social wealth and is meant to serve a variety of individual and collective purposes. It is characterized by allocating to individuals a measure of control over the use and alienation of, some degree of exclusivity in the enjoyment of, and some measure of obligation to and responsibilities for scarce and separable objects of social wealth.[302]

This argument is based on James Penner's structuring of the property norm, particularly Penner's emphasis on property's asymmetrical structure.[303] This means that exclusively allocating social resources to individuals essentially involves rights and powers, and as a result, duties and liabilities, these relations are facilitated through objects and, therefore, do not always correlate or flow in one direction. Penner notes this asymmetrical relationship is where the property's rights and duties can be found. Like Penner, Lametti maintains that private property is social because of its structural asymmetry:

> Private property is necessarily social because of its structural asymmetry and underlying value and purposes-human survival, human development and flourishing, and so on - coupled with its scarcity. In short, property is social because of its ethical dimensions and implications.[304]

This does not necessitate a rejection of the essential function that property fulfils in protecting individual interests; as such concerns are a necessary element in any system of social configuration. Instead, this thesis omits the notion that exclusionary

[301] See supra note 299, Alexander, G. at 813-814.
[302] Lametti, D. "The Concept and Conceptions of Intellectual Property as Seen Through The Lens of Property" in Science and Law in the Prism of Comparative Law. G. Comandé and G. Ponzanelli, (eds.). Torino: Giappichelli, 2004, p 269.
[303] See Penner, J. The Idea of Property in Law. Oxford: Clarendon Press, 1997.
[304] See supra note 286, Lametti, D. at 347.

rights to property assume an unequivocal precedence over other interests. To quote from Lametti:

> So the limits on property rights generally, and the specific duties imposed on certain property rights, will be seen to serve larger ethical and moral principles: the common good, the development of individual goods, and the like. These principles govern how human beings should interact with scarce resources.[305]

The implication of this conception of property is that it establishes stronger obligations on property owners. Cohen maintains that private ownership also confers positive duties to property owners, even though he did not go into detail about the boundaries of these duties:

> I wish however to urge that if the large property owner I viewed, as he ought to be, as a wielder of power over the lives of his fellow citizens, the law should not hesitate to develop a doctrine as to his positive duties in the public interest.[306]

Therefore, Cohen emphasized there was a moral dimension to property, in which the interests of the community prevailed over individual ambition in the commodification of property:

> Property owners, like other individuals, are members of a community and must subordinate their ambition to the larger whole of which they are a part. They may find their compensation in spiritually identifying their good with that of the larger life.[307]

From Cohen's property theory, one can gather that a property right holder has an responsibility or obligation to the public. Although resilient private rights may dominate several areas of property dialogue, the ranking of private rights is not a sound prerequisite of property, but rather a result of the social environment in which property rights have developed.[308]

As Laura Underkuffler advocates, the crucial question is not only about the rights of the individual property holder, but the relationship between the property right owner and the community. She claims that "the question of justice or fairness in law-on

[305] Ibid.
[306] See supra note 278, Cohen, M. at 26.
[307] Ibid, 19.
[308] Barnes, R. Property Rights and Natural Resources. Oxford: Hart Publishing, 2009 at 25.

which takings cases are purported to depend-is an inherently *relational* inquiry."[309] It is essential to recall that the grant of property to one individual inescapably prevents another from having that same right, which is that there needs to be a balancing "of competing interests and competing claims."[310]

It is submitted that private property must be limited in the interests of society. This thesis attempts to answer the question of if and to what extent patent rights on genetic sequences are beneficial to society overall. Although a society may favour strong private rights to exclude, private property may be and should be limited in the interests of society. Property for Alexander, Lametti, Cohen and Underkuffler share a similar feature, in that the need for private rights over objects is grounded in the purpose of providing some benefit to society. As a result, they maintain that property claims are not absolute, but are determined by the social context. It is submitted that property is a social correlative comprising a property owner's exclusionary entitlement over a claimed object, for the purpose of promoting the social good. First and foremost, it is a social relationship, and second, a relationship that encompasses an exclusionary privilege. When exclusive control cannot be established over a resource, then it cannot be reduced to private property. There are three instances when exclusive control cannot, or ought not to be imposed on a resource, which include physical, legal and moral factors.

The Max Planck Institute for Innovation and Competition issued a Declaration on Patent Protection and maintained that: "the patent system should ultimately serve the public good by fostering economic growth and technological progress for the benefit of

[309] Underkuffler, L. "Tahoe's Requiem: The Death of the Scalian View of Property and Justice," in Constitutional Commentary. Vol. 21, 2004 at 749.
[310] Ibid, 751.

society as a whole."[311] Thus, when present patent rights have substantial potential to hinder innovation, this may be a reason to remove them for the social good.

3.3.4. Protecting intangible goods

Property can be both tangible and intangible, and traditional conceptions of property often relate to tangible goods like land and water. Current legal systems protect tangible entities from trespassing activities and create ownership rights to limit their usage and protect their scarcity. On the other hand, intellectual property is inherently intangible subject matter and potentially boundless. It is not until the idea becomes public - which the issue of scarcity arises. This is because when an idea becomes available to the public, it stops being scarce. The thought is that property rights are required to manage the distribution of scare resources fairly, because intellectual resources are easily replicated if they are not necessary identified with an author/inventor. In several cases, the costs of replication are minimal, which could eradicate scarcity. Property rights are granted to maintain scarcity which assists the owners and sustains incentives to others for long-term collective prosperity.[312]

The abstract quality of intellectual property renders it unsuitable for being exclusively owned by any entity, and ideas can never be depleted or annihilated through exploitation, which begs the question: how can ideas be owned?[313] The answer lies in the fact that the law creates temporal scarcity, as demonstrated by Yates J in his dissenting opinion in *Millar v. Taylor*:

> Ideas are free. While the author confines them to his study, they are like birds in a cage, which none but he can have a right to let fly; for, till he thinks proper to emancipate them, they are under his own dominion. It is certain every man has a right to keep his own sentiments, if he pleases: he has certainly a right to judge whether he will make them public, or commit them only to sight of his friends. In that state, the manuscript is in every sense his peculiar property; and no

[311] Max Planck Institute for Innovation and Competition. Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm. Accessed April 15, 2014 at 13.
[312] Becker, L. "Deserving to Own Intellectual Property" in Chicago-Kent Law Review. Vol. 68, 1993 at 615-616.
[313] See 3.6.1 for a discussion on the topic of information as a public good.

> man can take it from him, or make any use of it which he has not authorized, without being guilty of a violation of his property.[314]

The inventor or creator of the idea retains property rights to his or her own process or product, but is also free to relinquish property rights by releasing the ideas into the commons. The law has institutionalized this property right to intangible matter through the intellectual property system. By employing the property structure once utilized for tangible matter and applying it to the intangible, intellectual property law safeguards creators and authors of those ideas a set of rights and ownership interests which are typical of powers of control over tangible property. Therefore, patented inventions are property and entitled to the same rights as other property.[315]

3.4. Patent rights

This section will elaborate on three characteristics of a patent right: (i) an exclusionary mechanism, (ii) a limited right and (iii) and performs a social function.

3.4.1. An exclusionary mechanism

Some scholars have adopted the view that IP is primarily a right to exclude and explained that the purpose of IP is to attain the normative utilitarian ideal of lessening information costs in the use of resources.[316] The impracticability of physical exclusion may be corrected by using the law to assure exclusion. "They are exclusive rights – rights to stop other people doing things."[317] Information found in genetic sequences that is published can be considered incapable of physical exclusion, and can be argued to be incapable of being considered the object of private property rights. The legal

[314] Per Yates J., *Millar v.Taylor* (1769) 98 ER 201.
[315] Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405, 425 (1908).
[316] See Smith, H. "Intellectual Property as Property: Delineating Entitlements in Information," in Yale Law Journal. Vol. 116, 2007 at 1745: "[I]ntellectual property's close relationship to property stems from the role that information costs play in the delineation and enforcement of rights." See Larissa Katz's article for further discussion on the structure of ownership in property law as an exclusive right, specifically the preservation of the right holder's position as the exclusive agenda-setter for the owned thing. Katz, L. "Exclusion and Exclusivity in Property Law," in University of Toronto Law Journal.Vol.58, No.3, 2008. Pp.275-315.
[317] Jacob, R. "Woolly Lines in Intellectual Property Law," in Patents and Technological Progress in a Globalized World. Wolrad Prinz zu Waldeck und Pyrmont et al. (eds.) Berlin: Springer, 2009 at 781.

mechanism of an intellectual property right in the form of a patent can be used to facilitate exclusion, which creates a property right to genetic information.

3.4.2. A limited right

Since property rights embody the property owner's power over third parties, the rights are limited.[318] Lametti clarifies that ownership rights are not absolute and private property is a limited concept.[319] He provides the example of patent rights:

> [P]atent rights, and the profits therefrom, are justified provided that the invention is put to use by the owner in such a way as to make its benefits available to society. When not so used, society is justified in otherwise licensing out the right, and sometimes even expropriating the right.[320]

For Lametti, there is a strong duty on the part of patent owners to use the claimed invention in a way that will provide some benefit to the public because the wider social context is the source of justification for private property and the limits of the institution itself.[321] Patents can only be justified if they provide more social good than bad.[322] There is the expectation that a protected resource needs to be useful to society to justify the exclusion of others:

> Certainly where objects of social wealth as understood by society contain a strong sense of expected uses or destination, it is part of the contours of property analysis that, in granting a property right in the resource to the exclusion of others, society expects the resource to be used.[323]

A patent right, then, can benefit society by incentivizing inventions and provide certainty to would be inventors which could encourage overall innovation. They can also promote better economic efficiency, such as preventing wasted research and too many overlapping works. [324] However, if the property right is used to only benefit the few, then greater state intervention may be required to rebalance the system in favour of

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[318] Martinez, J. (1987) at 188.
[319] Lametti, D. "Laying Bare an Ethical Thread: From IP to Property to Private Law?" in Intellectual Property and the Common Law. S. Balganesh (ed.). Cambridge: Cambridge University Press, 2013 at 363.
[320] Lametti, D. "The Morality of James Harris's Theory of Property" in The Properties of Law: Essays in Honour of James Harris. T. Endicott, J. Getzler and E. Peel, (eds.). Oxford: Oxford University Press, 2006 at 161.
[321] Ibid.
[322] "Genes and Patents: More Harm Than Good?" in The Economist. April 15, 2010. New York. Print.
[323] See supra note 320, Lametti, D. at 163.
[324] See supra note 265, Lametti, D. at 363.

the public to neutralize the effects of the patent system. “[I]t would be as absurd to argue that the distribution of property must never be modified by law as it would be to argue that the distribution of political power must never be changed.”[325] To rebalance the goals of the patent system, rights granted by the property system should be limited by public interest considerations, demonstrated through state regulation. "At any rate it is necessary to apply to the law of property all those considerations of social ethics and public policy which ought to be brought to the discussion of any just form of government."[326] The state can decide to bestow a property right by giving a person or group the right to request the state’s assistance to prevent others from using specific resources without the property right owner’s permission.[327]

3.4.3. A socially constructed right

An invention itself does not automatically acquire the status of a property right. It is through the social construction of a temporary monopoly, a patent, which a property right to the invention is granted to the inventor, by allowing the inventor to control the knowledge that defines the invention. Recognizing property as "a set of social relations among human beings,"[328] or an association between a right holder and non-right holders is the most applicable to intellectual property because it recognizes property as a socially constructed concept in which the law is used to demarcate rights for the goal of this legal bundle of rights benefitting society.

A patent is not a natural right.[329] Without the patent system, a right to an invention does not exist. Rather, the purpose of a patent is to provide would-be inventors the incentive of a temporary monopoly to commercially exploit the invention

[325] See supra note 278, Cohen, M. at 16.
[326] Ibid, 14.
[327] Ibid.
[328] Cohen, F. “Dialogue on Private Property” in Rutgers Law Review.Vol.9, No.2, 1954 at 365.
[329] See supra note 273, Honoré, A. at 129: "In any viable society we shall expect certain interests (having a house, clothes, food, preserving one's body from harm) to be protected, but, as regards many other interests, (copyright, reputation, privacy, shares) there will be nothing absurd in a system which does not protect them, though it may be an inconvenient system.”

in return for their divulging the knowledge. To benefit from this knowledge, society needs to be able to access this information. [330] It is submitted that the major benefit of patenting is disclosing useful knowledge to contribute to the public good when it is available and accessible.

3.5. Patents: a social contract

This section discusses the concept of a patent as a social contract between an inventor and society, and how patents on human genetic materials are a reflection of this bargain.[331]

3.5.1. A bargain between the inventor and society

A patent is a social contract between the inventor and state, [332] whereby the inventor discloses the new and useful information to the public in exchange for an exclusive right for a set period of time to exclude others from commercially exploiting the invention, which includes: using, making or selling the invention.[333]

> Simply put, a patent is the right granted by the State to an inventor to exclude others from commercially exploiting the invention for a limited period, in return for the disclosure of the invention, so that others may gain the benefit of the invention. The disclosure of the invention is thus an important consideration in any patent granting procedure.[334]

The patent system benefits the public by encouraging inventors to disseminate valuable knowledge that could otherwise remain undisclosed. The disclosure must

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[330] For a discussion on the importance of access to information, see: Davies, M. and N. Naffine. Are Persons Property?: Legal Debates about Property and Personality. Aldershot: Ashgate, 2001 at 12: "Genetic sequences, while derived from a physical body, are reduced to codes or information: it is not the ownership of the actual body which is at stake, but rather the control of information derived from the body."

[331] One can liken this conception of the social contract to that of Thomas Hobbes, who maintained the original state was a terrifying anarchy of a state of nature, and that of Locke, whose state of nature involves citizens willingly coming together to form a state. See Hobbes, T. Leviathan: Or the Matter, Forme, & Power of a Common-wealth Ecclesiasticall and Civill. Edited by I. Shapiro. New Haven: Yale University Press, 2010; Locke, J. Two Treatises of Government [1698] New Jersey: Lawbook Exchange Edition, 2010 and Macpherson, C. The Political Theory of Possessive Individualism: Hobbes to Locke. Oxford: Oxford Paperbacks, 1962.

[332] Geiger, C. "The Social Function of Intellectual Property Rights, or how Ethics can Influence the Shape and Use of IP Law" in Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, 2013. Geiger notes: "Intellectual property law is thus the product of a type of social contract between the author and society" at 165.

[333] Martens, J. Secret Patenting in the U.S.S.R. and Russia. Sante Fe: Deep North Press, 2010 at 31-32.

[334] World Intellectual Property Organization. WIPO Intellectual Property Handbook: Policy, Law and Use. 2004. Available at: http://www.wipo.int/about-ip/en/iprm. Accessed June 3, 2011. Chapter 2 at 17.

enable a person working in the state of the art to practice the invention.[335] Patent law is a social contract designed to promote societal well-being, evaluated both in terms of access to the benefits of knowledge divulged and the level of production of knowledge.[336]

3.5.2. The goals of the patent system

The goals of the patent system include incentivizing would-be inventors to produce new and useful products and processes that will ultimately benefit society. [337] As such, patents should be granted for inventions that are in the public interest. "Clearly the bargain of patent protection implies a goal or teleology to the right: societal needs for the new and useful product must be met."[338] The notion of the public interest dimension of intellectual property is reflected in the US Constitution. For instance, Article 1, Section 8, clause 8 of the US Constitution of 1787, ensures that the state promotes the freedom of arts and sciences:

> The Congress shall have Power …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.

In safeguarding the freedom of arts and sciences, exclusive rights are bestowed insofar as they enable progress.[339] The public interest is the reason for granting exclusive rights, but it can also be a reason for limiting them. [340] This line of reasoning rests on the social obligation theory[341] and Gregory Alexander's conception of

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[335] Ibid.
[336] Henry, C. & J. Stiglitz. "Intellectual Property, Dissemination of Innovation and Sustainable Development" in Global Policy. Volume 3, Iss.3, October 2010 at 239.
[337] See supra note 4, Burk & Lemley at 1580.
[338] Lametti, D. "The Concept and Conceptions of Intellectual Property as Seen Through The Lens of Property" in Science and Law in the Prism of Comparative Law. G. Comandé, G. Ponzanelli (eds.). Torino: Giappichelli, 2004 at 276.
[339] Geiger, C. "Implementing Intellectual Property Provisions in Human Rights Instruments: Towards a New Social Contract for the Protection of Intangibles," Max Planck Institute for Innovation and Competition Research Paper No. 14-10. 2014 at 17.
[340] See supra note 332, Geiger, C. at 153-176.
[341] See, for example: Coombe, R. "Objects of Property and Subjects of Politics: Intellectual Property Laws and Democratic Dialogue," in Texas Law Review, Vol. 69, pp. 853-1883, 1991; Netanel, Neil. "Copyright and a Democratic Civil Society," in Yale Law Journal, Vol. 106, pp. 283-387, 1996 and Fisher, W. "Reconstructing the Fair Use Doctrine," in Harvard Law Review, Vol. 101, pp. 1659-795, June 1988.

"property-as-propriety": "[P]roperty is the material foundation for creating and maintaining the proper social order, the private basis for the public good."[342]

This idea is developed on the basis of Aristotle's idea that private property can promote the common good, as it promotes like responsibility, yet at the same time, encourages citizens to practice the virtue of generosity:

> For the superintendence of properties being divided among the owners will not cause these mutual complaints, and will improve the more because each will apply himself to it as to private business of his own; while on the other hand virtue will be exercised to make 'friends' goods common goods,' as the Proverb 3 goes, for the purpose of use… for individuals while owning their property privately put their own possessions at the service of their friends and make use of their friends' possessions as common property…It is clear therefore that it is better for possessions to be privately owned, but to make them common property in use; and to train the citizens to this is the special task of the legislator.[343]

Therefore, Aristotle maintained that the common good could be maintained with the legal creation of private property, with the intention that private property owners will, in turn, share their property with others as common property, which will create an altruistic society.

> Metaphorically, the process of applying for a patent ensures that an object has an objective social utility-it must be <<useful>> - and the patent register objectifies the object or process that it is the subject-matter of the monopoly. In short, a patent is an object of social wealth which can be the subject of a general duty *in rem* on the part of non-holders not to interfere, and thus, can be safely considered to be an object of property in the analytic sense."[344]

If the social bargain no longer favours society, then society has every right to remove or alter that social construction. In UK case law, Lord Hoffman elaborated in *Kirin-Amgen v. Hoechst Marion Roussel*[345] on the primary object of the state in granting a monopoly:

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[342] Alexander, G. "Property as Propriety" in Nebraska Law Review. Vol. 77, 1998 at 668.
[343]Aristotle. Aristotle in 23 Volumes, Vol. 21, translated by H. Rackham. Cambridge: Harvard University Press; London, William Heinemann Ltd. 1944 at 1263a.
[344] Lametti, D. "The Concept and Conceptions of Intellectual Property as Seen Through The Lens of Property" in Science and Law in the Prism of Comparative Law. G. Comandé, G. Ponzanelli (eds.). Torino: Giappichelli, 2004 at 276.
[345] *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd*. [2004] UKHL 46 (21 October 2004). The case was between Amgen and Transkaryotic Therapeutics (TKT) regarding the scope of Amgen's patent to their method of producing erythropoietin (EPO). The issue was whether TKT's process violated Amgen's patent since it made use of the same gene, or whether TKT's process was a new way of producing the same protein which does not violate Amgen's patent. Lord Hoffman interpreted Amgen's patent claim as being restricted to the original claim, where the use of the DNA sequence to produce EPO in a host cell, which should not include TKT's different technique.

> [T]he social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims.[346]

The general benefits derived by the public from the disclosure of an invention come from being able to use the information during the patent term, provided it is a non-infringing use. Lord Hoffman asserted that Amgen's patent should not block others from using basic information about the DNA sequence to invent around the patented method of creating erythropoietin.[347] Patent law, then, does not exist as an end in itself, but as a means to an end of achieving a function.[348] This is because the patent system is not a natural entity, but a human construction. In other words, patent rights perform a social function, and the key concept behind social function is 'balance.'[349] As Manuel Desantes notes:

> The patent system should serve a purpose that is not getting a monopoly, but to encourage innovation and development. That is why the patent system is a social contract where society should win more than the patent holder.[350]

This means that there are no absolute rights that can be practised in a self-centred custom without any concern for the effects.[351] An example of the limits to a patent holders' property right is the existence of research exceptions in Europe. In the US, march-in rights apply to federally funded research, where any patented products or processes are required to be licensed. However, march-in rights do not apply to privately funded institutions. These limits are put in place by the state because as part of the social bargain of patents, there is an expectation on behalf of society that a patent holder must make use of the patent productively. In granting a property right to an

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[346] Ibid at 77.
[347] Erythropoietin (epo) is a hormone that regulates red blood cell production.
[348] Geiger, C. "'Constitutionalising' Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union" in International Review of Intellectual Property and Competition Law. Vol. 37, No.4, 2006 at 375.
[349] See supra note 332, Geiger, C. at 157.
[350] Desantes, Manuel. "Past, present and future of patent protection and patent litigation in Europe." European Patent Convention Course. London, Queen Mary University of London. Centre for Commercial Law Studies. March 18, 2014. Lecture.
[351] See supra note 332, Geiger, C. at 158.

object of social wealth to an entity to the exclusion of others, there is a societal expectation that the resource is used in an acceptable way - or else governance tools like compulsory licenses or revocation of the patent can be justified. As a result of these levers that are built into the patent system,[352] it can be maintained that the patent system is suitable in its current state and can continue to justify the grant of patents on inventions derived from human genetic materials, and that they are necessary in providing incentives for the creation of technology.

It is worth mentioning that good patents are meant to be a barrier.[353] As a part of the social bargain, the patent holder has a right to be compensated and rewarded for granting permission to others to use their product or process. It is important to note that the object of property in a patent is what is defined in the patent application's claim and description-nothing more and nothing less. The perception that some institutions hold a monopoly right to genetic information raises concerns, particularly with regards to the potential consequences for further innovation.[354] If someone obtains a patent, it does not mean that individual 'owns' the claimed gene sequence or protein. What the patent holder 'owns' are the commercial activities surrounding the biological material such as using it to develop a genetic testing kit or therapy, or licensing it to other companies. Other parties may look at it or do research with it, but they cannot commercialize it unless they pay the patent holder.

[352] See supra note 4, Burk & Lemley.
[353] Jacob, R. "IP Law: Keep Calm and Carry On?" in Current Legal Problems. Vol. 66, 2013 at 398.
[354] Stiglitz, J. "How Intellectual Property Reinforces Inequality" in New York Times. July 14, 2013. opinionator.blogs.nytimes.com/2013/07/14/how-intellectual-property-reinforces-inequality/. Accessed January 3, 2014. Likewise, a Marxist approach to patents is that they are intrinsically flawed and have no place in a socialist system. There are three main arguments against capitalist patent systems: (i) they stifle the talents of the masses because workers are disinclined to invent when their labours only enrich the capitalists, (ii) they repeatedly hinder the use of the most sophisticated technologies because the capitalists conspire to engineer markets and (iii) they cultivate industrial secrecy which obstructs the flow of significant technical knowledge because patent owners try to reduce the distribution of useful information pertaining to their inventions. Martens, J. Secret Patenting in the U.S.S.R. and Russia. Sante Fe: Deep North Press, 2010 at 32.

3.5.3. Accommodating human genetic inventions within patent law

The patent system has struggled to keep up with the pace of developments in biotechnology, yet the policy of choice in biotechnology rich countries is a pro-patent, "open doors" approach. This practice has recently been subject to legal evaluation both in Europe and the US, in which there has been a narrowing in the scope of patentable subject matter for biological materials. Court decisions challenging the patentability of human biological materials *per se* have been accompanied by patent offices issuing statements directing their patent examiners not to grant patents for certain subject matter. For instance, a day after the *Myriad* decision [355] the USPTO issued a memorandum explicitly stating that naturally occurring nucleic acids are not patent-eligible merely because they have been isolated. "Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. §101."[356] This decision may seem to signify a change in approach towards patenting genetic matter, and commentators have pointed out that the decision is a significant departure from US patent practice over the past thirty years since a genetically modified oil-eating bacterium was held to be eligible subject matter for patenting in *Diamond v. Chakrabarty*.[357]

A number of commentators propose that patent law should be changed to take into consideration the particular needs of the biotech industry. Some scholars suggest that genetic material is exceptionally more complex than any mechanical apparatus and this should be reflected in patent policy.[358] Another position is that patents on human

[355] *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 12-398 (2013)
[356] Commissioner for Patents, USPTO. Memorandum: Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc. June 13, 2013.
[357] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
[358] See Keller, E. Making Sense of Life: Explaining Biological Development with Models, Metaphors and Machines. Cambridge: Harvard University Press, 2003; Dutfield, G. "DNA patenting: implications for public health research", in Bulletin of the World Health Organization. Vol. 84, Iss. 5, pp. 388-392, 2006. Meanwhile, Nobel laureate John Sulston notes: "We are right at the beginning, not the end; we don't

genetic materials are inappropriate[359], while others dispute the types of inventions that should be protected.[360] Others contend that genes should be protected under a *sui generis* system.[361] Some suggest that the non-obviousness standard should be higher,[362] or that the scope of DNA sequence patents should be limited.[363]

In considering the elements of the social contract of the patent system, one must be willing to evaluate the social consequences of restricting the use of human genes by granting gene patents. James Watson notes that there are social consequences of restricting the use of human genes. Emphasizing the informational nature of human genes, Watson explains that they can reveal information that can be important in life-or-death situations:

> The information contained in our genes lets us predict our future. With a gene sequence in hand, we can know with some degree of certainty whether we will develop cancer, a neurological disease, or some other malady. This information should not be monopolized by any one individual, company, or government.[364]

Watson argues that patents for human genes are not necessary in incentivizing scientists to continue research and develop biotechnology inventions. Rather, the area

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know what most of the genes look like, or when or where they're expressed. The genome alone doesn't tell you any of these things. Nevertheless, the information is there as a resource and a toolkit to which people will come back again and again as they build up knowledge of the complete structure of the body from the foundation." Sulston, J. and G. Ferry. The Common Thread: Science, Politics, Ethics and the Human Genome. Great Britain: Bantam Press, 2003 at 287-288.

[359] See Gallini, N. "The Economics of Patents: Lessons from Recent U.S. Patent Reform" in Journal of Economic Perspectives. Vol. 16, No. 2, pp. 121-154. Spring 2002.

[360] For a general overview, see: OECD. Genetic Inventions, Intellectual Property Rights and Licensing Practices, Report of a Workshop Organized by the OECD Working Party on Biotechnology, at 11. www.oecd.org/dataoecd/42/21/2491084.pdf. Accessed February 5, 2012; see Burk, D. "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective" in Houston Law Review. Vol. 30, pp. 1650-68, 1993-1994. Burk argues that the benefits from patenting transgenic human embryos are dubious and may not be overcome by the benefits of the incentive. "Offering such a costly incentive in areas where it is unclear that society wishes to encourage activity is a strategy guaranteed to maximize the probability that the societal benefit from the patent will never exceed its costs." (1659)

[361] For discussion, see Palombi, L. Gene Cartels: Biotech Patents in the Age of Free Trade. Cheltenham: Edward Elgar Publishing Ltd., 2009 and Litman, M. "The Legal Status of Genetic Material" in B. Knoppers et al (eds.) Human DNA: Law and Policy: International and Comparative Perspectives. The Hague: Kluwer Law International, 1997 at 27.

[362] See Dastgheib-Vinarov, S. "Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill" in Marquette Intellectual Property Law Review. Vol.4, 2000 at 157-158 (advancing that the court should raise the non-obviousness standard to bring stability to biotechnology).

[363] See Wilson, J. "Patenting Organisms: Intellectual Property Law Meets Biology," in D. Magnus, A. Caplan & G. McGee (Eds). Who Owns Life? New York: Prometheus Books, 2002 at 42. Wilson advances narrow process claims and few product claims to prevent 'blocking' future innovations.

[364] Brief of James D. Watson as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398, 2013 at 14.

which requires patent protection are the technologies that use human genes, which is why he argues human genes should be accessible to as many researchers.[365] However, the financial realities in the biotechnology sector must also be taken into consideration in asking whether patents are necessary for human genetic materials.

3.6. The Biotechnology Industry and Innovation

A law-and-economics analysis of intellectual property rights has been the dominant approach since its emergence in the 1960s.[366] It presumes that the legal protection of property rights constructs reasons to exploit resources efficiently.[367] A law-and-economics approach to patents is that it promotes investment in R&D by granting investors an exclusive right so they can recoup on their costs.[368] If the investor is not able to recover the costs of the invention because the information pertaining to the invention was accessible to everyone, then the amount of innovation would be substandard.[369] In inciting a competitive and strong market economy, one is largely concerned with the level to which the distribution of resources will fulfil the economic wants and needs of society and the extent to which such distribution of resources among members of society will produce the greatest level of social good. When resources are optimally allocated, individuals who experience gains can do so without making others worse off, this is known as 'Pareto optimality'.[370] To attain a Pareto optimal or efficient

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[365] Ibid, 4.

[366] Rahmatian, A. "A fundamental Critique of the Law-and-economics Analysis of Intellectual Property Rights" in Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, Pp.71-113, 2013. Rahmatian provides a fundamental critique of the application of the law-and-economics analysis to intellectual property law.

[367] Posner, R. Economic Analysis of Law 5th edition. New York: Aspen Law and Business. 1998 at 36.

[368] Sir Robin Jacob writes: "Patents for inventions and the knowledge they can be obtained and relied upon to protect the investment and research that went into making and developing them have been really important drivers from the beginning of the industrial revolution to now." See Jacob, R. "IP Law: Keep Calm and Carry On?" in Current Legal Problems. Vol. 66, 2013 at 393.

[369] Dam, K. "The Economic Underpinnings of Patent Law" in The Journal of Legal Studies. Vol. 23, No. 1, pp.247-271. 1994.

[370] Samuelson, P. and W. Nordhaus. Economics. London: McGraw-Hill, 1989 at 548. Cooter, R. and T. Ulen. Law & Economics. Boston: Pearson Educational International, 2003. Pp.16-17. As a result of the existence of public goods and the consequential free-riding that can occur, Pareto optimality is extremely difficult to attain, and a slightly less demanding alternative is the 'Kaldor-Hicks' efficiency model. According to this model, society is better off as long as net gains to some part of society exceed the losses suffered. See Mercuro, N. & S. Medema. Economics and the Law: From Posner to Post-Modernism.

state, there needs to be a competitive market, a lack of externalities (public goods), and private property rights. However, the realization of Pareto efficiency is challenging when faced with public goods only regulated by the needs and demands of market forces, which could result in free-riding, which is a known externality in the field of intellectual property goods.[371]As Harold Demsetz remarks: "A primary function of property rights is that of guiding incentives to achieve a greater internalization of externalities."[372] He provides the example of land ownership, which, if land is held in common, will result in great externalities because each individual user of the land will not experience the entire impact of the land use. If hunting on the same area, there is the tendency to overhunt because there is no incentive to preserve the supply of game since the advantage of one person doing so cannot control whether others do the same. Therefore, the land will most likely be overhunted. The effects of the land and the supply of game will be felt by subsequent generations. The solution is private ownership, which will:

> Internalize many of the external costs associated with communal ownership, for now an owner, by virtue of his power to exclude others, can generally count on realizing the rewards associated

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Princeton: Princeton University Press, 1997. Pp18-22.Both the Pareto optimality and Kaldor-Hicks efficiency principles are indebted to the utilitarian theory, which developed from its two largest contributors, Jeremy Bentham and John Stuart Mill. Jeremy Bentham developed the "greatest happiness principle", or the principle of utility, stating that happiness equated to a prevalence of pleasure over pain:

> Nature has placed mankind under the governance of two sovereign masters, pain and pleasure. It is for them alone to point out what we ought to do, as well as to determine what we shall do. On the one hand the standard of right and wrong, on the other the chain of causes and effects, are fastened to their throne. They govern us in all we do, in all we say, in all we think.

See Bentham, Jeremy. Theory of Legislation: Being Principes de legislation, and Traites de legislation, civele et penale. Volume 1. London: Humphrey Milford, 1914.Chapter 1, p3.
Likewise, Mill's utilitarian theory justifies property rights because it can help maximize human happiness. Social utility theory maintains that society benefits from supporting individuals to take unexploited resources and develop them for a more competent function. Since the protection of property interests augments social well-being, individual claims to the created product needs to be protected. The theory also justifies a temporal monopoly awarded to inventors through the patent system. The benefit to society of obtaining scientific and technical advances justifies limiting property rights to inventions because complete ownership of inventions will be in direct conflict with society's well-being. If property interests do not promote the common good, then they are not protectable. See Mill, John Stuart. Utilitarianism. Chicago: University of Chicago Press, 1906.

[371] Externalities refers to situations when the effect of production or consumption of goods and services imposes costs or benefits on others which are not reflected in the prices charged for the goods and services being provided. OECD Glossary.

[372] Demsetz, Harold. 'Toward a Theory of Property Rights," in The American Economic Review. Vol. 57, No. 2, Papers and Proceedings of the Seventy-ninth Annual Meeting of the American Economic Association. May 1967 at 348.

> with husbanding the game and increasing the fertility of his land. This concentration of benefits and costs on owners creates incentives to utilize resources more efficiently.[373]

In addressing intellectual property rights specifically, Demsetz writes:

> Consider the problems of copyrights and patents. If a new idea is freely appropriable by all, if there exist communal rights to new ideas, incentives for developing such ideas will be lacking. The benefits derivable from these ideas will not be concentrated on their originators. If we extend some degree of private rights to the originators, these ideas will come forth at a more rapid pace.[374]

Thus, according to Demsetz, intellectual property protection is a mark of state intervention to correct market failure, which is to internalise the externalities brought up by the public goods experience.[375] This is perceived to be one of the most competent measures to acquire valuable development at the smallest cost.[376] Intellectual property protection then is required to promote innovative activities and the production and dissemination of valuable knowledge.

3.6.1. Public goods

Even though the patent system imposes a structure of scarcity, a patented invention is a 'public good' because the protected knowledge cannot be exhausted by

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[373] Ibid, 356.
[374] Ibid, 359.
[375] Mark Lemley challenges Demsetz's treating of intellectual property as 'real property,' and acting to internalise negative externalities such as free-riding. Lemley embraces the idea that 'intellectual property' as it exists and is understood today is fundamentally flawed, and subsequently the rhetoric of 'free-riding' in intellectual property is misguided. He argued that intellectual property should be limited to the extent that creators and inventors were sufficiently compensated to return a fair return on their initial investment. Lemley also attacked the notion that intellectual property existed to prevent free riding and combat the tragedy of the commons by highlighting the non-rivalrous nature of ideas, which cannot be used up. Lemley asserted that free riding was likely to occur in information goods, but this was not a problem because the use of ideas did not harm the originator of those ideas. In fact, he maintains that the entire purpose of intellectual property was to disseminate ideas that would have been held in secret. See Lemley, Mark. "Ex Ante versus Ex Post Justifications for Intellectual Property" in UC Berkeley Public Law Research Paper No. 144. 2004.
[376] Supporters of this view include: Landes, W.M. and R.A. Posner. The Economic Structure of Intellectual Property Law. Cambridge: Belknap Press, 2003 at 332 and F-K Beier & J Strauss, The Patent System and its Information Function-Yesterday and Today in International Review of Industrial Property and Copyright, Vol. 8, 1977 at 391. However, there is some scepticism regarding the part performed by the intellectual property system in contributing to industrial progress: See Machlup, Fritz. An Economic Review of the Patent System.65th Congress 2d Session. United States Printing Office Washington: 1958. After an intense economic review of the patent system commissioned by the United States Congress, Machlup determined that: "[I]f we did not have a patent system, it would be irresponsible, on our present knowledge of the economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible on the basis of our present knowledge, to recommend abolishing it." (80) Thus, despite some shortcomings, the patent system should not be abolished on the basis that dismantling it would be too costly.

use.[377] Protected knowledge is different from tangible property because knowledge is inexhaustible which is why information is classified as a 'public good.'[378]A public good possesses two qualities: non-rivalrous consumption and non-excludability. First, the subject matter of intellectual property, comprised of ideas, is non-rivalrous because an individual's use of the good does not leave behind less for others to use.[379] In fact, the more people use it, the more valuable it becomes, and restricting its use would actually be wasteful.[380] Second, a public good is non-excludable since the use of it by one individual does not restrict another's use of it.[381] Since knowledge and information are non-excludable and the reproduction costs are almost zero, access is restricted through the use of patents, which creates a temporary monopoly with which the inventor can exclude others from the protected information/knowledge. However, intellectual property's non-excludable nature raises the issue of free riding because once the knowledge is divulged in the public realm, it can be freely copied by others.

3.6.2. The Issue of Free-riding

Public goods may encounter a "free-rider"[382] problem because in a market where non-excludability and non-rivalry can exist, people can access and copy the good without paying for it.[383] It is argued that free-riding can negatively affect future

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[377] Samuelson defines a public good as: "[goods] which all enjoy in common in the sense that each individual's consumption of such a good leads to no subtractions from any other individual's consumption of that good..." in Samuelson, Paul A. "The Pure Theory of Public Expenditure" in Review of Economics and Statistics.Vol.36. Iss.4, 1954. Pp. 387–389.

[378] See Kaul, I., Isabelle Grunberg, Marc A. Stern (eds.). Global Public Goods: International Cooperation in the 21st Century. Oxford: Oxford University Press, 1999.

[379]Cooter, R. and T. Ulen. Law & Economics. Boston: Pearson Educational International, 2003 at 46. For instance, a person can listen to a piece of music without limiting another person's use of it.

[380] Fisher, M. Fundamentals of Patent Law: Interpretation and Scope of Protection. Oxford: Hart Publishing, 2007 at 65.

[381] For example, telecommunications is a non-excludable good because it is extremely difficult to exclude people from using infrastructure.

[382] Kaul, Grunberg and Stern define a free rider as: "someone who enjoys the benefits of a (public) good without paying for it. Because it is difficult to preclude anyone from using a pure public good, those who benefit from the good have an incentive to avoid paying for it - that is, to be free riders." See Kaul, I., I. Grunberg & M. Stern (Eds.). Global Public Goods: International Cooperation in the 21st Century. Oxford: Oxford University Press, 1999 at 509.

[383] Demsetz, H. "Toward a Theory of Property Rights," in The American Economic Review. Vol. 57, No. 2, Papers and Proceedings of the Seventy-Ninth Annual Meeting of the American Economic Association. Pp. 347-359, May 1967.

innovation because companies are less likely to invest resources in creating new products if they know that competing entities can easily recreate the product at a much lower cost since they do not have to bear the original cost of creating it the first time around.[384] Competitors ultimately decrease the cost of the product since they expend fewer resources on developing the product. As a result, the original creator of the product is less likely to recoup the original costs of development if competitors are allowed to copy and reproduce the product.

Intellectual property law is justified economically to prevent free-riding and ensure that creators and inventors are able to sufficiently profit in the marketplace and recover their total costs. This rationale is the underlying justification for the protection of intellectual property. The power to exclude is an essential feature of intellectual property rights, as it provides the incentive to invest time and resources in R&D. If creators of the intellectual property cannot recoup their initial costs, then would-be investors may be discouraged from investing. Economists Mazzoleni and Nelson note the benefits of patent protection:

> The collection of small and medium sized firms in the American biotechnology industry is, of course, a striking example of enterprises that would not have come into existence without the prospect of a patent, and which depend on patent protection to make their profits, and to attract capital.[385]

A strong claim for patents is that free-riding can easily occur in the biotechnology field, particularly within the drug industry, where drug companies can reverse-engineer molecules to develop bioequivalent versions of a patented drug and sell them at a lower rate compared to the patented drug.[386] However, the intellectual property system should not over-compensate the creators and inventors by granting

[384] See supra note 201, Landes & Posner at 16.
[385] Mazzoleni, R. and R. Nelson. "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate" in Research Policy.Vol.27, 1998 at 275-276.
[386] Cassier, M. & M. Correa. "Scaling-up and Reverse Engineering: Acquisition of Industrial Knowledge by copying drugs in Brazil" in Benjamin Coriat (ed.) The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access. Cheltenham: Edward Elgar, 2008 at 143. For more on reverse engineering, see: Ohly, Ansgar. "Reverse Engineering: Unfair Competition or Catalyst for Innovation?" in WolradPrinzzuWaldeck und Pyrmont et al. (eds.) Patents and Technological Progress in a Globalized World. Munich: Springer, Pp. 535-552, 2009.

them absolute property rights.[387] This is particularly true of genomic patents, which seek to acquire protection for naturally occurring substances. There is concern that the patenting of biological research tools may obstruct further biotechnological development:

> [P]rotection has gone overboard insofar as it allows those persons who have isolated the BRCA gene for breast cancer to patent not only its use outside the body, but to prevent persons from receiving treatment of their own genetic disorders without the approval of the gene patent holder. That protection is too broad. Gene patents should be limited to those substances that are in a commercialized test tube, not those that remained locked in a cell.[388]

Although patents can be a positive social tool as an incentivizing mechanism for the creation and development of socially desirable goods, there is also the cost of lack of access to patentable knowledge that forms the basic foundational unit from which to further technological advances. Products of biotechnology have the potential to benefit society, but this can only be actualized when resources are allocated in a way that maximizes wealth while minimizing transaction costs and waste. For example, if numerous individual patented gene fragments are required for developing a further product, the transaction costs of accumulating the necessary genetic material needed to create another manufacture are significant.[389] The social value of property rights could be insignificant if the costs of enforcement or appropriation are greater than the value of the right itself. This line of reasoning can lead to the rationale that for policy reasons, some intellectual property rights should be 'depropertized' and some forms of property should be accessible for widespread use rather than owned.

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[387] Lemley, M. "Property, Intellectual Property, and Free Riding," in Texas Law Review. Vol. 83, 2005. Lemley acknowledges that free riding occurs in information goods, but he does not perceive it as a negative thing. He maintains that as valuable information spreads, others are able to copy it and exponentially increase available resources, which enables more people to enjoy it. As long as inventors and creators are able to recoup on their average fixed costs, Lemley asserts that there is no economic justification for absolute intellectual property rights. "Granting intellectual property rights impose a complex set of economic costs, and it can be justified only to the extent those rights are necessary to provide incentives to create. The economics of intellectual property simply do not justify the elimination of free riding." (1065)

[388] Epstein, R "The Property Rights Movement and Intellectual Property" in Regulation. Vol. 30, No. 4, Winter 2007-200 at 61.

[389] See supra note 192, Heller & Eisenberg.

3.6.3. IP and Innovation

Joseph Schumpeter distinguishes innovation from invention,[390] observing that an invention itself has "no economically relevant effect at all."[391] On the contrary, innovation is an economic process between the invention of a product or process and bringing it to market.[392] Schumpeter argued that a patent monopoly encourages innovation better than competition, basing his argument on the fact that economic developments are usually attributed to large monopolistic entities rather than to firms in disparate competitive industries.[393] Similarly to Kitch, Schumpeter maintained that the protection afforded by the patent granted the firms the necessary time and space to create further developments. This 'prospect' of exceptional reimbursements allows innovators to generate investment.[394] This means that a monopoly acquired through patent protection could intensify the use of an invention by expediting its launch into the market. As a result, he held that patent monopolies were necessary to promote investment in innovation rather than inventions. In this scenario, an existing patent continues to incentivize after it has been granted, due to investment in its continual development during the course of the patent term. Ko maintains that Schumpeter's idea that patent monopoly exceeds competition in stimulating innovation is sustained in the field of biotechnology, pointing to the ability of small biotechnology start-up firms with patents that provide them with a monopoly over significant products or processes and allow them to overtake larger pharmaceutical companies.[395]

Although Schumpeter advances a broad scope of patent protection, he offers minimal assistance in how to determine the appropriate scope of the claim, only stating

[390] Schumpeter, J. Business Cycles I. New York: McGraw Hill, 1939.
[391] Ibid, 84.
[392] Machlup, Fritz. An Economic Review of the Patent System. 65th Congress 2d Session. United States Printing Office Washington: 1958.
[393] Schumpeter, J. Capitalism, Socialism and Democracy. New York: Harper & Row, 1950 at 102.
[394] Schumpeter, J. The Theory of Economic Development. London: Transaction Publishers, 2008 at 148-150.
[395] Ko, Y. "An Economic Analysis of Biotechnology Patent Protection" in Yale Law Journal. Vol. 102, 1992-1993 at 800.

that the scope should consider the cost and difficulty of the innovation.[396] Despite the prevalence of the law-and economics theory, the fact that economists are still unable to resolve the question of whether activity incentivized by the patent system improves or reduces social welfare suggests that an economic understanding of intellectual property law is insufficient.[397]

3.6.4. The nature of innovation in biotechnology

It is submitted that the particular characteristics of the biotechnology industry render patent protection necessary. The product development timeframe in biotechnology is extremely long and costly. Delays in bringing a product to market is partly because of the regulatory approval process over the safety of new products and processes pertaining to health. [398] As a result of the high degree of investment required for biotechnology R&D, a dependable and strong patent system and steadfast case law is necessary for biotech inventions. For instance, Sir Robin Jacob maintains that companies would not spend 20 percent of their income on R&D without the security of property provided by a patent. [399] This argument is also reflected in interviews with biotechnology industry stakeholders.[400]

It is also suggested that patent protection may be necessary not only to spur investment in R&D, but it allows an inventor to appropriate on the returns from the

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[396] Ibid..
[397] Priest, G. "What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung" in Research in Law and Economics. Vol. 8, 1986 at 21.
[398] For instance, in the pharmaceutical field, a company hoping to get one drug to the market can spend $350 million USD before the drug reaches the market. A company which brings between 8-13 medicines to market within a decade spends approximately $5.5 billion USD. The reason for this high cost is that 95% of experimental medicines are ineffective or unsafe for humans, and companies need to go back and develop new drugs until they are deemed effective and safe. Sometimes, drugs fail near the end of trials. (Herper, Matthew. "The Cost Of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change" in Forbes.www.forbes.com. August 11, 2013. Accessed October 14, 2013). Meanwhile, in the diagnostics industry, the cost to develop and launch a diagnostic in the US is between $50-75 million. The cost to develop and commercialize a diagnostic is subject to significant investment and if companies cannot obtain adequate legal protection for their considerable investments, it is uncertain whether R&D would be able to carry on at the same pace and concentration. (Mystery Solved! What is the cost to develop and launch a Diagnostic? Available at: http://www.diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic. 2014. Accessed 15 Aug. 2014)
[399] Jacob, R. "IP Law: Keep Calm and Carry On?" in Current Legal Problems. Vol. 66, 2013 at 394.
[400] See Chapter 5 for stakeholder interview responses.

invention.[401] The nature of DNA patents is that once a sequence is discovered, it can be readily copied. For example, the laborious effort required to produce a cDNA sequence that codes for a protein lies in identifying and isolating the correct sequence. Once the sequence is discovered, it is easily replicable. Patent law provides protection to the inventor to recoup on the costs of R&D.

Another characteristic associated with innovation in biotechnology is that there is significant uncertainty in research because biotechnology products come from living systems and are characteristically anticipated to interact with other living systems.[402] These interactions are complex and as a result, the functionality of biotechnology products is not completely predictable and "always involves a high degree of uncertainty and risk."[403] Consistent with these characteristics, the existence of several functional equivalents to a certain DNA sequence means that patent protection needs to be broad enough to exclude easy design-arounds.[404]

As a result, the entire process of innovation in biotechnology, involves not only the *research* aspect, but also the *development* stage, which is time-consuming, costly and carries potential risks, which is why patent protection may be necessary to bring products to market. Due to the extensive development and testing lead time required for DNA-related innovation, the production of the product, and obtaining regulatory approval.

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[401] See 3.7 for a discussion on the 'reward-by-monopoly' theory for patents.
[402] A controversial question in biotechnology pertaining to intellectual property rights is how much human intervention is necessary on a naturally occurring entity for a patent to be justified. It can be reasoned that some qualities of human genetic materials make them difficult for patenting. First, the substances are self-replicating. In addition, the substances exist naturally and are created by nature. The Nuffield Council on Bioethics issued a paper and adopted the position against patents for expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs) and receptors as they "will seldom deserve the status of patentable inventions." See the Nuffield Council on Bioethics. The Ethics of Patenting DNA. London: Nuffield Council, 2002.
[403] See supra note 4, Burk & Lemley at 1676.
[404] Ibid, 1625.

3.6.5. Why biotechnology needs patents

In the biotech industry, the value of knowledge is high. It is not the end product itself that is expensive to produce, but attaining the knowledge of a gene on a chromosome and the various mutations that can reveal whether one is susceptible to a disease. The number of hours in the laboratory finding that gene and sequencing it, and then developing a diagnostic kit to test for a gene that is related to a disease. Thus, it is necessary for products of biotechnology to have at least limited property rights in response to modern biological and economic actualities. Remigius Nwabueze observed the law should reflect the knowledge-based global economy:

> [T]here seems to be no reason in principle why the flexible qualities of property should not be applicable to commercially or medically valuable information; such pieces of information can be transferred for value and thus possess an essential characteristic of property rights...genetic information is a legally protectable property because it shares some of the characteristics of property and scales through the justificatory theories of property.[405]

New forms of technology bring about change in the form of property, which may result in a new conception of property that reflects societal expectations and needs. The current debate about gene patenting reveals society's expectation that a section of the public expects that the human body, or any component of it, should be subject to commercial interests, and that products of biotechnology will be beneficial to society. Thus, granting a legal property right to the human body and its components protects one of society's expectations.

Economic considerations also justify the need for the patentability of biotechnological inventions and shed light on appropriate patent scope. Intellectual property provides the necessary incentives to encourage investment in research and development that will ultimately benefit society. It emphasizes that society benefits from offering protection for useful ideas as they provide incentives and encourage progress. This position also maintains that intellectual property protection is necessary

[405] Nwabueze, R. Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information. England: Ashgate Publishing Limited 2007 at 183-184.

in protecting stakeholder interests, and acting as a reward to inventors and authors for their contribution. This approach is reflected in modern day legal instruments, such as the US Constitution, which states that the purpose of intellectual property rights is to "promote the progress of science and useful arts."[406] However, there are contentions between scholars about whether protection should be granted, and if so, how much.

Defenders of gene patents in biotechnology maintain that patents are necessary as they encourage incentives for innovations by attracting investors: "I think it's unfortunate that we create fictions in the law about why we file patents. It doesn't encourage invention, not in biotech, certainly. But it does encourage investment."[407] Joseph Straus notes that patents are not only attractive to investors, but also to the scientists and technicians who are the actual inventors:

> I'm sometimes a little bit surprised that people engaged in patenting and the day by day work underestimate the attractiveness of patents to scientists and technicians. It would be wrong to say that without patents there would be no inventions. But I think many things are invented because we do have patents. And not only the investment after the invention is incentivized by that, but also the invention itself.[408]

In the field of biotechnology, the business model and realities of investment in R&D make the patent system necessary as insurance that there is the possibility of recouping on a major investment.[409] As a result, other interests are denied protection as property. Therefore, the ways in which property rights are defined and allocated determine which interests are protected. One criticism of the system is that it can be argued that patent law represents the interests of businesses, corporations and other central investors in potential inventions. For instance, in *Monsanto Canada Inc. v*

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[406]US Constitution, Article 1, s.8, cl.8.
[407]Rowland, B. "Discussion: Session 1" in Vogel, F. and R. Grunwald (Eds.). Patenting of Genes and Living Organisms. New York: Springer, 1994 at 38.
[408] Straus, J. "Discussion: Session 1" in Vogel, F. and R. Grunwald (Eds.). Patenting of Genes and Living Organisms. New York: Springer, 1994 at 39.
[409] However, the recent Max Planck Declaration on Patent Protection stipulates that the patent system is not a defensive mechanism to exclude other research and development outcomes, but is used as an offensive tactic to "influence the conditions of competition." The report, however, does not further discuss what these conditions of competition (i.e. patent trolling, licensing). A further elaboration on how patents are used as a strategic asset would have been beneficial. Max Planck Institute for Innovation and Competition. Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm. Accessed on April 15, 2014 at 2.

Schmeiser,[410] the Canadian Supreme Court decided whether a genetically modified gene in a canola seed was eligible for patent protection.[411] There was a possible collision between Monsanto's intellectual property rights and Schmeiser's own property rights as a farmer over his canola seeds. It was submitted that the Canadian Supreme Court decided the issue was one of intellectual property protection instead of Schmeiser's property rights over his canola seeds, reflecting the importance attached to upholding intellectual property rights, particularly with respect to maintaining an friendly environment for continued investment in biotechnology in safeguarding business interests. The majority held that Schmeiser's ownership of his seeds was not a valid argument against an infringement of Monsanto's patent right.[412] This approach allowed the court to dissolve the issue of personal rights over property and intellectual property rights.[413]

The fusion of these two questions is analogous to the decision adopted by the Californian Supreme Court in *Moore v. Regents of the University of California*.[414] The court opted to focus on intellectual property right protection, whilst diminishing potential property rights over genetic materials. The majority established that Moore had no property rights to his discarded body parts or the commercial gains derived from them. The court held that once an individual's cells are removed from one's body, there

[410]*Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.Monsanto Canada Inc. was granted a patent for the invention of a genetic insert which, when introduced into the DNA of canola by way of a transformation vector, produced a variety of canola with a high level of resistance to glyphosate. Glyphosate is harmful to plants; most plants sprayed with an herbicide containing glyphosate will not survive. However, Monsanto developed a seed which was comprised of cells containing a modified gene which enabled the resulting canola plant to survive if sprayed with a glyphosate-based herbicide. This modified gene is the subject of the Monsanto patent. Monsanto claimed that Percy Schmeiser, a Saskatchewan farmer, infringed its patent as Schmeiser's 1998 canola crop was found to contain glyphosate-resistant canola. Schmeiser maintained that he had merely saved the seed from the glyphosate-resistant canola found on his property from his 1997 crop. Moreover, Schmeiser claimed he did not infringe Monsanto's patent since he did not actively spray his crop with Roundup to control weeds within the crop, which meant that he did not take advantage of the crop's glyphosate resistant-quality.
[411] Makin, Kirk. "Canada Rules in Favor of Monsanto over Seed Saving Farmer Percy Schmeiser" in Globe and Mail Update (Canada). May 21, 2004. Accessed November 3, 2013.
[412] Ibid, 96.
[413] DeBeer, J. "Reconciling Property Rights in Rights" in The Journal of World Intellectual Property. Volume 8, Issue 1, January 2005. P5.
[414]*Moore v. Regents of the University of California*, 793 P.2d 479 (California 1990) at 51.

is no longer any legally protected property interest in the removed cells. The court was unwilling to acknowledge a protected property interest in the genetic information enclosed in Moore's excised cells, explaining that Moore did not intend to preserve his excised cells after the splenectomy. In effect, the court relied on the fact that Moore was deficient in one property right - the right to possess one's cells after their removal-to circumvent the realization of a property right possessed by Moore to his genetic material encoded in his cells. Although it was determined that Moore did not possess a property interest in his spleen, he had a cause of action for lack of informed consent. The court recognized that Moore had a "limited right to control the use of excised cells,"[415] maintaining that Dr.Golde had a duty under the doctrine of informed consent to make known his underlying interests in the excised cells to Moore before he recommended the splenectomy. However, in holding that Moore possessed a cause of action for lack of informed consent, the Court actually established that Moore had a property interest in the information encoded in his DNA.

As demonstrated above, state power defines and allocates property rights to society and in turn, property rights allocate power and vulnerability. In the present system, it gives investors in inventions a property right, whilst denying individuals a property right in their own bodily materials. The two cases above illustrate the fact that there is an emphasis by the courts in upholding patents to naturally occurring living organisms to continue to provide incentives for innovation in biotechnology. This argument is part of the law-and-economic analysis of patent rights and intellectual property in general.

[415] Ibid.

3.6.6. Arguments for granting broad gene patents

One convincing argument for granting broad patents is from Edmund Kitch's prospect theory of patent law.[416] Kitch argues that a patent right provides the chance to develop a recognized technical possibility; this is a 'prospect' with related possibilities of costs and returns.[417] "By a prospect I mean a particular opportunity to develop a known technological possibility."[418] Kitch argues that patents perform a function in the market by internalizing the costs and benefits and serving as the exclusive right to exploit a resource. He draws an analogy between awarding exclusive mineral claims in America and patents. Like mineral claims, which grant property rights to those who discover new and valuable minerals, which in turn encourages landowners to develop the land efficiently, patent owners are also offered the chance to further exploit their inventions through commercialization. Kitch maintains that patent rights provide the patent owner with exclusive rights over auxiliary exploitation of the invention like improvements which are essential:

> [A] patent "prospect" increases the efficiency with which investment can be managed…[T]he patent owner has an incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors. This is important only if the development of patented inventions generally requires significant investments that lead to unpatented information a competitor can appropriate...In the case of many patents, extensive development is required before any commercial application is possible…The investments may be required simply to apply existing technology to the manufacture and design of the product and be so mechanical in their application as to be unpatentable.[419]

Kitch's prospect theory maintains that the patent scope should not be limited to the invention that is described in the patent claim, but should also encompass further changes as well. This means that if the patent holder's competitors' research yields

[416] Kitch, E. "The Nature and Function of the Patent System" in Journal of Law and Economics. Vol. 20, pp. 265-290, 1977.
[417] Ibid.
[418] Ibid, 266.
[419] Ibid, 276.

improved adaptations of the patented invention, those versions will still fall under the jurisdiction of the patent owner until the patent elapses.[420]

Another rationale for granting broad patents to pioneer inventions is Kitch's articulation of coordinated developments.[421] Kitch clarified that patents should be broad because the information contained in the patent claim is not exhausted by use; thus, providing a property right to the invention advances the efficiency in which the resources are managed.[422] It is believed that if a patent owner holds an exclusive right to commercially exploit and enhance the technology as stated in the patent claims, then others will not invest in advancing this technology without seeking a licensing agreement with the patent holder.[423] As a result, the patent owner can compel their competitors to share their information and avoid similar research efforts and a waste of resources.[424]

A third justification for broad patents connects to the issues that can emerge when overly narrow patents are methodologically granted.[425] If too many narrow patents are granted in a particular field to multiple entities who are also likely to be competitors with one another, it could lead to an area that is overly fragmented, requiring competitors to coordinate their efforts to develop any practical product or process without the occurrence of infringement.[426]

3.6.7. Potential risks of broad patents

Critics of the prospect theory question whether the grant of a broad patent, particularly for 'pioneering inventions', can induce further development and innovation.

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[420] See supra note 201, Landes & Posner at 13 (noting that broad patents enable inventors to "reap where they have sown. Without that prospect the incentives to sow is diminished").
[421] See supra note 416, Kitch, E. at 279.
[422] See supra note 416, Kitch, E. at 275- 276.
[423] Ko, Y. "An Economic Analysis of Biotechnology Patent Protection" in Yale Law Journal. Vol. 102, 1992-1993 at 801.
[424] See supra note 416, Kitch, E. at 276-279.
[425] Yu, A. "Why It Might Be Time to Eliminate Genomic Patents, Together with the Natural Extracts Doctrine Supporting Such Patents," in IDEA: The Intellectual Property Law Review. Vol.47, No.5 2006-2007 at 720.
[426] See 2.5 for further discussion of the 'tragedy of the anticommons'.

For instance, Merges and Nelson argue that there is more technical change when there is greater competition between groups vying to invent a product than in an environment where few groups dominate a monopoly and control developments. Merges and Nelson differ from Kitch's prospect theory in holding that patent scope should not be of 'unduly wide scope.'[427] Due to the nature of biotechnology technologies, it is essential that patents do not act as a hurdle towards further research. They argue that overly broad patents have stifled the pace of development in the science-based industries, particularly in the field of biotechnology.[428] For instance, they disapprove of Genentech's patent for the recombinant DNA technique developed by Cohen and Boyer, asserting that they "simply were the first to practice techniques that persons 'skilled in the art' knew could be made to work."[429] Whilst the authors recognize that Cohen and Boyer made a clear contribution to gene expression techniques, they hold that the breadth of the patent scope raises problems.

> Holders of broad patents would be operating as tollkeepers, not coordinators, and the subsequent development of prospects would proceed in spite of, or at least in indifference to, the broad patent. Nevertheless, if a broad prospect patent is granted and upheld, we would much rather see the patent holder widely granting licenses than trying to develop the prospect herself.[430]

Merges and Nelson's general conclusion is that they would prefer multiple competitive sources of invention rather than a few. They argue that patent law should promote inventive rivalry rather than obstruct it, and warn against the social danger of permitting the advancement of a technology to be under the dominion of a single or a few entities.[431] It is reasonable to believe that a broad patent, or the expectation on the part of potential inventors that they will be granted one may in the beginning encourage more inventive attempts compared to if the expectation for a patent was strictly pared down to the actual realization. However, when a patent is granted, the scope of the

[427] Merges, R. & Richard Nelson, "Market Structure and Technical Advance: The Role of Patent Scope Decisions," in Thomas M. Jorde David J. Teece (eds.) Antitrust, Innovation and Competitiveness. Oxford: Oxford University Press, 1992 at 187.
[428] Ibid, 213.
[429] Ibid, 214.
[430] Ibid, 215.
[431] Ibid.

patent weakens incentives for others, compared to a patent whose claims are reduced to the actual accomplishment.[432]

One justification for restricting patent scope to what is actually a contribution to the art is that it brings into line patent incentives with the objectives they are meant to promote. [433] An operative patent system "should effectively and promptly mete out incentives that foster innovations that fill those gaps. To do so: the patent system needs to accurately assess the contours of the state of the art and the contributions made by alleged innovations."[434] This entails a legal grasp of innovation that is on par with the actual technological landscape. When overly-broad or overly-narrow patents are systematically granted, a chasm between the legal interpretation and technological actuality can ensue, which can diminish the efficacy of patent law in promoting technological innovation.

Exceedingly broad patents can excessively credit innovations that have not yet been invented. As a result, this could dis-incentivize prospective innovative activities because when an invention is ultimately produced, there is no patent. Moreover, overly broad patents can incite wasteful patent races and inspire precarious research.[435] For instance, Tim Hubbard and James Hubbard note that higher incentives brought about from increased levels of patent protection have actually resulted in promoting R&D of 'diminishing returns.'[436] Thus, the emphasis on patenting in biotechnology may be indicative of excessive incentives created by very broad patents.

A counterargument to Merges and Nelson's argument for restricting broad patents is that biotechnology requires substantial investment. Hence, a broad patent is

[432] Ibid, 217-218.
[433] Yu, A. "Why It Might Be Time to Eliminate Genomic Patents, Together with the Natural Extracts Doctrine Supporting Such Patents," in IDEA: The Intellectual Property Law Review. Vol.47, No.5 2006-2007 at 721.
[434] Ibid, 722.
[435] See supra note 201, Landes and Posner at 361: Landes and Posner explain that "excessive investment by those seeking patent protection" is "most wasteful when the cost of making the invention is falling rapidly over time…then the making of the invention should probably be deferred."
[436] Hubbard T. and James Love. "A New Trade Framework for Global Healthcare R&D" in PLoS Biology. Vol. 2, Iss.2, 2004 at 150.

necessary to carve out an area so patent holders can continue to develop and expand upon the claimed invention to recoup on their investment. This line of argument is consistent with Kitch's 'prospect' theory which favours broad patent scope for inventions to allocate the coordination of ensuing research.[437]

A broad "upstream" patent does not automatically mean that it will deter downstream research from being conducted. For instance, Human Genome Science's (HGS) broad patent on Neutrokine-a did not deter its competitors from researching and finding major benefits within the broad claim.[438] In *HGS v. Eli Lilly*,[439] Lilly argued that HGS' identification of the neutrokine-a polypeptide as a member of the TNF ligand family and description of its activities and uses was not supported by data obtained from *in vitro* or *in vivo* studies. Rather, the description was based on knowledge known about other members of the TNF superfamily. Lilly maintained that the patent should be revoked on the basis that the claims were a speculative prediction and the scope of protection exceeded what HGS actually contributed to the state of the art. However, Kitchin J at first instance noted that despite HGS' broad patent, it did not stop research from being conducted, specifically highlighting the efforts and results of Biogen and Lilly.[440]

> Biogen conducted a range of studies to try and find where the protein was expressed, where its receptors were expressed and how the two interacted to produce a biological response. Again, this was a precursor to the research necessary to begin to find a diagnostic or therapeutic application…Lilly workers also tried to develop assays but, without any idea of the function of the protein, they could not determine the reason for their failure to identify activity. It was only in 1999 and with the benefit of their work with transgenic animals and having read the Moore paper that they appreciated that Neutrokine-*a* induced B cell proliferation and was a potentially important therapeutic target. Ultimately they developed a lead candidate relatively quickly but they did so by using the Medarex mice, which was seen as a powerful technology and one which was not established to be generally available to anyone who was prepared to pay for it.[441]

[437] See 3.6.6.
[438] HGS was granted European Patent (UK) 0,939,804 claiming Neutrokine-a, a novel member of the TNF ligand superfamily of cytokines, consisting of the encoding nucleotide and the amino acid sequence.
[439] *Human Genome Sciences Inc v Eli Lilly and Company* [2011] UKSC 51
[440] *Eli Lilly & Company v Human Genome Sciences Inc* [2008] EWHC 1903 (Pat), Para. 142-168.
[441] Ibid, Para. 258.

Moreover, Lilly spent about $50 million acquiring a monoclonal antibody to Neutrokine-a and intended to spend another $250 million for clinical trials.[442] Therefore, despite HGS' patent claims on Neutrokine-a, it did not deter one of its competitors from conducting downstream research and finding a lead antibody within the broad claim.

Another illustration where broad patents do not necessarily inhibit downstream research is regarding Chiron Corporation's (Chiron) patents on the Hepatitis C virus. By 2004, Chiron acquired over 100 patents in 20 countries on the virus and successfully sued its infringers.[443] Although Chiron licensed to its competitors, there were complaints that Chiron's licensing terms delayed research, particularly for smaller companies who maintain that they have abandoned research because they could not afford Chiron's licensing fees. While Chiron's patents may have halted some research for smaller companies, it cannot be said that it completely blocked all downstream research given that Chiron had licensed its patent to five pharmaceutical companies for drug development work.[444] Moreover, in 2004, Chiron altered its licensing policies to allow smaller businesses to conduct research. Under this agreement, companies can license Chiron's patents without having to pay upfront fees. In return, once these companies have attained certain targets in their research, they would they have to pay steeper royalties for products they bring to market.[445] The first start up company to license Chiron's patents under the new conditions was Prosetta.[446] Therefore, a hold-up created by a broad patent tends to be a theoretical construct rather than a real problem, as companies can find practical solutions to ensure research is not stifled.

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[442] Ibid, Para. 10.
[443] Storz, U., W. Flasche & J. Driehaus. Intellectual Property Issues: Therapeutics, Vaccines and Molecular Diagnostics. Springer: Heidelberg, 2012 at 92.
[444] Mazzucato, M. & G. Dosi. Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech. Cambridge: Cambridge University Press, 2006 at 302-303.
[445] Gellene, D. "Chiron Relaxes Patent Licenses" in Los Angeles Times. June 22, 2004. http://articles.latimes.com/2004/jun/22/business/fi-chiron22 Accessed November 25, 2014.
[446] "Chiron Grants Nonexclusive HCV License to Prosetta," PR Newswire. June 22, 2004. http://www.prnewswire.com/news-releases/chiron-grants-nonexclusive-hcv-license-to-prosetta-75096622.html Accessed November 25, 2014.

3.7. Economic justifications of patents

It may be enlightening to begin this section with a quote from Fritz Machlup:

> If one does not know whether a system 'as a whole'...is good or bad, the safest 'policy conclusion' is to 'muddle through' - either with it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. However, since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.[447]

This statement sheds light on what can be regarded as a lack of clear foundation for granting legal protection to objects of IP. For the time being, the dominant justification for intellectual property rights is grounded in utilitarian theory, which asserts that intellectual property rights are justified because their exclusionary effects are outweighed by their incentivizing effects on the possible creation of new inventions and their commercialization which increases overall societal welfare. [448] This section discusses and analyzes the main utilitarian theoretical justifications for the patent system: (i) reward by monopoly (ii) incentive to invent and (iii) exchange for secrets.[449] The incentive to invent theory and exchange for secrets theory are the most capable of substantiating the modern patent system.[450] Each of the three theories will be addressed

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[447] Machlup, Fritz. An Economic Review of the Patent System. 65th Congress 2d Session. United States Printing Office Washington: 1958 at 80.

[448] For a critique of the law-and-economics approach to intellectual property rights, see: Rahmatian, A. "A fundamental Critique of the Law-and-Economics Analysis of Intellectual Property Rights" in Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, 2013. Rahmatian argues that an economic analysis is actually damaging to the structure of patent law and its legal goals because they possess the essential, yet unpredictable facet of human inventiveness and creativity at their centre, which cannot be assessed by economic models (86-87). In a similar vein, Bernier notes that:

> The economic incentive aspect of the utilitarian theory focuses on a limited set of stakeholders, on those who value patented products the most in economic terms rather than considering the needs of all agents, including the less powerful. In fact, the only need that seems important is the need for efficiency, while the link between IP and other social needs remain unaddressed.

Bernier, L. Justice in Genetics: Intellectual Property and Human Rights from a Cosmopolitan Liberal Perspective. Cheltenham: Edward Elgar, 2010 at 110.

[449] See Fisher, M. Fundamentals of Patent Law: Interpretation and Scope of Protection. Oxford: Hart Publishing, 2007. Pp. 65-81. A similar classification is provided by Lawrence Becker "Deserving to Own Intellectual Property" in Chicago-Kent Law Review. Vol. 68, pp.609-629. 1993. The goal here is not to provide a comprehensive description of patent theory, but to briefly discuss some of the main theoretical arguments of the dominant patent theories. For a more thorough analysis, please see Hughes, J. "The Philosophy of Intellectual Property" in Georgetown Law Journal. Vol. 77, pp.287-367, 1988.

[450]Fisher, M. Fundamentals of Patent Law: Interpretation and Scope of Protection. Oxford: Hart Publishing, 2007 at 89.

in the following subsections, with a particular emphasis on the two more relevant to this analysis: the incentive theory and the exchange for secrets theory.

A. Reward by monopoly

The reward-by-monopoly thesis claims that an individual needs to be proportionally rewarded for their contribution to society. Since conventional market forces cannot guarantee this reward, the state needs to intervene to guarantee the reward through the patent system.[451] "Inventors render useful services, and the most appropriate way to secure them commensurate rewards is by means of temporary monopolies in the form of exclusive patent rights in their inventions."[452] Economists Adam Smith, John Stuart Mill and Jeremy Bentham supported the reward by monopoly approach in justifying patents.

Adam Smith held that the patent system was economically justified and necessary, stating that the state intervention was essential because unregulated market forces are not optimal. He maintained that the state needed to use the legal system to ensure that resources were allocated proficiently and to preserve a competitive economy. Smith's justification for the patent system is grounded in two claims. First, a temporary monopoly was "the easiest and most natural way in which the state can recompense…for hazarding a dangerous and expensive experiment, of which the public is afterwards to reap the benefit."[453] He says this is preferable to a prize system, as prizes "would hardly ever be so precisely proportioned to the merit of the invention."[454] Smith's second claim is that granting monopolies to inventors is harmless to society because if the invention is useful, it will benefit the public and the inventor will be rewarded for this invention. However, if the invention is not useful to society, then the

[451] Ibid, 68.
[452] Machlup, F. An Economic Review of the Patent System.65th Congress 2d Session. United States Printing Office. Washington: 1958 at 80. Machlup acknowledge the shortfalls of this theory, noting that patenting rewards seldom go towards the inventors and may not be proportionate to the benefit brought to society, and may cause injustice and injury to others.
[453]Smith, A. The Wealth of Nations. New York: The Modern Library, 1937 at 712.
[454]Ibid at 83.

inventor will not be compensated.[455] Hence, Smith's support for patents rests on the assumption that a patent is the best form of reward for the inventor and the temporary monopoly will not be harmful to society.

Applying Smith's rationale would justify patenting human biological materials like genetic modification techniques and product patents like isolated genes and chemicals like epo on the basis that doing so was harmless to society. "[I]f the invention be good and as such is profitable to mankind…will probably make a fortune by it; but if it be of no value he also will reap no benefit."[456] Smith's rationale does not hold because there are some patents on human biological materials are damaging and harmful to society, and it presumes that patent holders will act in a certain way. It can be argued that companies like Myriad Genetics, which isolated two profitable genes related to breast and ovarian cancer and aggressively asserted their patent rights whilst refusing to license, did cause some harm to society. The gene sequence coding for breast cancer is profitable to mankind and Myriad did make a fortune from their patents, but on balance, it tipped towards the rights holder whilst holding the public in a hostage position, particularly because Myriad Genetics was not the only researcher who worked on sequencing the BRCA1 and BRCA2 genes.[457] Whilst not all diagnostic companies act like Myriad Genetics, it can be argued that the grant of such a broad monopoly on a genetic sequence can be harmful and, in some cases, a patent grant may not be an economically justifiable means to an end, particularly when there are numerous parties engaged in the same research. The question turns to whether the research would have even begun had there not been the potential of receiving a patent.

[455] Ibid.
[456] Ibid.
[457] There was fierce competition amongst 7 major research teams from the US, UK, France, Japan and Canada in locating and identifying the BRCA1 and BRCA2 genes. See: Gold, R. and J. Carbone, "Myriad Genetics: In the eye of the policy storm" in Genetics in Medicine. Vol. 12, No.4, S39–S70. April 2010 Supplement at 42.

John Stuart Mill, another candid supporter of the reward-by-monopoly theory, observed that the purpose of the institution of property was to reward individuals with a property right to their own exertions:

> The institution of property, when limited to its essential elements, consists in the recognition, in each person, of a right to the exclusive disposal of what he or she have produced by their own exertions, or received either by gift or by fair agreement, without force or fraud, from those who produced it…together with his right to give this to any other person if he chooses, and the right of that other to receive and enjoy it.[458]

Mill's statement could be a foundation for a property right in that an inventor should be rewarded and compensated for the invention, and not doing so "would be a gross immorality in the law to set everybody free to use a person's work without his consent, and without giving him an equivalent."[459] But Mill was convinced that the exclusive reward should be proportional to the level of utility of the invention:

> [T]he reward conferred by it depends upon the invention's being found useful, and the greater the usefulness, the greater the reward; and because it is paid by the very persons to whom the service is rendered, the consumers of the commodity.[460]

Like Mill, Jeremy Bentham justifies the existence of patents on the basis of reward. He maintained that property is a social construction in which the state uses the law to create property rights. [461] For Bentham, the state grants patent rights to reward inventors:

> With respect to a great number of inventions in the arts, an exclusive privilege is absolutely necessary, in order that what is sown may be reaped. In new inventions, protection against imitators is not less necessary than in established manufactures protection against thieves. He who has no hope that he shall reap, will not take the trouble to sow. But that which one man has invented, all the world can imitate. Without the assistance of the laws, the inventor would almost always be driven out of the market by his rival who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his *deserved* advantages, by selling at a lower price.[462]

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[458]Mill, J. Principles of Political Economy: With Some of Their Applications to Social Philosophy. Vol. 1. New York: D. Appleton and Company, 1864 at 278.
[459]Mill, J. Principles of Political Economy, Vol.2. London: Green & Company, 1929 at 933.
[460]Ibid, 932.
[461] Bentham, J. Principles of the Civil Code. Edinburgh: The Works, published under the superintendence of John Bowring. 1843. Part 1, chapter 8.
[462]Bentham, J. The Works of Jeremy Bentham/Published Under the Superintendence of His Executor, John Bowring Vol. III. Edinburgh: William Tait, 1843 at 71

B. Incentive to invent

The "monopoly-profit-incentive" rationale is perceived as the primary underpinning of the patent system[463], which advocates that for investment to occur in research and development and rectify the issue of underinvestment in public goods, patents are essential to incentivize investment in the creation of new inventions with the assurance of an exclusive right. The transaction is the social cost of the grant of a temporary monopoly in exchange for the betterment of society through new and useful inventions that are produced and disclosed through the patent system.[464] The thesis presumes that inventions are required for progress to occur, but cannot be adequately exploited without society intervening to increase investors' profit expectations, and granting temporary monopolies is the "simplest, cheapest and most effective way."[465] The theory is based on the following assumptions:

1. Growth and industrial progress are desirable
2. Inventions are a necessary requirement for industrial progress
3. Too few inventions will be made or used unless there are effective incentives
4. Patents are the cheapest and most effective incentives[466]

Machlup ultimately holds that the patent system's incentive effects are due to expected profits arising from output restrictions produced from patented inventions.[467] "These output restrictions are the very essence of the patent system because only by restricting output below the competitive level can the patent system secure an income to

[463] See e.g. The Banks Committee, The British Patent System: Report of the Committee to Examine the Patent System and Patent Law, Cmbd 2207, July 1970 at 1: "The primary intention of the patent system is the encouragement of new industries in the country." Merges, Robert P. and Richard R. Nelson, "Market Structure and Technical Advance: The Role of Patent Scope Decisions," in Thomas M. Jorde David J. Teece (eds.) Antitrust, Innovation and Competitiveness. Oxford: Oxford University Press, 1992. Pp.185-232.
[464] Eisenberg, R. "Patents and the Progress of Science: Exclusive Rights and Experimental Use" in University of Chicago Law Review. Vol. 56, 1989 at 1025-1028.
[465] See supra note 447, Machlup, F. at 21.
[466] Ibid.
[467] Ibid, 77.

its owner."[468] In other words, the patent system rests on the need to incentivize and efficiently exploit inventions to create a competitive market economy and maximize social wealth. Although there are some critiques of this theory[469], this is the common economic justification for intellectual property rights, with one commentator stating that it has been *the* economic model for the last 200 years.[470]

Despite the agreement among most scholars that intellectual property rights are justified by the incentive to invent theory, there is conflict as there continues to be problems in empirically assessing the costs of monopoly patent exclusion and the benefits of inventions and their contribution to enhancing social welfare. This type of empirical analysis requires information to determine whether the economic trade-off is favourable insofar as the benefits offset the costs. However, when speaking of intellectual property rights, "the variables have proven extremely complex and heterogeneous."[471] Therefore, there is no definite empirical data that can prove definitely if the patent system, through the grant of exclusive rights, incentivizes new

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[468]Ibid.

[469] Two common limitations of the incentive theory are that (i) innovation will still occur without an intellectual property system and (ii) patents can discourage further inventions by curbing follow on inventions. See Palombi, Luigi. Gene Cartels: Biotech Patents in the Age of Free Trade. Cheltenham: Edward Elgar Publishing Ltd., 2009; Abramowicz, Michael. "Perfecting Patent Prizes" in Vanderbilt Law Review. Vol.56, No.1 pp. 114-236, 2003 and Merges, Robert P. and Richard R. Nelson, "Market Structure and Technical Advance: The Role of Patent Scope Decisions," in Thomas M. Jorde David J. Teece (eds.) Antitrust, Innovation and Competitiveness. Oxford: Oxford University Press, 1992. Pp.185-232. Another argument is that the justification for the patent system is not to create incentives, but that it redirects and focuses research and development efforts into particular useful areas (See Taussig, Frank W. Inventors and Money-Makers. New York: 1915 at 17)

> The defenders of patent legislation often descant on the public's benefit from inventions as if there were a special moral desert on the part of the projectors and patentees. They put their case badly. What deserves emphasis is the influence of calculated profit in directing the inventor's activity, spontaneous though it be, into channels of general usefulness.

[470]Lemley, Mark. "Reconceiving Patents in the Age of Venture Capital" in Journal of Small and Emerging Business Law. Vol. 4, 2000 at 139:

> [T]he patent law model we have is quite simple: the government issues you a patent; the patent gives you the right to exclude; you can use that right to exclude competitors in order to raise your price, and therefore make more money; and that fact in turn gives you an incentive to create. That is, you get an exclusive right; the exclusive right gives you more money. The prospect of more money encourages you to go out and innovate. It's a very simple model. It's been the model for 200 years.

[471]Mossoff, A (ed.). Intellectual Property and Property Rights. Cheltenham: Edward Elgar, 2013 at xv.

inventions.[472] However, some scholars have reconfigured the justification for patents as commercializing new inventions rather than incentivizing inventions.[473]

C. Exchange-for-secrets

The "exchange-for-secrets" theory maintains there is a deal between society and inventors, in which the inventor exchanges their knowledge with society for temporary protection of that knowledge. This argument assumes that progress cannot occur without complete disclosure of new and useful knowledge. "Hence, it is in the interest of society to bargain with the inventor and make him disclose his secret for the use of future generations. This can best be done by offering him exclusive patent rights in return for public disclosure of the invention."[474] Machlup disagrees with this thesis, claiming that in reality, society would not lose any valuable information because very few innovators can succeed in safeguarding their secrets and, furthermore, it is likely that several people simultaneously develop similar ideas within a short time span.

Despite highlighting the shortfalls of economic justification of the patent system, Machlup ultimately believes that the patent system is worth having on the basis that dismantling it would be too costly. He contends that there is no empirical evidence for why it should not be in place.

> No economist, on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates confers a net benefit or a net loss upon society. The best he can do is state assumptions and make guesses about the extent to which reality corresponds to these assumptions.[475]

3.8. Conclusion

This chapter started by discussing the dominant conception of property as a 'bundle of rights' designed by human beings. These social relationships are essential

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[472] See Priest, G. "What Economists Can Tell Lawyers about Intellectual Property" in Research in Law & Economics. Vol. 8, pp.19-24, 1986; Kitch, E. "The Nature and Function of the Patent System" in Journal of Law and Economics. Vol. 20, pp. 265-290, 1977.
[473] See Kieff, F. "Property Rights and Property Rules for Commercializing Inventions" in Minnesota Law Review. Vol. 85, pp. 697-754. 2001.
[474] Kieff, F. "Property Rights and Property Rules for Commercializing Inventions" in Minnesota Law Review. Vol. 85, 2001 at 21.
[475] See supra note 447, Machlup, F. at 79-80.

power relations and property is a form of power over third parties. More specifically, the form of power best translates as an exclusionary mechanism, which requires an obligation, that is implementable by the state to submit to the property right holder's will, which is what is known as the 'common conception of property,' the idea that property protects individuals' interests against collective forces. Property plays only a marginal role in a far-reaching institutional unit whose primary purpose is to achieve societal good. Moreover, right owners have an obligation to their community to promote the capabilities that are indispensable to human flourishing and nurture the realization of a just and desirable society.

The need for symmetry between individual rights and the societal good is epitomized in the way a patent is structured: a limited right, both in time and scope, to its claims. As property rights, particularly in the biotechnology industry, patents are necessary tools to incentivize investment due to the financial realities of R&D. Next, patent rights were discussed from a law-and-economics perspective, maintaining that the intangible nature of intellectual property can lead to free-riding, which is why a state-created patent right is necessary. The advantages and disadvantages of broad patents were also discussed in relation to biotechnology. The two economic justification theories underlying the grant of genetic inventions are incentive-to-invent and exchange-for-secrets.

It is submitted that patented inventions are forms of intangible property that perform a social function. Inventors are granted a limited exclusionary right in both length and scope of the property claims in exchange for disclosing new and useful knowledge to the benefit of society through the publication of the claimed invention. A patent right is an economically efficient way to distribute resources due to the fact that invented knowledge is a public good. Protecting knowledge through patents can incentivize further innovation and lead to technological advancement by carving out a

small segment of the field to encourage inventors to develop further add-on inventions. Due to the nature and costs of creating genetic inventions, patent protection is essential to encourage the patent owner to exploit and improve the invention because locating and identifying the correct region of the genome and linking it to a disease or target may only be the starting point. It is a worthwhile bargain to exclude others and give a temporary exclusionary right to reward the inventor and exchange for secrets, all in the name of promoting the social good. At the same time, in the name of the promoting the social good, patents should not act as a blockade towards further research. This means that overly broad patents like claims to entire genetic sequences that disallow other parties from conducting research should not be permissible.

Chapter 4: Comparative analysis of the legal approaches adopted in Europe and the United States

4.1. Introduction

This chapter explores how the state can use the category of "patentable subject matter" as a policy lever to limit the acceptable scope of patents and to direct patent protection towards completed products.[476] An analysis of the conception of 'invention' within patent law reveals how principles like the 'product of nature' doctrine in the US and the dichotomy between invention/discovery in Europe exist to ensure that things that should not be patented are not patented. US patent legislation does not specifically exclude any type of subject matter from patent protection, whilst European patent laws provide for specific articles for patentable and non-patentable subject matter.

An examination of European and US patent law jurisprudence illustrates how Europe and the US have addressed human genetic material in determining patent eligibility and the scope of protection. This will include a comparative review of how the US Supreme Court and the EPO Board of Appeal addressed Myriad's BRCA1 and BRCA2 gene patents, followed by an overview of the patent eligibility status of hESCs in the two jurisdictions.

4.2. Invention vs. discovery

The onset of a patent claim is that the subject matter qualifies as an invention. The discrepancy between invention and discovery is particularly significant in the area of patenting human genetic resources. The meaning of the term 'invention' suggests the production of an intellectual pursuit in the creation of new knowledge of a technical nature and implies a distinction between a creation and a mere discovery.[477] Meanwhile, a discovery refers to finding something, which already exists but was unknown. This is

[476] See supra note 4, Burk & Lemley at 1642.
[477] Correa, C. Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement. Oxford: Oxford University Press, 2007.

in contrast to an invention, which is the creation of something that does not exist in nature. There is a blurred distinction between a discovery and an invention.

The central area of disagreement on the patentability of bioscience lies in the definitions of "invention" and "discovery" and the uncertain demarcation of the two terms. In patent law, patents are only granted for inventions, not for discoveries. The definition of "invention" in patent law differs from the more familiar term of invention that emphasizes ingenuity. In the patent realm, an invention consists of anything that (i) involves human intervention, (ii) altered something from its original form and developed something that did not exist before, (iii) is inventive and (iv) the resulting product or process is useful.[478]

There is a fine line between a discovery and an invention, especially since an invention may ensue from a discovery, which is why it may be challenging to differentiate between them.[479] The standard distinction between a "discovery" and "invention" was made in the following statement by English judge Buckley J. in *Reynolds v. Herbert Smith & Co., Ltd.*:

> Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result.[480]

From the above statement, a "discovery" can refer to the acquisition of knowledge of a new gene and subsequently what protein the gene codes for. In contrast, an "invention" can refer to a new tool developed from knowledge of the gene, and this

[478] This mechanical definition of invention explains why in the E.U. isolated human genes may qualify as inventions under the customary tenets of patent law.
[479] Crespi, S. "Patenting and Ethics--A Dubious Connection" in Journal of the Patent and Trademark Office Society. Vol.85, January, 2003 at 34.
[480] 20 *Reports of Patent, Design & Trademark Cases*.123 (Ch. D.) 1902. In this case, the patent claim was for a material composed of commonly used materials. The invention consisted of a strip of canvas with a piece of India rubber attached to it for the purpose of wrapping around damaged tires to make a repair.

tool should qualify for patent eligibility given that it did not exist prior to the acquisition of the gene.

4.2.1. What is an invention?

Patents are only granted for 'inventions.' The requirements of an invention according to legislation in both jurisdictions seem to indicate that the requirements are stagnant. However, the meaning of 'invention' is hugely contested.[481] It is actually an evolving concept which has accommodated policy considerations based on three main factors: (i) justification of granting patents; (ii) economic policy and (iii) the national legal system itself.

The common theme underlying the definition of an invention is that the idea has to be "technical". Li Westerlund proposes the idea of the inventive kernel:

> The notion of invention indicates the presence of a technical idea, and this idea must relate to 'something,' we can call this the inventive kernel. To look at the definition as it already has been elucidated what it reveals is that an invention within its legal meaning can only be a creation of technical ideas by which a law of nature is used. As explained the given definition does not suffice for reasons of imprecision. Since otherwise it scope may further be broadened at the expense of discoveries precision that makes possible to reliably control eligibility for patent protection is desirable for future development of biological matter.[482]

The problem is that when talking about invention, there is the tendency to discuss it by differentiating it from a discovery.[483] Understandably, the distinction is

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[481] Amani, B. State Agency and the Patenting of Life in International Law. Surrey: Ashgate Publishing Limited, 2009.

[482] Westerlund, L. Biotech Patents, Equivalency and Exclusions Under European and US Patent Law. New York: Kluwer Law International, 2002 at 40.

[483] Resnik, D. "Discoveries, Inventions and Gene Patents," in D. Magnus, A. Caplan and G. McGee (eds.) Who Owns Life? New York: Prometheus Books, 2002. David Resnik maintains that the academic focus on distinguishing between 'inventions' and 'discoveries' is misguided because the distinctions are not entirely objective and possess subjective values. Resnik claims that since there is always a combination of natural forces and human intervention present in 'discoveries,' or 'inventions,' the discussion should focus on policy objectives and the values, interests and goals that inform them (152), which ultimately draw the line between a discovery and an invention. "Where we decide to draw the line between discovery and invention depends more on our purposes in making the distinction than on objective demarcations or divisions." (136) Resnik also points out that it is insufficient to consider one set of values in discussing gene patenting. Economic values typically dominate the discussion, including commercial interests, research development returns, etc. These values are the ones that are considered by the courts. Resnik argues that focusing on economic values is inadequate, and despite what some may believe, not entirely 'objective' either, as it creates consequences founded on upholding some values and discounting others. (153) Instead, groups with a stake in the issue all need to engage in dialogue. "Since gene patenting is a controversial public policy issue, we should find a way of giving serious consideration to different sides of this debate through a democratic process." (154) Resnik recognizes potential critiques of

helpful to an extent, but it may be difficult to draw a clear distinction between a discovery and an invention. As Antony Taubman notes:

> I think there's inevitably a limited role for the legislators to actually draw a bright line. The principle, I think it's not too hard to understand. The principle has been around a long time. It's like the idea/expression dichotomy in copyright. I mean, you kind of, intuitively, it makes sense. But can the legislature actually pre-emptively apply that distinction? Is it its job to articulate that distinction very clearly, or is its job to pre-emptively apply that to already carved up subject matter? Well, an analogy would be with the EU Biotech Directive, where there's a general rule on ethical exclusion from patentable subject matter. And it goes on to say "and in particular, we had in mind human cloning and whatever." Do we want to do that with the invention/discovery dichotomy? So the legislators say: "Patents are not for mere discoveries, but they are for true inventions, in particular we say this precludes from patentability the following...[484]

In effect, it may be difficult to clearly identify a discovery from an invention. However, to understand that particular dichotomy better, it may be helpful begin with a discussion of invention on its own.[485] This is important because the entire purpose of the patent system is to grant a temporary exclusive monopoly right to an invention, and therefore it is essential to determine the requirements of an invention.

4.2.2. Positive and negative definition

A legal definition of an invention can take two forms: a positive one and a negative one. It is rare for countries to adopt a positive legal definition of 'invention,' whereby patent laws identify eligible subject matter.[486] This may be because a positive definition intended to cover all eligible subject matter can only be conveyed in an abstract form, which "might not serve as a practical legal standard applicable to inventions not yet anticipated."[487] This could explain why a negative legal definition of 'invention' may be more appropriate. Relying on a list of subject matter that does not

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his position, acknowledging that legal courts and patent examination offices may not be ideal settings to discuss noneconomic values in gene patenting. However, he counters by stating that he sees no reason why the courts and patent examination boards cannot address noneconomic values, as they rely on expert testimony before making their decision (159).

[484] Interview with Antony Taubman WTO on February 23, 2012.

[485] Justine Pila maintains that a positive definition of "invention" is both possible and necessary, and that the concept of 'technological' is not particularly helpful in its definition. Instead, Pila maintains that the requirements for an invention has been influenced and shaped by policy, yet a "more meaningful definition of the invention than that which currently exists" (88) is needed. In Pila, Justine. "The Future of the Requirement for an Invention: Inherent Patentability as a Pre- and Post-Patent Determinant," in Arezzo, E. and G. Ghidini (eds.) Biotechnology and Software Patent Law: A Comparative Review of New Developments. Cheltenham: Edward Elgar Publishing Limited, 2011.

[486] Westerlund, L. Biotech Patents, Equivalency and Exclusions Under European and US Patent Law. New York: Kluwer Law International, 2002 at 24.

[487] Ibid, 25.

qualify as 'inventions' is the current standard of the courts in both Europe and the US. "[T]hey have all but ignored the fundamental question, '*what does it mean for a subject matter to be patentable* qua *invention*?'"[488] Without a coherent theory underlying it, the concept of an invention results in uncertainty and confusion in understanding the requirements of an invention. For instance, it is difficult to ascertain the 'technical' aspect and the categories or properties that are necessary for something to be classified as 'technical'.

4.2.3. Are gene sequences inventions?

Scholars have shied away from this question,[489] and responses from interview participants also emphasize that this question has not been adequately addressed. There has been a tendency to conflate, rather than to distinguish between public policy in the broader sense and the technical patentability criteria - whether the thing is in itself an invention and whether the outcome is useful. This is unfortunate because the technical patentability criteria are a distillation, a codification of centuries of debate, litigation and legislation that is exactly focused on public policy interests. The technical patentability criteria did not emerge from the patent office as a technical filter, but from the legislature as an articulation of public policy, which applies in the area of biotechnology inventions. This is why in the gene patenting debate, there is an important conclusion to clear up: Is there really no invention? The following sections will illustrate how the courts in Europe and the US have struggled to find an answer to this question

4.3. Patenting Human Genetic Materials in the US

"Invention" in the US refers to either an "invention or discovery," although the term "discovery" refers to the practical arts rather than theories.[490] US patent law

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[488] Ibid.

[489] See Kevles, D. & A. Berkowitz. "The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics," in Brooklyn Law Review. Vol. 67, pp. 233-248, 2001; See supra note 133, Conley & Makowski.

[490] US law on the distinction between invention and discovery has been described as puzzling. James Swanson notes: "What U.S law says about discovery and invention is extremely confusing, especially if

requires that an invention must pass the standard subject matter test in order to be patentable.[491] In particular, claimed DNA sequences and biotechnology inventions which include living organisms or naturally occurring substances cannot include those that merely exist in nature.[492]

4.3.1. Patent eligibility

Section 101 of the Patent Act defines the subject matter eligible for patent protection. "Whoever **invents or discovers any new and useful** [emphasis added] 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."[493] 'Discoveries' are recognized as patentable subject matter under Article I, section 8, clause 8 of the U.S Constitution: "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** [emphasis added]." Thomas Jefferson's term 'Discoveries' has evolved through common law to mean inventions, which require some sort of human ingenuity, as established in *Diamond v. Chakrabarty*.[494] This means that true discoveries are not patentable, as they are something that already exists in nature, but that someone has acquired new knowledge of.[495] As the following will establish, US case law has a lengthy custom of rejecting patents for products of nature, despite the fact that the word 'discoveries' still exists in statutory provisions. It is due to the judicial interpretation of statutes as reflected through case law in which US patent law in the area of 'discoveries' has evolved.

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one applies modern meaning to the terms 'discover' and 'invent." Swanson, J. Scientific Discoveries and Soviet Law. Gainesville: University of Florida Press, 1984 at 9.

[491] Ibid.

[492] See 66 Federal Register 1093, 2001.

[493] 35 U.S.C. §101

[494] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

[495] Westerlund, L. Biotech Patents, Equivalency and Exclusions Under European and US Patent Law at 24.

4.3.2. Exceptions to 35 U.S.C. §101

Even though Section 101 of the Patent Act stipulates that a patent can be granted for any new and useful process, machine, manufacture, or composition of matter, the provision includes judicially-created exceptions: laws of nature, natural phenomena and abstract ideas.[496]

Some of the underpinning rationales of *Myriad*'s[497] invalidation of isolated gene patents are apparent in earlier US Supreme Court cases such as *Bilski v. Kappos* ("*Bilski*")[498] and *Mayo v. Prometheus* ("*Mayo*") [499]

In *Bilski,* the US Supreme Court held that a business method of hedging risk in commodities trading not eligible for patent protection. The court held the claims at issue constituted abstract ideas, which were not patent eligible. In addition, the court held that the machine-or-transformation test is not the only test for determining the patent eligibility of a process, but rather "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."[500] The court stated that the abstract ideas could not be patented to prevent patents from pre-empting access to foundational features, which also include laws of nature and physical phenomena. Citing *Funk Bros.*, the court stated that the purpose of excluding subject matter including laws of nature, natural phenomena and abstract ideas is because these articles are considered to embody the "storehouse of knowledge of all men."[501] Even though the case was about hedging risk, the case has relevance to *Myriad* as it has

[496] For instance, in *Diamond v Diehr*, 450 U.S. 175, 185 (1981), the Supreme Court held that patent protection is not granted to "laws of nature, natural phenomena, and abstract ideas."
[497] *AMP v Myriad* (2013)
[498] *Bernard L. Bilski and Rand A. Warsaw v. David J. Kappos, Under Secretary of Commerce for Intellectual Property and Director, Patent and Trademark Office 561 U.S. 593 (2010).*
[499] *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc. 566 , 132 S.Ct. 1289, 101 USPQ2d 1961 (2012)*
[500] Ibid, 8.
[501] Ibid, 5 (citing Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 130 (1948))

implications in how the judiciary interprets "nature."[502] The notion of preserving essential articles within the public domain was also reiterated strongly in *Mayo.*

In *Mayo,* the US Supreme Court unanimously held that claims involving methods optimizing the therapeutic efficacy of a drug was not patentable subject matter under 35 U.S.C. § 101. [503] The claims were directed to optimizing treatment of an immune-related disorder by administering a drug and determining whether the level of a metabolite in a patient's blood was within a desired range. The issue was whether the claims merely described laws of nature, natural phenomena, and abstract ideas, or whether they described patent-eligible applications of those concepts. The court maintained that "scientists already understood that the levels in a patient's blood of certain metabolites"[504] and the claimed method "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."[505] Notably, the court maintained that the patent application must include a significant inventive component past the abstract idea or the natural process. [506] Thus, upholding the claims which were directed to routine application of a law of nature would result in a "monopolization of those tools" and

[502] This opinion was expressed by Judge Rader in the Federal Circuit decision: "Natural laws and phenomena can never quality for patent protection because they cannot be invented at all." In *re Bilski*, 545 F.3d 943, 1013 (Fed. Cir. 2008) (Rader, J., dissenting).

[503] In response to the Supreme Court's ruling in *Mayo v. Prometheus* for more constrained rules for patenting, the United States Patent and Trademark Office (USPTO) recently issued a memorandum involving the eligibility of process claims involving laws of nature under 35 U.S.C. §101. The memorandum presents three questions essential for examining subject matter eligibility:

(1) Is the claimed invention a process? If so, then,

(2) Does the claim focus on the use of a "natural principle"? If so, then:

(3) Does the claim include the "additional steps" or an element combination that incorporates the natural principle into the claimed inventions such that it moves the invention beyond the natural principle, as stipulated by the *Mayo v. Prometheus* decision?

If the answer to the third question is 'yes,' then the claim is deemed to be eligible for patentability. However, one of the more challenging tasks is determining when the additional steps or element combinations in the claim meet the requirement set out in *Mayo v. Prometheus.*
Since the United States does not apply any of the exclusions listed in Article 27.3(b) of the TRIPS Agreement, the memorandum could potentially apply to microbiological, biological and non-biological process claims for the production of plants and animals. If the claim is a process claim and includes the use of a "natural principle," and includes the "additional steps" or combination of elements which incorporates the use of the natural principle into the claimed invention which moves the invention beyond the natural principle, then the process claim could be patent eligible.

[504] Ibid at 4

[505] Ibid at 3

[506] Ibid

"impede innovation more than it would tend to promote it."[507] In articulating the importance of excluding laws of nature from patentability, this line of reasoning could be applied to *Myriad* in that the failure to invent around genetic sequences increases the necessity of keeping them in the public domain.

It appears that in addition to the three categories of patent ineligibility, which include laws of nature, abstract ideas and natural phenomena, the courts seem to be creating another item to add to the list of exceptions to patentability. In the case where a claimed product is technical, but possesses the genetic character of something which already exists in nature, then that product is an exclusion to eligible subject matter for patent protection, irrespective of the degree of inventiveness required in the creation of the invention. Justine Pila characterizes this distinction in US patent law as between inherently patentable and inherently unpatentable technical subject matter.[508] For instance, in *Myriad,* the US Supreme Court clearly labelled Myriad's DNA claims as falling within the law of nature exception.[509] The court acknowledged Myriad had narrowed the possible locations for the BRCA1 and BRCA2 sequences and sought to import those extensive research efforts into the §101 patent eligible criteria, yet "extensive effort alone is insufficient to satisfy the demands of §101."[510] The reasoning of the Supreme Court suggests that there was not sufficient human intervention and the decision helps establish a robust exclusion for natural phenomena from patentable subject matter.

Recently, the US Supreme Court addressed the patent eligibility of method and system claims in *Alice Corp. v. CLS Bank International*.[511] The issue was whether claims directed to a computer-implemented scheme for mitigating settlement risk by

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[507] Ibid at 2
[508] Pila, J. "Isolated Human Genes: The Patent Equivalent of a Non-Copyrightable Sound Recording" in Law Quarterly Review (forthcoming) 2014 at 3.
[509] Ibid at 2.
[510] *AMP v. Myriad (2013)* at 14.
[511] *Alice Corporation Pty. Ltd. v. CLS Bank International, et al.* 573 U.S._2014

using a third-party intermediary amounted to an abstract idea. The case is a restatement of the pre-emptive reasoning for the barring of laws of nature, natural phenomena and abstract ideas from patentable subject matter under 35 U.S.C. § 101. The court referred back to its decision in *Mayo* in laying out a framework for addressing patent eligibility. Using this framework, the first step includes deciding whether the claims at issue fall into one of the patent-ineligible categories. If so, one then considers the parts of each of the claims both individually and in combination to assess whether there is an inventive concept present which adds 'enough' to transform the abstract idea into a patentable invention.[512] As a result, the 'inventive concept' as stated by Justice Breyer in *Mayo* has led to the interpretation of patent eligibility that is ultimately a fusion with patentability requirements in assessing claimed methods under 35 U.S.C. § 101.[513]

Regarding the first step, the court maintained that Alice's claims are directed to the abstract idea of intermediated settlement.[514] Comparing the similarities of the claims to the abstract idea in *Bilski*, the court held that Alice's claims constituted an abstract idea, and merely requiring generic computer implementation was insufficient in transforming the abstract idea into a patent-eligible invention.[515]

Pertaining to the second step, the court noted that assessing the claim elements separately, the function performed by the computer at each step of the process is purely conventional.[516] Considered as a combination, the components of the method do not add anything "that is not already present when the steps are considered separately."[517] Therefore, the court held that the method claims do not improve the functioning of the computer itself or "effect improvement in any other technology or technical field."[518] Ultimately, the ruling in *Alice Corp. v. CLS Bank International* states that any claims

[512] Ibid, Slip op at 7.
[513] Ibid.
[514] Ibid.
[515] Ibid at 10.
[516] Ibid at 15.
[517] Ibid.
[518] Ibid.

over an implementation of an abstract idea requires proof of an inventive concept which adds 'enough' to transform the idea into a patentable invention, be it in the form of new steps rather than routine steps.[519]

The case provides a few lessons pertaining to patent eligibility under § 101. The court provided some guidance, albeit incomplete, on what constitutes an abstract idea. The court explicitly highlighted that in the past, ideas, algorithms, mathematical formulas and fundamental economic practices like hedging risk and using intermediated settlements are not eligible for patent protection. Yet, the court does not provide any assistance in defining the boundaries of the abstract idea exception. But it does suggest that a technological requirement is important for eligibility, noting in *Diamond v. Diehr*[520] that a technological improvement is important in solving an industry problem.

It is important to note that unlike *Myriad*, the Supreme Court in *Alice* seems to be unwilling to hold business methods *per se* ineligible, as it notes that many computer-implemented claims are eligible subject matter. Yet, all four cases above demonstrate that there is an eagerness to maintain an area of nonpatentability for natural phenomena to keep the "basic tools of scientific and technological work" available to potential researchers.[521]

4.3.3. Genesis of the product of nature doctrine

The difference between unpatentable and patentable subject matter for 35 U.S.C. §101 is whether the claimed object is a product of nature (whether living or not) or a man-made invention.[522] A product of nature does not fall within the invention category.

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[519] Ibid.

[520] *Diamond, Commissioner of Patents and Trademarks v. Diehr, et al*. 450 U.S. 175 (1981) at 177, 178. The US Supreme Court held that directing implementation of a physical process (which in this case, involved curing rubber with a rubber-curing machine) through the use of computer program does not preclude it from being eligible for patent protection as a whole. Even though the claim involved a well-known mathematical formula, the computer used the equation in a way that solved a technological problem in conventional industry practice.

[521] *AMP v. Myriad* at 14, citing *Mayo*.

[522] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) at 313 and reiterated in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*., 534 U.S. 124 (2001) at 134: "As this Court held in *Chakrabarty*, "the

The crux of the doctrine is that the unearthing of something that naturally exists is not patentable because it is not an invention.[523] The "product of nature" doctrine developed in two separate but linked ways. The doctrine first emerged in *Ex parte Latimer*[524] ("*Latimer*") when the Commissioner of Patents rejected a patent for an extracted plant fiber. The doctrine was reaffirmed by the Supreme Court in *Funk Bros v. Kalo Inoculant Co.*[525]("*Funk Bros*."), *Diamond v. Chakrabarty*[526] ("*Chakrabarty*") and its resurgence in the recent *AMP v. Myriad*[527] ("*Myriad*"). In these cases, the product of nature has referred to a composition of matter which did not fall within the patentable subject matter category because it was found to be undifferentiated from a naturally occurring entity. The second way the doctrine has been interpreted is in terms of the reference to claims which fall short of novelty and non-obviousness because they encompassed natural substances which were obtained from a new process or are in only a slightly purer form than their naturally occurring counterparts.[528] This reading of the product of nature doctrine appears in *Parke-Davis v. H.K. Mulford,*[529] ("*Parke-Davis*") and *Merck & Company v. Olin Mathieson Chemical Corporation*[530] ("*Merck*").

A. *Ex Parte Latimer*

The 'product of nature' principle was first asserted in *Latimer,* which has been used as a guiding point in the judiciary in deciding between discovered objects (not patentable) and processes used to extract those objects (patentable).[531] In 1889, the

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relevant distinction" for purposes of §101 is not "between living and inanimate things, but between products of nature, whether living or not, and human made inventions."

[523]Conley, 113.

[524] *Ex parte Latimer*, Decisions of the Commissioner of Patents. Decided March 12,1889

[525] *Funk Brothers Seed Co. v. Kalo Inoculant Co*. 333 U.S. 127 (1948)

[526] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

[527] *AMP v. Myriad* (2013)

[528] See supra note 133, Conley& Makowski at 320.

[529] See supra note 135.

[530] *Merck & Company v. Olin Mathieson Chemical Corporation* 116 U.S.P.Q. 484 (4th Circuit 1958)

[531] *Ex Parte Latimer*, March 12, 1889, C.D., 46 O.G. 1638, United States Patent Office, "Decisions of the Commissioner of Patents and the United States Courts in Patent Cases." 1889 (Washington, D.C.: Government Printing Office, 1890). The patent examiner initially refused the application, stressing the indistinguishability of characteristics between the claimed element and its naturally existing counterpart: "The claim and description do not set forth any physical characteristics by which the fiber can be distinguished from other vegetable fibers…Hence, since the fiber claimed is not, and cannot be,

Commissioner of Patents rejected an application for a fibre in a needle of a pine tree, maintaining that the fibre was not an 'invention.'[532]

While the Commissioner noted that the process of producing the claimed fiber constituted an invention,[533] the Commissioner considered it unreasonable to allow something that already existed in the earth to be patented merely because someone discovered it even if the claimed product is useful and has value to society.[534] The finding of the fibre in the needle of a pine tree could not be patented, "anymore than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found."[535] The reasoning was that granting a patent for the claimed substance itself would have detrimental consequences.

> Otherwise, it would be possible for an element or principle to be secured by patent, and the patentee would obtain the right, to the exclusion of all other men, of securing by his new process from the trees of the forest (in this case the *Pinus australis*) the fiber which nature has produced and which nature has intended to be equally for the use of all men.[536]

As a result, granting a patent on a tree fiber would exclude everyone else from the use of a natural product with the outcome that "patents might be obtained upon the trees of the forest and the plants of the earth."[537]

The Commissioner explained if the applicant's process included another step in which (i) the fiber was withdrawn or separated from the leaf or (ii) the natural state of

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distinguished from other fibers by any physical characteristic, the claim therefor must be refused." 124. The Commissioner agreed with the patent examiner's denial of the patent and expanded on the subject of indifferentiability: "It is also well known that the pure fiber after it has been eliminated from the natural matrix of the leaf or stalk or wood in which nature forms and develops it is essentially the same thing and possesses the same construction. The chemical formula for this cellulose in all these varieties of plants, I am advised, is the same." 125

[532] The claim was for "a new article of manufacture…consisting of the cellular tissues of the *Pinus australis* [southern pine] eliminated in full lengths from the silicious, resinous, and pulpy parts of the pine needles and subdivided into long, pliant filaments adapted to be spun and woven." Ibid, 123.

[533] The patent for the process of producing the claimed fiber was granted. Ibid.

[534] The Commissioner considered the economic argument to grant a patent on such a claimed product, exposing the burden he felt to authorize the patent because he felt it was a valuable contribution to society:

"I have given this application no little consideration, and have experienced an anxiety, if possible, to secure the applicant a patent. The alleged invention is unquestionably very valuable, and one, according to the statements presented to me, of immense value to the people of the country…but while the production may be thus regarded as a very valuable one, the invention resides, I am compelled to say, exclusively in the process and not at all in the product." Ibid, 127.

[535] Ibid.

[536] Ibid, 125-126.

[537] Ibid.

the fiber was changed so it acquired a new quality or function which did not exist in its natural state, the fiber might have qualified as an invention as a product.[538]

Therefore, one can derive three elements of the product of nature doctrine from *Latimer*:

1. A claimed product whose physical traits are undifferentiated from those of its naturally occurring counterpart is not patentable subject matter.
2. The novelty of the discovery is not connected to the product's patentable subject matter status. However, there may be an argument for a patent for the process used in the discovery of the product provided the nature of the process fulfils the patentability requirements.
3. If a product is inherently unpatentable, the product's utility and value to society is not a justification for making the product patentable subject matter.

The significance of this judgement is that the Commissioner emphasized that there are some things that are inherently unpatentable, despite their utility and value to society. Indeed, a string of cases followed this principle and upheld the 'product of nature' doctrine after *Latimer*.[539] The product of nature doctrine was referred to in subsequent cases.[540]

B. *Funk Bros. Seed Co.*

A key case in the context of biotechnology and anti-patentability decisions on natural products is *Funk Bros. Seed Co.v. Kalo Inoculant Co. (1948),*[541] which was one of the leading cases guiding the *Myriad* decision. Notably, in *Funk Bros*., the Supreme

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[538] Ibid.

[539]The court in Farbenfabriken of Elberfeld Company v. Kuehmsted, 171 F. 887 (7th Circuit 1910) held that aspirin was patentable; in General Electric Company v. De Forest Radio Company 28 F.2d 641 (3d Circuit 1928) the Court found that tungsten wire was patentable subject matter; Merck & Company v. Olin Mathieson Chemical Corporation 116 U.S.P.Q. 484 (4th Circuit 1958) found that a fermented-derived vitamin B-12 was patentable subject matter.

[540] See e.g. *DeForest Radio Co. v. General Electric Co*., 283 U.S. 664 (1931), *In re Marden* 47 F.2d 958 (C.C.P.A. 1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co*. 333 U.S. 127 (1948), *In re Williams* 80 U.S.P.Q. 150 (C.C.P.A. 1958), *Merck & Co. v. Olin Mathieson Chemical Corp*. 116 U.S.P.Q. 484 (4th Cir. 1958), *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc*., 534 U.S. 124 (2001).

[541] *Funk Brothers Seed Co. v. Kalo Inoculant Co*. 333 U.S. 127 (1948)

Court reaffirmed the strength of the product of nature doctrine and established the rule that natural existing subject matter is not patentable by invalidating a product patent claiming strains of root-nodule bacteria, which were combined together to fix nitrogen in the soil. The mixture of bacteria infected the roots of plants so that plants could absorb nitrogen more easily. The Court held that the claimed strains of bacteria as a product was not eligible for patent protection, because each of the bacteria existed in nature and its combination was a discovery. In addition, the mixing of the strains did not change the bacteria's natural function. The Court emphasized two points. The first was a general statement that laws of nature are not patentable subject matter: "manifestations of laws of nature"[542] are "part of the storehouse of knowledge,"[543] and "free to all men and reserved exclusively to none."[544] The case was a restatement of the nineteenth century law of nature cases, with attention focused on where to draw the line between an unpatentable law of nature and a prospective patentable application.[545] Second, the Court held the claimed application of the discovery unpatentable, even though the mixed culture was commercially useful, the mixture fell "short of invention within the meaning of the patent statutes."[546] Justice Douglas emphasized the inventiveness requirement, explaining that "the state of the art made the production of a mixed inoculants a simple step. Even though it may have been the product of skill, it certainly was not the product of invention."[547] Justice Douglas' statement emphasized that an obvious application of an law of nature was unpatentable even if the natural event itself is a new and nonobvious discovery. This judgement added to the law-of-nature principle

[542] Ibid, 130.
[543] Ibid.
[544] Ibid.
[545] Beauchamp, C. "Patenting Nature: A Problem of History," in Stanford Technology Law Review. Vol. 16, 2013 at 302.
[546] *Funk Brothers Seed Co.* (1948), 130.
[547] Ibid, 132.

with a deeper inventiveness requirement.[548] Moreover, it was a resurrection of the product of nature doctrine as stated in *Latimer*.[549]

What was noticeably missing in this judgement was any reference to *Parke-Davis* and the principle of "useful difference" in differentiating a non-patentable natural substance to a useful application of scientific knowledge to things which do not exist naturally.[550] However, the court opted to disregard *Parke-Davis*. It was not until another chemical case came along that Learned Hand's comments in *Parke-Davis* became a standard reference in case law.[551]

C. *Diamond v. Chakrabarty*

Prior to the Supreme Court decision in *Chakrabarty*, the Court for Customs and Patent Appeals consolidated two cases, *Bergy* and *Chakrabarty*,[552] to decide whether living organisms constituted either a "manufacture" or "composition of matter" under 35 U.S.C § 101[553] The majority referred to three 'doors' that the inventor must pass through "on the difficult path to patentability" which include section 101 (eligibility criteria), section 102 (novelty) and section 103 (non-obviousness). The first door that the inventor must pass through is section 101, where the inventor must possess a certain kind of invention which falls into one of the named categories: a process, machine,

[548] Beauchamp, 302.
[549] "Bond does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable…For the qualities of these bacteria, like the heat of the sun, electricity, and or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." Funk Brothers Seed Co. v. Kalo Inoculant Co. - 333 U.S. 127 (1948) at 130.
[550] See supra note 135 for full case citation and refer to 4.3.4 for a summary on the case.
[551] Beauchamp, 303-304.
[552] See *In re Bergy*, 563 F.2d 1031, 1036 (C.C.P.A. 1977) (maintaining that a purified strain of bacteria was patentable subject matter), *cert. granted and vacated sub nom.* Diamond v. Bergy, 444 U.S. 924 (1979) (mem.), *vacated in part sub nom. Parker v. Bergy*, 438 U.S. 902 (1978) (mem.), *on remand sub nom. In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), cert granted sub nom., No. 79-136 (U.S., Oct. 29, 1979). *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) (mem.), aff'd, 447 U.S. 303 (1980).
[553] *In re Bergy*, 596 F. 2d 952, (C.C.P.A. 1979) at 960. Dr. Bergy created a novel process to prepare the antibiotic lincomycin using a previously unknown microorganism, *Streptomyces vellosus*, in a biologically pure culture. The second patent at issue was Chakrabarty's claim for a genetically engineered strain of bacteria which allowed for a more effective invention of a new genetically engineered strain of bacteria for the more effective disintegration of oil spills. For both patents, the CCPA held that the claimed inventions were patentable subject matter within 35 U.S.C.S. § 101.

manufacture or composition of matter, or any improvement thereof. Even though section 101 mentions three requirements, novelty, utility and statutory subject matter, the court insisted that the three requirements are *separate and distinct*.[554] "Thus, the questions of whether a particular invention is novel or useful are questions wholly apart from whether the invention falls into a category of statutory subject matter."[555] Therefore, the question of whether a claimed invention falls within statutory subject matter should be determined solely by whether it is a machine, manufacture or composition of matter, and not affected by the existence or lack of novelty or utility.[556] There are three points worth mentioning from the majority's decision:

1. Chakrabarty's genetically engineered bacteria amounted to a "manufacture" or "composition of matter".[557]

[554] The court emphasized that this understanding is long-standing and universally accepted. *In re Bergy*, 596 F. 2d 952, (C.C.P.A. 1979) at 960.
[555] *In re Bergy*, 596 F. 2d 952, (C.C.P.A. 1979) at 960-961.
[556] See supra note 133, Conley & Makowski at 374.
[557] *Diamond v. Chakrabarty*, 213.Previously, the oil-eating bacterium would have been conceived as a 'product of nature,' and may have been denied a patent based on it being a living thing. However in this case, the Court chose to view the bacterium as a natural compound that had been modified structurally, which made it a new 'composition of matter,' or 'manufacture' that was not natural. See Dutfield, Graham, "Who Invents Life: Intelligent Designers, Blind Watchmakers, or Genetic Engineers?" in Journal of Intellectual Property Law & Practice. Vol. 5, *No. 7, 2010. 535* .In addition, since the Court adopted the 'life as chemistry' approach , the bacterium was now perceived to be a natural chemical matter in which a new and useful trait was introduced into it and made it 'unnatural,' and subsequently, patentable. This is in agreement with the customary practice with regards to chemical products, where a natural chemical becomes an 'invention' upon human modification through various methods, including removing something from the substance and purifying it and adding something to it like a gene. See Dutfield, G. and Uma Suthersanen. Global Intellectual Property Law. United Kingdom: Edward Elgar Publishing Limited, 2008, 301. Classifying life as 'chemicals' is a controversial issue. The Courts have interpreted living organisms as chemicals, but there is a debate as to whether this is the correct approach. There is the view that employing terms like "life is largely chemical" misleads judges into wrongly thinking things are inventions when, in fact, they are merely discoveries. Graham Dutfield claims there are limitations to metaphors and analogies used by scientists, particularly in the field of synthetic biology, a new branch of biology that has created minimal genomes, standardized parts, devices and systems, and metabolic engineering. (Dutfield, Graham. "'The Genetic Code is 3.6 Billion Years Old: It's Time for a Rewrite' Questioning the Metaphors and Analogies of Synthetic Biology and Life Science Patenting" in Annabelle Lever's (ed.) New Frontiers in the Philosophy of Intellectual Property. Cambridge: Cambridge University Press. 2011, 4.) In addition, Rebecca Eisenberg, a respected academic in the field, criticizes the chemical analogy that is employed in respect to DNA sequences, which fails to associate the sequences to valuable information that is intellectual property. (Eisenberg, Rebecca. "How Can you Patent Genes?" in David Magnus, A. Caplan and G. McGee (eds.) Who Owns Life? New York: Prometheus Books, 2002, 118.)

2. The bacterium was new and a product of human ingenuity, possessing characteristics that were **markedly different** from ones found in nature, and had the potential for considerable utility.[558]
3. Broad interpretation of §101: it **did not matter whether it was living or non-living** because Congress anticipated and expected patentable subject matter to include organisms that were created with human involvement.[559]

The Supreme Court observed the product of nature question was solely a §101 patentable subject matter query.[560] The main question the judges had to answer was whether Chakrabarty's claimed bacterium was the type of phenomenon that could be patented. Unlike the approach adopted by the lower courts, the court chose not to focus on novelty and non-obviousness.[561] Rather, the court opted to cite *Funk Bros.* for the suggestion that patents could not be granted for "'manifestations of…nature, free to all men and reserved exclusively to none.'"[562] The Court made a distinction between *Funk Bros.* and *Chakrabarty*. Writing for the majority, Chief Justice Burger noted that the patentee in Funk had merely discovered a natural opportunity: the amalgamation of

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[558] Supra note 64, *Diamond v. Chakrabarty* at 310. "[T]he 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."

[559] The speaker for the majority, Chief Justice Warren Burger, rested his judgement on interpreting Thomas Jefferson's patent law of 1793, declaring that patents could be granted for "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement thereof.' By adopting a broad interpretation of s.101, the Court stretched the scope of patentable subject matter. Even though the code did not make specific reference to patenting living organisms, the Court interpreted the broad language of the patent code as including "inventions in areas unforeseen by Congress, including genetic technology, and to cover living organisms." (Kevles, D. Of Mice & Money: The Story of the World's First Animal Patent" in Daedalus, vol. 131, No. 2, On Intellectual Property (Spring 2002), p78). The minority, on the other hand, did not accept the majority's broad interpretation of Jefferson's Act, arguing that the purpose of the act was not to extend patents for every progress made.

> The patent laws attempt to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress...Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available. *(Diamond v. Chakrabarty*, 319)

[560] See supra note 133, Conley& Makowski at 376.

[561] "The unambiguous implication is that arguments about novelty and non-obviousness are unresponsive to an objection that something is unpatentable because it is a product of nature." Ibid.

[562] *Diamond v. Chakrabarty*, citing *Funk*, 333 U.S. at 130.

certain root-nodule bacteria. On the other hand, Chakrabarty had genetically manipulated the bacterium which nature did not create:

> Here, by contrast, 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; accordingly it is patentable subject matter under § 101.[563]

The notion behind the distinction between natural and artificial materials was shown to have played a significant role in the decision. Therefore, it would seem that any genetic modification could end up being a possible patentable invention.[564] The case is significant because it is the first case in which the court decided that an microorganism as an end product could be patented. The decision also redefined the boundaries of the product of nature doctrine, clearly stating that living organisms are patentable subject matter despite the fact that two statutes had been legislated for a special type of patent protection for specific living organisms.[565] It appears that the majority extended the scope of patent protection without considering the effects of patenting living organisms by adopting a narrow interpretation of statute law rather than addressing the larger issue of the patentability of higher life forms and the policy issues surrounding it.[566]

As mentioned above, the purpose of patent law in the United States is to promote the progress of science, which is found in the Constitution. Biotechnology in the US is a substantial filed and the reasonable explanation for this is patent law and policy.[567] After the Supreme Court expressed a liberal benchmark for patentable subject matter in *Chakrabarty*, it opened the floodgates for patents on other living organisms, which contributed to the growth of biotechnology. Despite criticisms of this close

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[563] Ibid.
[564] See supra note 133, Conley & Makowski at 375.
[565] 1930 Plant Patent Act and 1970 Plant Variety Protection Act
[566] Worth noting are the four dissenting opinions. Justices Brennan, Marshall, Powell and White claimed that the 1930 Plant Patent Act did not cover living organisms and the 1970 Plant Varieties Protection Act excluded bacteria from the scope of patentable subject matter. These two points led to their argument that Section 101 did not "encompass living organisms." U.S. Supreme Court Bulletin, 1980, pp. 3139-41.
[567] Ebermann, P. Patents as Protection of Traditional Medical Knowledge? A Law and Economics Analysis. Cambridge: Intersentia, 2012 at 79.

decision, it is a coherent decision and follows US patent case law in the essential distinction between a discovery and an invention.

4.3.4. Intertwining the product of nature doctrine with novelty and utility

The blending of subject matter (section 101) with novelty (102) reflects the duplicitous feature of the product of nature doctrine. This is especially evident in cases where natural products that were purified or modified by human intervention that were of practical, commercial, and therapeutic value could be eligible for patent protection. As a result, judges may concurrently hold that the claimed subject matter is unpatentable because it is a product of nature whilst maintaining that it also falls short of the novelty requirement because the claimed subject is a product of nature and therefore already known.[568]

A. *Parke-Davis v. H.K. Mulford Co.*

A legal principle that has been dominant in the patenting of life science inventions in the US stems from Learned Hand's dicta: if the claimed invention has a practical purpose, then there is a good ground for a patent.[569] The crux of the principle stems from the usefulness of a claimed invention to society and that social policy should not create barriers to research groups acquiring temporary exclusive rights to genetic sequences. The facts and issues of the case will be discussed and analyzed below.

In *Parke-Davis,* a patent for isolated and purified hormone adrenaline was upheld. [570] Learned Hand addressed the product of nature argument as a technical objection to the patent and emphasized that purified adrenaline did not naturally exist and that the value of adrenaline in its pure form was a better treatment for patients with

[568] Chisum, D. Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement. New York: Matthew Bender, 1978-, Release 140, 2013 at 57.
[569] See supra note 135.
[570] Ibid. Dr. Jokichi Takamine, the inventor was granted patents for the extraction process and product. The issue was whether an isolated purified substance, in this case, adrenaline, a naturally occurring hormone in mammals, was patentable. H.K. Mulford challenged the validity of the patent, claiming that naturally occurring products were unpatentable.

low blood pressure.[571] Learned Hand reasoned that isolating and purifying a substance constituted a "new" thing which was patentable. Notably, Learned Hand held that an isolated purified substance without any difference in function from its naturally occurring counterpart was patentable:

> But, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.[572]

Learned Hand applied a pragmatic approach to reward Takamine, the inventor, for creating a valuable product. A line of rationalization emerged which requires two conditions to be met to prevail over the product of nature doctrine for naturally occurring subject matter: (i) the purified version of the claimed product must not naturally exist and (ii) the pure form must possess a greater value than its naturally occurring counterpart. However, there is an exception to the purity rule, in that the new pure compound must differ "in kind" and not merely "in degree." Learned Hand explained that a difference "in kind" could be established if the purified compound has an completely novel utility from the original one.[573]

The way in which the doctrine was interpreted and applied to later cases, particularly in those concerning chemical patents, ultimately distorted the limit of the doctrine as stated in *Latimer*.[574] What emerged from *Parke-Davis* was the 'useful difference' which would influence future cases.[575] In fact, Learned Hand's "failure to take *Ex parte Latimer* into account" has been described as one of the "greatest shortcomings" of this opinion.[576] Subsequent cases, particularly those concerning

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[571] Ibid, 102-103.
[572] Ibid, 103.
[573] Ibid.
[574] It is only in the last decade that the US Supreme Court has shown a desire to narrow the scope of patentable subject matter under 35 U.S.C. §101 using the product of nature doctrine.
[575] Beauchamp, C. "Patenting Nature: A Problem of History," in Stanford Technology Law Review. Vol. 16, 2013 at 285.
[576] Harkness, J. "Dicta on Adrenalin (e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in Parke-Davis v. Mulford" in Journal of Patent & Trademark Office Society. Vol. 93, 2011 at 391.

chemical patents, reveal a blurring of the *Latimer* definitional restrictions and, accordingly, an effective slackening of the product of nature barrier.[577]

B. *Merck & Company v. Olin Mathieson Chemical Corporation*

Learned Hand's dicta were applied in *Merck*,[578] in which the product of nature doctrine shifted to an emphasis on demonstrating something novel and useful to society. This line of argument is essentially a conflation of sections 101 and 102 in determining patentable subject matter. There are some similarities with *Parke-Davis*. It was found in 1926 that pernicious anemia patients benefitted from including substantial amounts of cattle livers in their diet.[579] For the next twenty years, researchers struggled to isolate and identify the substance in the liver which created the anti-pernicious anemia effect.[580] In 1947, Merck researchers isolated a pure, red crystalline material from several fermentates of microorganisms and the livers of cattle. The isolated crystalline material possessed the same chemical structure and function to that of the fermentates. The Merck researchers labelled this pure substance as a vitamin and because it was water-soluble, it was put in the B group, and was given the number "12" since it was the twelfth member to be added.[581] Like in *Parke-Davis*, the isolated and purified vitamin B12 swiftly displaced the rudimentary extracts previously on the market.[582] The issue before the Court pertained to the product claims entitled "Vitamin B (12)-Active Composition and Process of Preparing Same."[583] Merck's patent claims were directed at the composition vitamin B12, which had a level of activity lower than the pure substance.[584] The District Court held the product claims invalid, maintaining that the

[577] See supra note 133, Conley& Makowski at 325.
[578] *Merck & Company v. Olin Mathieson Chemical Corporation 116 U.S.P.Q.* 484 (4th Circuit 1958)
[579] Ibid, 158.
[580] Ibid.
[581] Ibid, 160.
[582] Ibid, 158.
[583] Ibid, 157.
[584] The process claims of the patent were not the issue in this case, as they were withdrawn from the case. Ibid, 157.

claims covered a 'product of nature' based on evidence that the claimed B12 compound existed naturally in the livers of cattle and, thus, there was no invention.[585]

However, the Fourth Circuit reversed the decision, maintaining Merck's creation was not a product of nature and provided an appraisal of the doctrine:

> There is nothing in the language of the [Patent] Act [of 1952] which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability. All of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials.[586]

Two main points can be taken from this statement. First, whilst the Court recognized the ongoing strength of the doctrine, it undercut the power of the doctrine by interpreting the doctrine as a 'label' rather than a 'freestanding bar to patentability.'[587] Where as in *Latimer*, the product of nature doctrine was regarded as a separate restriction to patentable subject matter, the court in *Merck* construed a product of nature as a category for claimed products which are not 'new' or 'useful': "A product which is not a 'new and useful' machine, manufacture, or composition of matter' is not patentable, for it is not within the statutory definition of those things which may be patented."[588] Reading the doctrine as a mere identifier of claimed compositions that are not "new and useful" significantly redefines the boundaries of the product of nature doctrine. Secondly, in identifying the doctrine as a category label for things that are not 'new and useful,' the court narrowed the scope and meaning of "products of nature."

> The compositions of the patent here have all the novelty and utility required by the Act for patentability. They never existed before; there was nothing comparable to them. If we regard them as a purification of the active principle in natural fermentates, the natural fermentates are quite useless, while the patented compositions are of great medicinal and commercial value.…The new and useful compositions are not the same as the old, but new and useful compositions entitled to the protection of the patent.[589]

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[585] *Merck & Company, Inc., v. Olin Mathieson Chemical Corp., D.C.W.D.Va.*, 152 F.Supp. 690. 1957.
[586] Ibid, 161-162.
[587] See supra note 133, Conley & Makowski at 327.
[588] *Merck & Company v. Olin Mathieson Chemical Corporation 116 U.S.P.Q.* 484 (4th Circuit 1958) at 162.
[589] Ibid, 164.

The *Merck* decision altered the meaning of the doctrine from *Latimer*, in which the main question in considering whether a claimed substance constituted a product of nature was whether it was differentiable from the natural correspondent. If the claimed object was not distinguishable, then it was declared unpatentable irrespective of how useful or surprising its detection may be. But in *Merck*, the product of nature doctrine was tied to novelty and utility.[590] The court remarked on the novelty of the claimed product: "The new product, not just the method, had such advantageous characteristics as to replace the liver products. What was produced was in no sense an old product."[591] Also puzzling was the Fourth Circuit's emphasis on the claimed substance's utility and value to society. "The patentees have given us for the first time a medicine which can be used successfully in the treatment of pernicious anemia, a medicine which avoids the dangers and disadvantages of the liver extracts, the only remedies available prior to this invention."[592] These interpretations made by the Fourth Circuit seem to recommend that the abundant utility of a claimed product alone can trump the product of nature doctrine in determining patentable subject matter.[593] This is in contrast with the conventional view of the product of nature, which was as a primary and autonomous barrier which must be surpassed before utility, novelty and non-obviousness could be measured.

> Merck and some of the other purity cases…seem to treat the patentable subject matter standard as nothing more than a summary of the novelty, utility and non-obviousness requirements. By treating the product of nature doctrine as merely a subset of the novelty test (and by finding utility somehow relevant to whether something is a product of nature), those cases effectively hold that if a claimed invention is novel (in section 102 terms), useful and non-obvious, then it automatically comprises patentable subject matter.[594]

This case put forward an exception to the general principle that renders natural products as unpatentable: as long as the claimed product is purified or modified, it can

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[590] Novelty was relevant almost as an afterthought: the inherent unpatentability of a product of nature could be restated in terms of the impossibility of anything found in nature being new." See supra note 133, Conley & Makowski at 329.
[591] *Merck & Company v. Olin Mathieson Chemical Corporation 116 U.S.P.Q. 484 (4th Circuit 1958*) at 163.
[592] Ibid, 164.
[593] See supra note 133, Conley & Makowski at 329.
[594] Ibid, 330.

be patented. The conception that purification can singlehandedly differentiate a claimed product from a naturally occurring one ultimately took command in the subject matter case law.[595]

However, current biotechnology practice has once again adopted the traditional understanding of patentable subject matter and put aside the logic of *Merck* and those of the purification cases. This thesis argues that this is due to the slackening of the application of the product of nature doctrine, combined with the treatment of biotechnology inventions as chemical patents that has allowed gene patents to flourish for thirty years.

4.3.5. Summary of the product of nature doctrine after Chakrabarty

What can be derived from the above discussion about the status of the product of nature doctrine is the following:[596]

1. The status of patentable subject matter for an invention is a separate and distinct issue that is to be decided by the courts without reference to novelty, utility and non-obviousness. The question to be decided is whether the claimed subject matter falls within one of the categories of patentable subject matter: an invented machine, manufacture or composition of matter.
2. Product of nature is a section 101 subject matter query. If the claims are found to constitute a product of nature, then it cannot be an invented machine, manufacture or composition of matter. As a result, a product of nature should be deemed unpatentable subject matter without having to assess its novelty, utility or non-obviousness.
3. However, there have been cases where the courts have considered questions of novelty and utility in deliberating the product of nature doctrine. Some courts

[595] Ibid, 326.
[596] The following six points are based on Conley & Makowski at 377-379, supra note 133.

have dealt with the doctrine as a label for claimed inventions which are found to lack novelty, rather than as a separate and distinct bar to patentability.

4. The approach in point 3 has been renounced by the Supreme Court decision in *Chakrabarty*.
5. The distinction between a product of nature and an invented machine, manufacture and composition matter is unclear. Some guidance can be found in the Supreme Court decisions in *Funk* and *Chakrabarty* who provided examples of two types of inventions that fall on either side of the line. In *Funk*, the court maintained that the mixing of different strains of bacteria that could occur in nature but had not been detected constituted the plain discovery of a product of nature. In *Chakrabarty*, the court maintained that the introduction of new DNA into a bacterium to produce an organism that does not naturally exist is the invention of a composition of matter. This means that it is not adequate to merely combine existing biological entities without doing any more. Equally, it is satisfactory to change the genetic composition of a species into something that does not presumably occur in nature.
6. Decisions resulting from the lower courts have not been accommodating in demarcating the line between a product of nature and a patentable invention. This is because courts have been inconsistent in how they address product of nature. Some have interpreted it as a section 101 subject matter query, whilst others have dealt with it as a section 102 novelty question or section 103 non-obviousness question, or some have combined all three in assessing product of nature. Yet, what has consistently emerged is that a claimed invention derived from a living organism must be different in some significant and substantial way from its natural counterpart. In deciding this, courts have looked to both the chemical structure and the characteristics of the matter at issue. In addition, there

has been the common suggestion that purification can, in principle, operate to differentiate a claimed matter from its naturally occurring equivalent.

4.3.6. The product of nature doctrine and current biotechnology practice

Natural compounds like DNA sequences and proteins are not 'living' *per se*, but naturally occur. Until recently, under US patent law, they have been patentable provided they are new and purified from nature.[597] This is because patent claims for DNA sequences have been considered to be chemical molecules no different from other chemicals and as such, have been treated like chemical patents in which 'isolated' and 'purified' have become magic words to overcome the product of nature objection.[598] Although claims to DNA sequences may prompt the product of nature exclusion, courts have upheld patent claims for isolated and purified DNA sequences as new compositions of matter stemming from human intervention.[599]

> [B]y 1991, the Federal Circuit had acquiesced in the proposition that the words "purified and isolated" were sufficient to distinguish a claimed gene from its naturally occurring counterpart…The acceptance of this fundamental distinction by the courts and the USPTO has underlain all subsequent gene patenting.[600]

This is reflected in what is one of the most important Federal Circuit biotechnology cases in *Amgen Inc. v. Chughai Pharmaceutical Co.* ("*Amgen*").[601] Three companies battled over the patent rights to the genetic sequences which encoded the human erythropoietin (EPO) protein, which promotes the production of red blood cells. Amgen's patent claims were quite broad: "A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."[602] This means that Amgen claimed all purified and isolated genetic sequences that coded for the

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[597] *See* 66 Federal Register 1093, 2001 and *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al*. 569 U.S. 12-398 (2013)
[598] *See* Golden, J. "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System" in Emory Law Journal. Vol.50, 2001 at 128 and Conley & Makowski, supra note 133 at 381.
[599] See 66 Federal Register 1093, 2001
[600] Conley, J. "Gene Patents and the Product of Nature Doctrine" in Chicago-Kent Law Review.Vol.84, No.1, pp.109-132, 2009-2010 at 116.
[601] *Amgen Inc. v. Chughai Pharmaceutical Co., Ltd*., 927 F.2d 12000 1203 (Fed. Cir. 1991)
[602] Ibid, 1204.

EPO protein. The court held that the DNA sequences were patentable provided they were newly "purified and isolated" sequences from the original source found in nature.

> The invention as claimed in the '008 patent is not as plaintiff argues the DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon 'free to all men and reserved to none'…Rather, the invention…is the 'purified and isolated' DNA sequence encoding erythropoietin.[603]

Although the case did not mention the "product of nature" doctrine by name, it signifies the negligible part the doctrine should perform. It seems that after *Chakrabarty* and *Amgen*, a "specialized interpretation of the purification rule" had "all but mooted the product of nature doctrine."[604]

It is submitted that purity should be assessed if the claimed product is different from its naturally occurring counterpart "in kind", rather than merely "in degree." This means that purity is only a beginning for patentability if it results in a material difference between the claimed product and its natural predecessor.[605] Chisum maintains that what can be derived from *Parke-Davis* is that a claim to purity offers a review into the physical alteration; it does not offer a blanket exemption from the product of nature inspection.[606] Chisum further noted that a new utility may be indicative of a claimed substance being different "in kind" from the naturally occurring compound:

> Thus, the aspirin exception to the purity rule comes into play only if the new pure compound differs 'in kind' rather than merely 'in degree' from the old compound. A difference 'in kind' will normally be found only if the new pure compound has an entirely new utility from the old one.[607]

In 2000, the USPTO issued revised utility guidelines which demonstrated the organization's pragmatic departure from the product of nature doctrine.[608] It is maintained that the Office perceived the utility requirements to be a means to regulate

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[603] Ibid.
[604] See supra note 133, Conley & Makowski at 381.
[605] Ibid, 386.
[606] Chisum, D. Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement. New York: Matthew Bender, 1978-, Release 140, 2013 at 57.
[607] Ibid.
[608] United States Patent and Trademark Office. "Utility Examination Guidelines" in Federal Register. Vol. 66, No.4, Friday, January 5, 2001. Pp.1092-1099. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.Accessed October 18, 2012.

the abundance of gene related patents, and wanted to constrict its utility standards.[609] In addition, the focus on changing its examination procedures regarding utility is a reflection of the widely-held belief that the utility requirement is an arduous hurdle to acquiring patents in biotechnology.[610] The reason for this belief is that it has become standard routine to identify base pair sequences, but more difficult to identify the function of those sequences.[611]

The 2001 guidelines require that the patent claims include a "specific and substantial utility" which "would be considered credible by a person of ordinary skill in the art" to satisfy the 'usefulness' requirement under Section 101, which excludes 'throw-away,' 'insubstantial,' and 'non-specific' utilities.[612] This requirement will have an effect on biotech patent applications, particularly those connected to DNA like ESTs. In other words, if the claimed invention fails to perform a 'specific and substantial utility,' then it may be rejected for a patent under Section 101 and 112.

This requirement that the disclosed utility be 'specific and substantial' is aimed at resolving the issues that have come up in biotechnology. The utility requirement may be difficult to satisfy for genetic inventions because a substantial amount of research is required to be able to confirm a speculated utility. However, finding one specific, substantial and credible function may not be adequate to satisfy the utility requirement, because the substance may have more than one function. A sequence can target numerous different genes, and several DNA sequences can code for the same gene, which is why product claims for entire genetic sequences may be inappropriate in scope.

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[609] See supra note 133, Conley & Makowski at 381.
[610] See Dastgheib-Vinarov, Sara. "Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill" in Marquette Intellectual Property Law Review. Pp.143-180. (2000). Similarly, see Forman, Julian David. "Timing Perspective on the Utility Requirement in Biotechnology Patent Applications" in Albany Law Journal of Science & Technology.Vol.12. Pp. 647-682. (2001-2002).
[611] Holman, M. & S. Munzer. "Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags" in Iowa Law Review. Vol. 85, No.3, March 2000 at 758-760.
[612] United States Patent and Trademark Office. "Utility Examination Guidelines" in Federal Register. Vol. 66, No.4, Friday, January 5, 2001 at 1098. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf. Accessed October 18, 2012.

This could have blocking effects on downstream research on the substance if researchers find associated functions that are specific, substantial and credible.

Another issue related to utility is whether it is a 'predicted utility' or 'real world utility.'[613] Concerning DNA fragments, this means that the patent application must demonstrate that the fragment is useful in the 'real world.' Another instance is when a newly isolated protein is claimed to be useful, yet its function is unknown. Thus, inventions which need further investigation to determine what their 'real world' functions are deemed to lack utility. This approach is in harmony with *Brenner v. Mason*.[614] This assessment is a means of narrowing the claims in which utility is demonstrated, and of fully rejecting claims that fail to demonstrate substantial and specific utility. By enacting these new utility guidelines, the US patent office is attempting to deter claimed inventions which satisfy the 'usefulness' category merely because they could be used as landfill.

The USPTO invited comments regarding gene patents after publishing its new Interim Utility Guidelines on December 21, 1999.[615] The 2000 revised guidelines included the comments and also the USPTO's responses to those comments. Revealingly, the Office published the comments pertaining to the utility requirement and many of them went beyond the topic of utility and addressed the patentable subject matter:

> Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions.[616]

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[613] As some scholars note, it is difficult to find the 'real world' utility of miRNAs. See Bonnie W McLeod et al., 'The 'real world' utility of miRNA patents: lessons learned from expressed sequence tags,' Nature Biotechnology. Vol. 29, no. 2, February 2011 at 129.

[614] *Brenner v. Mason*, 383 U.S. 519 (1966)

[615] United States Patent and Trademark Office. "Revised Utility Examination Guidelines, Requests for Comments" in Federal Register.Vol.64, Iss. 224. Pp. 71440-71442. December 21, 1999.

[616] United States Patent and Trademark Office. "Utility Examination Guidelines" in Federal Register. Vol. 66, No.4, Friday, January 5, 2001 at 1092. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf. Accessed October 18, 2012.

However, the Office rejected this approach and responded by declaring that the isolation, purification and synthesis of DNA sequences would make them eligible for patent protection:

> A patent claim directed to an isolated and purified DNA molecule could cover, e.g., a gene excised from a natural chromosome or a synthesized DNA molecule. An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound. [617]

The terms 'isolation,' 'purification,' and 'synthesis' have been used synonymously by the USPTO in holding DNA molecules to be patentable once they are isolated, purified or synthesized from their chemical origins. This meaning is disconcerting in numerous respects, because it is based on the notion that DNA molecules are merely chemical compounds. As Arti Rai compellingly advocates: "Although DNA is, obviously, enough, a chemical compound, it is more fundamentally a carrier of information."[618] As a result, the value of DNA molecules is not just an end product in itself, but also a necessary means for further innovation.[619] Therefore, making the leap from regular chemicals to DNA sequences and the resulting products is a doubtful suggestion. It is submitted that these utility examination guidelines are somewhat incoherent because they confuse isolation with purification and synthetic biology.

4.4. Patenting Human Genetic Materials in Europe

Article 52 of the European Patent Convention[620] (EPC) is comparable to 35 U.S.C. §101, in that both address patentable subject matter. The EPC clearly states that patents are only to be granted for inventions, although it does not provide a statutory

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[617] Ibid, 1093. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.Accessed October 18, 2012.
[618] Rai, A. "Intellectual Property Rights in Biotechnology: Addressing New Technology," in Wake Forest Law Review. Vol. 34. 1999 at 836.
[619] See supra note 133, Conley and Makowski at 387.
[620] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, Munich.

definition of the concept of an invention.[621] But the mere presence of an invention is insufficient to warrant a patent, as there are other patentable requirements which include novelty, inventive step and susceptibility to industrial application.[622] In addition, the patent claim has to fulfil the written description requirements which must be clear, concise and supported by the description.[623]

The EPC includes a list of exclusion provisions in Articles 52(2) and (3) by excluding certain subject matter: (a) **discoveries,** (emphasis) (b) scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.[624] This list of exclusions, in reference to Article 52(1) of the EPC, holds that items that are abstract in nature and lacking of technical attributes fall beyond the scope of what is deemed to be an invention. This list of exclusions, in reference to Article 52(1) of the EPC, can be considered a negative definition of "invention".

4.4.1. Discoveries and Inventions

Of particular relevance to this thesis is the explicit exclusionary provision regarding discoveries as stated in Article 52 (2) (a) EPC. Some guidance can be obtained from the Examination Guidelines for the EPO on the distinction between a discovery and an invention, stating that a discovery as such is abstract and does not possess a technical nature in itself, which is why it is excluded from patent protection: "If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not

[621] There is no definition of an 'invention' in the EPC, and an search through the Travaux Préparatoires does not provide any further assistance as to the definition. See: European Patent Office. Travaux Préparatoires EPC 1973. Available at: http://www.epo.org/law-practice/legal-texts/archive/epc-1973/traveaux.html. Accessed November 8, 2013.
[622] In addition, the patent claim has to fulfil the written description requirements which must be clear, concise and supported by the description. Article 84 of the EPC states: "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."
[623] EPC Article 84: "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."
[624] EPC Article 52(2)

an invention within the meaning of Art.52(1)."[625] However, a discovery can be the source of an invention if it is practically applied in some manner, such as:

> [T]hat of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.[626]

This is also recognized in Article 52 (3) EPC which restricts the limitations on the exclusions from patentability to the extent to which the patent claims are directed at the subject matter as such.

Moreover, while a claim that comprises subject matter found in Article 52(2) EPC is not patentable, the restriction does not expand to claims which incorporate both technical and non-technical subject matter. Although discoveries 'as such' are commonly recognized as the mere identification of what already exists and are thus excluded from patent protection, human intervention or a technical application of what already exists can establish the distinction between a discovery as such and an invention.[627] This means that inventions which possess both technical and non-technical features can be patentable as long as the technical features of the invention do not lie within the excluded field of Article 52(2).[628]

4.4.2. The importance of 'technical character'

In the US, there is a distinction between inherently patentable and inherently unpatentable technical subject matter.[629] Conversely in Europe, this distinction has not tended to appear, as the EPO has long considered inherent patentability generously, as long as it is for a *technical* invention.[630] In Europe, technical subject matter refers to

[625] Guidelines for Examination in the European Patent Office, Revised edition, September 2013. Part G, Chapter II, 3.1.
[626] Ibid.
[627] Paterson, G. The European Patent System: The Law and Practice of the European Patent Convention. London: Sweet & Maxwell, 2001 at 413.
[628] Ibid.
[629] Pila, J. "Isolated Human Genes: The Patent Equivalent of a Non-Copyrightable Sound Recording" in Law Quarterly Review (forthcoming) 2014.
[630] See e. g. T 22/85, OJ 1990, 12; T 154/04, OJ 2008, 46

subject matter that is the instrumental and observable outcome of any purposive human action on the physical world.[631] This broad understanding of technical subject matter is sufficiently generous to sustain the patenting of isolated human genes and is also consistent with entrenched EPO case law and legislation in this area.[632] It is submitted that the requirement of an inventor showing an invention is 'technical' is a policy lever to encourage innovation.

A reading of Article 52(1) which defines "invention" alongside the exclusionary provisions found in Articles 52(2) and (3) by the EPO Boards of Appeal suggests that an invention is technical when a technical effect is accomplished by the invention or if technical considerations are needed to carry out the invention.[633] This means that 'technical character' is essential to the concept of 'invention' when discussing patentable subject matter. Even though European jurisprudence shows that patent protection is limited to a *technical* invention,[634] Sir Robin Jacob maintains that "technical" is a fuzzy concept: "what is 'technical' (a test often asked) is an easy question to ask but not to answer."[635] As a result, it is up to judges to draw the line between what is technical and what is not.

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[631] See G 0002/07 (Broccoli/PLANT BIOSCIENCE) of 9.12.10 and G1/08 BROCCOLI & TOMATOES/Essentially biological processes [2011] EPOR 27 (Tomatoes 1). These are two important decisions that the Enlarged Board of Appeal of the European Patent Office (EBoA) recently issued relating to patenting essentially biological processes for the production of plants and animals. The cases were combined and in December 2010, the EBoA held that methods for the traditional breeding of plants and animals did not amount to technical processes and are therefore unpatentable. The EBoA decided that claims directed at any non-microbiological processes for the sexual crossing of the whole genome of plants are considered to be 'essentially biological.'

[632] See Article 3(2) of EU Directive 98/44/EC on the Legal Protection of Biotechnology Inventions: "Biological material which is isolated from its natural environment or produce by means of a technical process may be the subject of an invention even if it previously occurred in nature" as well as HOWARD FLOREY/Relaxin [1995] E.P.O.R. 388

[633] "Article 52(1) EPC plainly expresses that patent protection is reserved for creations in the technical field. In order to be patentable, the subject-matter claimed must have which have do you need? therefore have a 'technical character' or, to be more precise, involve a 'technical teaching', i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means." Official Journal of the European Patent Office Special Edition. 4, 2007. p48.

[634] See e. g. T 22/85, OJ 1990, 12; T 154/04, OJ 2008, 46

[635] Jacob, R. "Woolly Lines in Intellectual Property Law," in Patents and Technological Progress in a Globalized World. Wolrad Prinz zu Waldeck und Pyrmont et al. (eds.) Berlin: Springer, 2009 at 787.

For instance, the EPO Board of Appeal in *Novartis*[636] noted that a patent claim for a specific plant variety as the subject matter is not patentable. However, claims in which certain plant varieties are not claimed as subject matter are not excluded from patentability. The *Novartis* decision was so influential on European practice that the decision is reflected in the EPO's Implementing Guidelines, which held that inventions regarding plants and animals were patentable as long as the *technical feasibility* was not restricted to an individual plant or animal variety.[637] This can account for the patents granted for transgenic plants, which are not claimed as plant varieties in the application.

Also, in T 154/04,[638] 'technical subject matter' was defined for the first time, which included the causal, perceivable result of a purposive human action on the physical world. In addition, this expansive understanding of a technical invention is found in the 'broccoli' and 'tomato' cases.[639] But lately, the expansive understanding of inherent patentability reinforced by the EPO was confronted before the Enlarged Board of Appeal in *Tomatoes II*.[640] The issue in this case was whether a technical plant or animal is excluded from patentability if the process used to make it is essentially biological. The problem surfaces because essentially biological processes for the production of plants or animals are excluded from patentability. Article 53(b) EPC prohibits patents for plant and animal varieties.[641] However, plants and animals are patentable provided the technical feasibility of the invention is not constrained to a plant or animal variety.[642] As stated in *Tomatoes I*, the EPO's interpretation of that exclusion includes any conventional plant breeding process which, even if it involves the use of

[636] *Novartis*, Decision T 1054/9S Technical Board of Appeal 3.3.4. 1997.
[637] EPC Rule 23c (b): "Biotechnological inventions shall also be patentable if they concern plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety."
[638] T 154/04 Duns Licensing Associates/Estimating Sales Activity [2007] EPOR 38
[639] G2/07 & G1/08 BROCCOLI & TOMATOES/Essentially biological processes [2011] EPOR 27 (Tomatoes 1).
[640] Case G 2/12 - Referral under Art 112(1)a) EPC by the Technical Board of Appeal T 1242/06 - 3.3.04 (Appl. No. 00940724.8) to the Enlarged Board of Appeal, pending under Ref. N° G 2/12 (Tomatoes II).
[641] Article 53(b) of the EPC
[642] See Directive 98/44/EC of the European Parliament and of the Council of July 1998. In fact, the EPO began granting patents for plants and animals in the beginning of the 19909s.

technical means, is distinguished by the fact that the traits of the plant or animal resulting from it are governed by underlying natural forces and not by the technical process itself.[643]

4.4.3. *Ordre Public* and Morality

Objections to increasing fields of patentable subject matter may be linked to arguments stemming from morality, particularly with respect to patenting inventions derived from hESCs. In the US, arguments based on morality have failed to gain any ground. There is the opinion that, in the US, the courts have declined to make moral judgements in patent cases involving innovative technologies.[644] In regards to the patent office, the courts have argued that patent examiners' influence should be limited to their technical expertise in assessing an invention's patentability requirements.[645] As a result, through case law, issues of morality and ethics are not within the realm of patent offices but left to Congress.[646]

However, in Europe, there is greater room for morality arguments to be heard in an official setting, given the morality clause in Article 53 of the EPC and Article 6.1 of the Directive 98/44/EC.[647] Moral concepts in patent law are found in the Strasbourg Convention (1963), which influenced the EPC (1973).[648] Article 53(a) of the EPC excludes patent protection for any invention "the publication or exploitation of which is contrary to morality or *ordre public.*" Article 6 of Directive 98/44/EC excludes some

[643] G 0001/08 (Tomatoes/STATE OF ISRAEL) of 9.12.2010
[644] Whitehill, J. "Patenting Human Embryonic Stem Cells: What is so Immoral?" in Brooklyn Journal of International Law. Vol. 34, Issue 3, pp. (2009) at 1075.
[645] Ibid at 1050.
[646] Ibid at 1075.
[647] According to Article 53(a) of the EPC, European patents will not be granted for innovations whose exploitation will be contrary to the *ordre public* or morality. Regrettably, neither the EPC nor the Biotech directive provides guidance on how to interpret '*ordre public* and morality', which is problematic since there are various moral views in the EU.
[648] The 1977 Guidelines for Examination by the EPO explain the policy basis of how Article 53 (a) should be interpreted, which is "to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable." The Guidelines for Examination of the European Patent Office (2007), Part C, Ch. IV, s.4.

inventions on moral and ethical grounds.[649] Whilst Article 6(1) contains the morality clause which states that inventions cannot be patented if their commercial exploitation is contrary to the *ordre public* or morality, Article 6(2) provides a list of unpatentable inventions. These provisions are in line with Article 27.2 of the TRIPS Agreement, which allows Member States to prohibit the commercial exploitation of inventions that is "necessary to protect *ordre public* or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment." This means Member States would be required to show that commercial exploitation of the invention would be contrary to *ordre public* or morality. Although the provision has been applied in regional legislation, such as Article 53(a) in the EPC and underlined in Article 6(1) in Directive 98/44/EC, the exception has not sanctioned a common exclusion of the patentability of living organisms.

A. Article 53(a) EPC

Article 53(a) of the EPC is relevant when discussing the patentability of DNA sequences and biotechnology inventions. The article denies patents for inventions whose commercial exploitation would be contrary to the *ordre public* or morality.[650] The concept has been developed in paltry case law as "the culture inherent in European society and civilisation."[651] However, Article 53(a) of the EPC is not a suitable instrument for establishing exceptions to patentability. First, it is difficult to determine

[649]Article 6 of Directive 98/44/EC:

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

[650] Article 53(a) of the EPC
[651] The Nuffield Council on Bioethics. The Ethics of Patenting DNA. London: Nuffield Council, 2002 at 34.

what the "public in general" believes is right and wrong, who the group includes/excludes, and how to measure the general consensus, if there is one. The Guidelines do not address this question. It is suggested that the lack of guidance and clarity from the Guidelines is an indication that "the EPO Guidelines support the view that it was never, and is not now, the intention of the drafters of the EPC to permit European institutions to determine patentability using moral criteria on anything more than a cursory basis. That the Guidelines are unclear is testament to the fact that there exists no single European concept of morality."[652]

B. Objections to morality considerations in patent law

The morality/*ordre public* consideration as an exclusion of patentability has been argued by some scholars as inappropriate in a European Directive.[653] This can be particularly problematic in terms of implementation given that each legal system within an EU Member State may have a different opinion of what constitutes morality. This is not aided by the presence of a legal gap in common assessment of this undefined legal term. As there is no single European concept of morality, it may be helpful if the EPO Member States develop a stance on the role of morality within the patent system in order to develop effective harmonized legislation. The revised 2000 EPC shows that exceptions to patentability are determined not simply on substantive patentability criteria, but also on ethical principles and social policy, which add even more confusion to biotech patent applications.[654] Both the 2000 EPC and EPO cases indicate that morality should be handled by European institutions, which must be worked out practically in national legislation. Unless individual Member States do that, the implications of EPO jurisprudence will continue to dictate what and potentially cause more confusion. Also, because there is no criterion for assessing *ordre public* and

[652]Mills, O. Biotechnological Inventions: Moral Restraints and Patent Law. England: Ashgate Publishing Limited, 2010 at 56.
[653] Chemtob-Concé M. C. et Gallochat A., Le Brevetabilité des inventions technologiques appliquées à l'homme. (Ed. Lavoisier, Tech & Doc, Paris 2ème ed., 2004).
[654]See supra note 652, Mills, O. at 79.

morality, divergent approaches to biotech inventions amongst member states could continue.

Stephen Crespi proposes that there needs to be an "overwhelming consensus that a particular invention is immoral" before a patent should be revoked: "[i]t should not be invoked by patent authorities merely on the basis that some section of society condemns the activity as immoral."[655] In a similar vein, Lord Hoffman believes that ethics and morals should in some way be incorporated into the patent system, but only for activities that are especially repulsive, like creating human monsters, and that the exclusions in the Biotech Directive are a good example of excludable patentable subject matter for matters relating to ethics and morality. Lord Hoffman states:

> The only reason I can think of on ethical grounds for not granting a patent is that what you're trying to patent is an activity which is so repulsive that the state ought not to give its support to it by property or monopoly. But there are very few activities that fall into that category.[656]

In fact, a reading of case law reveals there are already issues with biotech inventions meeting the substantive criteria of patentability, and morality creates further difficulties if it is introduced as another requirement for patentability.[657] Even if there is a moral policy, it is questionable whether it can clearly set out its goals and whether they can be achieved through the patent system. If these questions can be answered, there is the further necessary consideration of balancing the economic and moral policies equally.[658] Unfortunately, there is no legal test in respect to assessing what counts as offensive to morality. Thus, it is up to the courts and the patent offices to decide what type of invention would offend public morality. The EPO has attempted to shed more light on the concept by suggesting that the test be based on whether the

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[655]Crespi, S. "An Analysis of Moral Issues Affecting Patenting Inventions in the Life Sciences: A European Perspective" in Science and Engineering Ethics (2000) Vol. 6 at 163.
[656] Interview with Lord Hoffman, March 21, 2012.
[657] See supra note 652, Mills, O. at 11: Patent law "is not designed, or, indeed, appropriate to regulate biotechnology and any attempt to do so, in particular by denying patents on the basis of morality, is misplaced as such a solution does not match the nature of the problem...There is little doubt that economic policy lies at the heart of, and has been advanced by means, is the comma here or after of? of patent law."
[658]Ibid.

public deems such an activity as so 'abhorrent' that granting a patent on said activity would be 'inconceivable'.[659]

Moreover, some patent professionals are doubtful of the correctness of inserting ethical considerations into patent law, which is mainly focused on the evaluation of novelty, inventive step and utility/industrial applicability. Patent law "is not a suitable medium for the raising of philosophical objections to the patenting of living organisms and genetic inventions."[660] Rather, there is the view that any questions of morality should be handled by the national legislators rather than the patent system.[661]

> I don't think there is a place for the moral aspect here. It should be outside patent law, definitely. I think there's an ongoing debate, as there always is in terms of national and international ethical issues which you can bring philosophers and scientists in [to], and they will discuss that. Government[s] themselves will or will not approve those components. I don't think you need to bring it into a case of patents because then it becomes very confusing as to what exactly are the issues. What you should try to address is: is it moral? Is it ethical? Or is it a business decision? So I would prefer that those issues are actually dealt with at a national level rather than a patent level.[662]

C. Greenpeace v. Plant Genetic Systems NV

In *Greenpeace v. Plant Genetic Systems NV,*[663] Greenpeace objected to an application claiming herbicide-resistant transgenic plants, arguing that the creation of the engineered plant was immoral and contravened Article 53(a) of the EPC. Greenpeace further elaborated that it was immoral to claim ownership of plants, which were the common heritage of mankind. At the European Patent Office Boards of Appeal, the panel sided with the examination's view that it was not the appropriate forum for discussing the "pros and contras" of the genetic engineering of plants.[664]

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[659] Clark, Smyth and Hall. Intellectual Property Law in Ireland 3rd edition. Dublin, Tottel Publishing at 71.
[660] Crespi, S. "Ethico-Legal Issues in Biomedicine Patenting: A Patent Professional Viewpoint," in Science and Engineering Ethics. Vol. 11, Iss.1, pp. 117-136, 2005 at 119.
[661] Chambers, J. "Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy," in The George Washington International Law Review. Vol. 34 (2002-2003) at 243.
[662] Interview with Pete Coffey, February 29, 2012.
[663] *Decision T 356/93* (OJ EPO 8/1955 545)
[664] Ibid at 4.

D. Harvard/Onco-Mouse T 19/90

Likewise, in Harvard/Onco-Mouse T 19/90,[665] the Examining Division at first instance of the EPO did not apply Article 53(a) to the case, as the Division reasoned that patent law was not the right legislative tool for resolving such problems, although it did list some ethical issues related to patenting higher organisms. At the Technical Board of Appeal, however, the board held that in that particular case, there were compelling reasons to assess the ethical and moral questions in relation to patent eligibility, and remitted the case back to the Examining Division, which was required to carry out the balancing test.[666]

This thesis maintains that the granting of an exclusive right to an invention for twenty years is mostly ethically neutral. This is because a patent is representative of a state stamp of approval on an invention, which signifies that the invention is worthy of an exclusive right. It is up to human action whether a patent is enforced or not. A patent enables the patent holder to exclude others from infringing on the patent but if infringement does occur, there are several options available to choose from. One option is for the patent holder to sue the alleged infringer. Second, the patent holder can offer the alleged infringer a license for the patented invention. And third, if the infringement is not serious or worth the cost of litigation, the patent holder can ignore the infringement. It can be argued, then, that patenting itself as an action is not inherently right or wrong, as "[t]he grant of a patent is an event from which nothing follows consequentially and inevitably in terms of human action."[667] Therefore, patenting, as such, is ethically neutral. However, what can be ethically contentious are particular inventions, for instance, those directed or derived from hESCs.

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[665] *Harvard/Onco-Mouse* T 19/90 Examining Division (14 July 1989) [1990] EPOR 4
[666] Ibid.
[667] Crespi, S. "Biotechnology Patenting: The Wicked Animal Must Defend Itself," in European Intellectual Property Review. Vol. 17, Iss.9, 1995 at 437.

4.4.4. Directive 98/44/EC

European policy makers acknowledged that the products and processes of modern biotechnology are not as well adapted as to the traditional principles of patentability and issued the Directive 98/44/EC for Biotechnological Inventions (1998), which required the EU Member States to adopt and harmonize their legislation pertaining to biotechnology inventions.[668] Article 1 of the Directive includes the broad requirement to protect biotechnological inventions, although there is no definition of a biotechnological invention in Directive 98/44/EC.[669] However, the Administrative Council of the EPO provides the following definition:

> "Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.[670]

This definition includes DNA-derived inventions like isolated DNA sequences and the encoding gene.[671] However, Article 52(2) (a) EPC states that discoveries are not patentable. This clear exclusion of discoveries may seem to be at odds with the enclosure of biological materials within the capacity of patentable inventions in Directive 98/44/EC, which illustrates the complexities of the boundaries between

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[668] The EPC was not created by the EU. Thus, EU directives do not have a binding effect on the EPO. But in 1999, the Administrative Council of the EPO decided to include provisions of the EU Biotech Directive in their Implementing Regulations by creating a new Chapter VI "Biotechnological Inventions" in Part II of the EPC Implementing Regulations. See Official Journal of the EPO, Administrative Council of June 16, 1999, amending the Implementing Regulations to the European Patent Convention, available at: http://archive.epo.org/epo/pubs/oj99/7_99/7_4379.pdf. Accessed May 5, 2014.

[669] The EPO Examination Guidelines provide the following definition:
"'Biotechnological' inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. 'Biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system." Guidelines for Examination in the European Patent Office, Revised edition, September 2013. Part G, 5.1.

[670] See Official Journal of the EPO, Administrative Council of June 16, 1999, amending the Implementing Regulations to the European Patent Convention, available at: http://archive.epo.org/epo/pubs/oj99/7_99/7_4379.pdf. Accessed May 5, 2014. Rule 23b.

[671] Rule 23c maintains that inventions which encompass biological materials like DNA, microbiological processes, plants and animals are patentable. However, the claimed invention is patentable only if the technical feasibility of the invention is not confined to a certain plant or animal variety. See Official Journal of the EPO, Administrative Council of June 16, 1999, amending the Implementing Regulations to the European Patent Convention, available at: http://archive.epo.org/epo/pubs/oj99/7_99/7_4379.pdf. Accessed May 5, 2014. Rule 23b.

discoveries (which are not patentable) and biotechnological inventions (which are protected).

Moreover, certain inventions are excluded from patent protection because they would transgress the EPC's ban on patents whose commercial exploitation is contrary to the *ordre public* or morality:

- Processes for cloning human beings
- Processes for modifying the germ line genetic identity of human beings
- Uses of human embryos for industrial or commercial purposes
- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.[672]

4.4.5. Isolation and purification: sidestepping the product of nature objection

In the EPO, an isolated and or purified DNA sequence is not patentable without disclosing a function, which is in line with industrial application requirements. Since the 1980s, the techniques of isolation and purification have become increasingly accepted as a justification for removing a DNA sequence from the unpatentable realm of either a "product of nature" in the US or a "discovery" in the EPO into the ambit of patentable subject matter.[673] The Preamble to Directive 98/44/EC indicated that research regarding the isolation of elements of the human body that are deemed valuable to the production of medicine should be promoted by the patent system.

Article 5(1) of Directive 98/44/EC states: "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions."[674] This means a mere DNA sequence without suggestion of a function is

[672] Article 6 of Directive 98/44/EC
[673] See supra note 133, Conley and Makowski.
[674] Article 5(1) of Directive 98/44/EC

deemed not to carry any technical information and therefore is not patentable. Genes clearly constitute a part of the human body and this exclusion, at first glance, may imply that genes are unpatentable in the EPO. However, Article 5(2) affirms that naturally occurring substances are patentable subject matter provided they are isolated from their natural environment.[675]

This provision is comparable to the 'human intervention' element constructed by the US Supreme Court in *Chakrabarty*, and the UK Court in *Amgen* when it determined that gene sequences are only required to be 'purified and isolated' to be patentable. Article 5(3) of Directive 98/44/EC emphasizes that the importance of the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.[676] The inclusion of this clause is likely to be of significance for assessing new techniques and products in biotechnology, such as recognizing cDNA as being essential for developing diagnostic therapies.

According to the EPO, biotechnological inventions are patentable under the EPC even if they already occur in nature, provided they are isolated from their natural environment. This also applies to the human body, where an element like a gene sequence that is isolated from the body using a technical process can be patented. This reaffirms Rule 29(1) and (2) of the EPC.

4.4.6. Limitations of Article 5(2) of Directive 98/44/EC

In respect to the human body, Article 5(2) of Directive 98/44/EC is inadequate and outdated given the current state of biomedical research. There are three reasons why Article 5 is no longer relevant. First, the isolation and purification technique has become a standard research tool. Unless there is a new and better isolation technique that is developed, products which are isolated and purified should not be perceived as new and inventive. Moreover, the concept of isolation and purification is inadequate. It is a legal

[675] Article 5(2) of Directive 98/44/EC
[676] Article 5(3) of Directive 98/44/EC

term, artificially constructed to draw a line between what is/not patentable pertaining to human genetic information. However, the concept of isolation has been adopted by the EPO and USPTO with a legal value. In the US, this has taken place through case law. In the EU, this development was through the enactment of Directive 98/44/EC. It is submitted that principles such as 'isolation,' 'purification' and 'modification' of naturally occurring substances are emphasized in determining whether the claimed product or process constitutes an 'invention,' ridding decision makers the task of making decisions based on policy.

4.5. Patenting isolated genes in the EPO and US

4.5.1. *AMP v. Myriad* (2013)

In the United States, isolated genes are no longer considered inventions after *Myriad* because they are 'products of nature.'[677] The Supreme Court decided whether Myriad's claimed isolated DNA sequences were products of nature using *Chakrabarty*'s "markedly different" test. The 'markedly different' test is now being utilized in assessing whether there is a difference in the information between the claimed sequence and the naturally occurring one. The Supreme Court maintained that Myriad's BRCA sequences were not 'markedly different' from the naturally occurring sequences. Unfortunately, the Supreme Court failed to provide further clarification of what the

[677] *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al*. 569 U.S. 12-398 (2013) Ten amicus briefs were filed from groups with an economic stake in biotechnology patents. These groups included Genentech, the Pharmaceutical Manufacturers Association, the New York Patent Law Association, and the American Society for Microbiology, the American Patent Law Association, the American Bar Association, James Watson, Eric Lander and James Watson. James Watson, co-discoverer of the double helix structure of deoxyribonucleic acid, maintains that human genes should not be patented, emphasizing the informational nature of a gene and that it is a product of nature. See: Brief of James D. Watson, as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 4. The American Bar Association submitted that isolated DNA compounds should be held eligible for patenting. Otherwise, it would disrupt decades of reliance on the Court's precedent and the USPTO's practice in allowing such claims. See: Brief of the American Bar Association as Amicus Curiae in Support of Respondents. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 4. Eric Lander, a geneticist and molecular biologist, maintained that in the scientific community, it is a well-accepted fact that isolated DNA fragments of the human genome (including isolated DNA fragments of the BRCA1 and BRCA2 genes) are routinely discovered in the human body and are thus, products of nature and not eligible patent subject matter. See Brief for Amicus Curiae Eric S. Lander in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013 at 29.

notion of 'markedly different characteristics' encompasses, and how these differ from characteristics that are not markedly different. It is uncertain whether the markedly different test is based on a different chemical structure or a greater concentration, or whether the utility of the claimed function needs to be entirely different from the natural function.

The reason why the case is confusing is because prior to this case, the product of nature doctrine had been circumvented by novelty and utility of the invention through isolation and purification (*Parke-Davis*). In the Federal Circuit, the court applied the *Parke-Davis* line of argument to the tools for isolation and purification of genes in determining whether they were new and useful.[678] Novelty was determined by considering the chemical differences between the naturally occurring gene and the claimed isolated gene, rather than the informational content. For the utility requirement, the court considered the isolated sequences useful in developing a diagnostic test for BRCA1 and BRCA2 genes. However, this argument was not adopted by the Supreme Court, which instead has returned to an 'old school' product of nature interpretation as found in *Latimer* and *Funk Bros* by holding that the claimed isolated genes are not markedly different enough to qualify as an invention, which is the first of its kind since the industry expected the acts of isolation and purification to overcome the product of nature doctrine.

It is submitted that the observance of isolated genomic sequences as products of nature is a result of the emphasis on their informational qualities. As a result, there seems to be a shift in perception of DNA, as it is no longer considered to be a mere chemical molecule no different from other chemicals. It can be argued that information inherent in DNA represents a law of nature, although there are still disagreements over

[678] *Association for Molecular Pathology v United States Patent and Trademark Office et al* (2011)

how DNA should be understood.[679] But for now, it seems in the US that the function of a claimed DNA sequence (and not merely its chemical structure) needs to be markedly different, or possess a completely new genetic identity from any that naturally exists in the human body.

The day before the US Supreme Court issued its judgement, Senator Leahy wrote to Francis Collins, Director of the NIH to enforce its march-in rights found in section 203 of the Bayh-Dole Act of 1980.[680] Leahy emphasized that a part of Myriad's research was federally funded and, therefore, was required to offer licenses to a "responsible applicant or applicants."[681] If Myriad remains unwilling to license its cDNA patents, then the NIH can grant the license. Myriad's sole recourse would be to litigate in the Court of Claims. Leahy wrote that the "health needs of the public are not reasonably satisfied by the patentee…because many women are not able to afford the testing provided by Myriad."[682] Myriad's continued refusal to license its patents and pursuance of law suits against its competitors may have been the motivation for Leahy's letter to Collins. Interestingly, the day after the Supreme Court invalidated Myriad's

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[679] Interview with Trevor Cook, April 20, 2012. Trevor Cook states:
"Everything holds information in a way. It may mean that perhaps the basis for the inventive step analysis is different. It may mean that you need to claim things functionally. But I don't see that just because something has an information-rich quality that you should have some sort of miraculous effect in and of itself. The early days of DNA patenting, like EPO, or the HGS type of patenting, people are not actually concerned with protecting the DNA itself even though they claim the DNA. They claim the DNA because of the information inherent to those claims as a way of seeking to monopolize the proteins to which those sequences code it. Thus, you have DNA claims in the EPO patent, DNA claims in the HGS patent. But the interest was not in the DNA, the interest was that it was a good way of claiming the protein itself, or claiming the protein when produced by recombinant DNA technologies. Because the protein itself was already isolated and thus lacked novelty." With the quotes I think you need to go over them and add missing words in square brackets so the meaning is clearer

[680] 35 USC § 203 (a)(3)"With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."

[681] 35 USC § 203(a)

[682] Leahy, P. Letter to Dr. Francis Collins. July 12, 2013. http://www.patents4life.com/wp-content/uploads/2013/07/LeahyGeneTesting.pdf. Accessed October 2, 2013.

BRCA1 and BRCA2 gene patents, the NIH offered BRCA1 and BRCA2 testing on its website.[683]

4.5.2. Impact of *AMP v. Myriad*

In the immediate aftermath of the decision, there was a plethora of opinions on the decision and the practical impact it would have on innovation in the field of biotechnology. [684] Whilst it can be argued that the ruling means there is greater liberty for research due to the constraint on patentability, others perceive a decrease in incentives for investing in tentative and expensive research. There does seem to be some agitation experienced by members of the US biotechnology industry. Expectations that the ruling will be applied to other molecules and organisms have left some clients in biotechnology with feelings of uncertainty. "'It's a mess…We had a lot of clients saying, 'What are we going to do?'"[685]

Meanwhile, Trevor Cook, a former partner at Bird & Bird in London, viewed the decision as damaging to the integrity of the patent system.

> I do think it most unfortunate that yet again the US Supreme Court is looking at issues from the point of view of patent eligibility, which has a tendency to result in arbitrary, policy based decisions which undermine the predictability provided by accepted and well understood concepts in patent law such as novelty, obviousness and sufficiency. In this particular case this has resulted in the frustration of the settled expectations of users of the patent system and serves to cast doubt on the patent eligibility of other useful compositions that occur naturally and that have long been considered to be patentable, such as novel antibiotics produced by certain microorganisms.[686]

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[683] National Institute of Health Genetic Testing Registry. GTR News: Supreme Court Gene Patent Decision Immediately Impacts GTR. June 17, 2013. http://www.ncbi.nlm.nih.gov/projects/gtr/gtr_news.cgi?id=8. Accessed July 18, 2013.

[684] Had the US Supreme Court upheld Myriad Genetics' patents on BRCA1 and BRAC2 genes, the company would have continued to hold exclusive rights to the genes even if other companies develop improved tests. Greenpeace criticizes Myriad Genetics for prohibiting third parties from performing other tests associated with the BRAC1 and BRAC2 genes. The BRCA1 and BRCA2 tests Myriad created do not cover newly-found mutations, and approximately 36% of diseases associated with BRCA are affected by the mutation, which the Myriad tests do not detect. In addition, because Myriad prohibits all others from performing any type of testing, health centres are not able to use this enhanced test due to fears of patent infringement. As a result, owners of gene patents may prohibit others from creating new and improved tests. See: Greenpeace, The True Cost of Gene Patents: The Economic and Social Consequences of Patenting Genes and Living Organisms. March 2004. www.greenpeace.de. Accessed April 7, 2013.

[685] Ledford, Heidi. "Myriad Ruling Causes Confusion: Change to Gene Patents Leaves US Biotech in a Lather" in Nature. 498, 281–282 (June 20 2013) www.nature.com. Accessed June 21, 2013.

[686] Interview with Trevor Cook, April 30, 2012.

Practically speaking, the case will immediately affect only the businesses who offer diagnostic testing for which there is already a patent on a particular gene that is linked to a disease. Most respondents engaged in the area of genetic testing viewed the case as having only a modest impact on their operations.[687] On the other hand, companies who possess existing patents on isolated DNA sequences may encounter some problems. As a result of the decision, there are likely thousands of patents covering isolated DNA sequences that may be no longer valid. This can create certain risks for individuals and companies with an interest in these patents. For future innovators in the area, there may be a tendency to keep information found on valuable DNA sequences a secret, as sharing the information with the public may be detrimental for their commercial potential. In the past, when a gene was newly discovered, it could be submitted to a public database like GenBank. Since isolated DNA could be patented, sharing such information was not detrimental to one's commercial interests. As such, companies may opt to keep newly identified genes secret until their commercial prospects can be determined, in order for patent applications to be filed for all commercially workable and artificially modified forms of the DNA.

Confusion remains as to the distinction the Supreme Court makes between isolated DNA and cDNA in regards to patent eligibility. Although cDNA is synthetically produced, it contains identical sequences to naturally occurring DNA. While the court seems to espouse the condition that a technical product must possess physical characteristics chosen by human effort, the holding that cDNA molecules are eligible for patent protection undercuts that rationale, because "the properties of an isolated DNA sequence are no less attributable to the technician responsible for isolating the sequence than those of cDNA."[688] The Supreme Court appears to

[687] The various views on the impact of limiting patent protection on isolated genes on future innovation will be discussed in chapter 5.
[688] Pila, J. "Isolated Human Genes: The Patent Equivalent of a Non-Copyrightable Sound Recording" in Law Quarterly Review (forthcoming) 2014 at 4.

acknowledge this point,[689] but insisted that cDNA is patentable subject matter.[690] As a result, there is no clear-cut distinction between what constitutes inherently patentable and inherently unpatentable technical subject matter.[691] Even though isolated DNA is no longer eligible for data patentability, the court is continuing the gene patent saga, because cDNA continues to be patentable, and as a result, there will be a shift in focus and efforts towards getting the cDNA patented, even though the product claims of cDNA are considered problematic. Thus, the problems with patenting isolated DNA persist with patenting cDNA, whilst industry continues to be able to potentially exclude others from an economically viable piece of the human genome in order to commercialize on its functions.

Even though the US Supreme Court held that cDNA is patent eligible, in terms of practice, the effects of the case to industry will likely result in a small change in tactic in patenting new DNA-derived invention as isolated DNA sequence claims are just one of several types of claims that can be in a patent application. Although innovators must now avoid claiming DNA which contains a naturally occurring sequence, only a minor portion of patents will be absolutely lost. The usefulness of isolated DNA is greatly narrow in the context of biotechnology, and its exclusion from patent eligibility should not thwart other areas of patenting. Myriad itself announced after the Supreme Court decision that its patent portfolio contained around 500 other claims on the BRCA test that was untouched by the decision. Moreover, given that the Court's holding that cDNA is patentable subject matter simply maintained the status quo, it is tricky to determine any real effect from this specific decision.

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[689] *AMP v. Myriad* (2013) at 17.
[690] Ibid. "[T]he lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a 'product of nature' and is patent eligible under § 101."
[691] Pila, J. "Isolated Human Genes: The Patent Equivalent of a Non-Copyrightable Sound Recording" in Law Quarterly Review (forthcoming) 2014 at 5.

A. Response from the USPTO

The day following the decision in *Myriad*, the USPTO issued a statement with regards to changes to its examination policy pertaining to nucleic acid-related product claims:

> As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated. Examiners should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C.§101.[692]

Most recently in March 2014, Deputy Commissioner Hirschfield published a guidance memorandum pertaining to subject matter eligibility involving laws of nature, natural phenomena and natural products in view of recent Supreme Court decisions including *Myriad*.[693] The Guidance instructs new procedures to address legal changes relating to eligible subject matter under 35 U.S.C. § 101. According to the guidelines, a natural product is not patentable. There is a set of questions the guidelines ask to find out whether something is patentable. The first is whether the claim is directed at one of the four statutory categories: process, machine, manufacture or composition of matter. If the answer is yes, then the second question is whether the claim involves any judicial exceptions: abstract ideas, laws of nature/natural principles, natural phenomena, and natural products. If the answer is yes, then one proceeds to the third question: whether the claim as a whole recites something significantly different from the judicial exceptions. Therefore, based on the guidelines, if a claim involves a judicial exception like a natural product, then it can only qualify as eligible subject matter if the claim as a whole recites something that is significantly different from the judicial exception.[694]

Commissioner for Patents, "Memorandum" United States Patent and Trademark Office, June 13, 2013.

[693] United States Patent and Trademark Office. Memorandum: Guidance For Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena. March 4, 2014. The cases include: *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S., 133 S. Ct. 2107, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S., 132 S. Ct. 1289, 101 USPQ2d 1961 (2012).

[694] United States Patent and Trademark Office. Memorandum: Guidance For Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena. March 4, 2014 at 3.

The Guidelines elaborated that 'significantly different' can be demonstrated in multiple ways:

> (1) The claim includes elements or steps in addition to the judicial exception that practically apply the judicial exception in a significant way, i.e. by adding significantly more to the judicial exception
>
> (2) The claim includes features or steps that demonstrate that the claimed subject matter is markedly different from that which exists in nature (and therefore not a judicial exception)
>
> (3) Such differences can be assessed by considering factors that either weigh toward eligibility (which are significantly different) or those that that weigh against eligibility (not significantly different)[695]

Factors that weigh against eligibility include claims reciting "something that appears to be a natural product that is not markedly different in structure from naturally occurring products"[696] at a "high level of generality,"[697] include additional elements/steps that are "well-understood, purely conventional or routine"[698] or are "insignificant extra solution activity,"[699] or "that amount to nothing more than a mere field of use."[700]

The guidelines highlight that even if there initially appears to be a difference between a recited product and the naturally occurring product, the identified differences need to rise to the level of a marked difference in structure:

> Not all differences rise to the level of marked differences, e.g., merely isolating a nucleic acid changes its structure (by breaking bonds) but that change does not create a marked difference in structure between the nucleic acid and its naturally occurring counterpart. Myriad, 133 S. Ct. at 2116-2118 (even though an isolated gene is a non-naturally occurring fragment of chromosomal DNA, it is not markedly different from the chromosomal DNA because its nucleotide sequence

[695] Ibid.
[696] Ibid at 4.
[697] Ibid.
[698] Ibid at 5.
[699] Ibid.
[700] Ibid.

> has not been changed). Instead, a marked difference must be a significant difference, i.e., more than an incidental or trivial difference.[701]

Factors weighing towards eligibility include claims that "include a particular machine or transformation of a particular article," or "add a feature that is more than well-understood, purely conventional or routine in the relevant field."[702] In sample cases provided in the guidelines, if there is a marked difference between the claim and the naturally occurring product, it does not matter that the process for creating the change is routine. This point is particularly relevant for cDNA product claims. The guidance provides the following example: "cDNA having a nucleotide sequence that is markedly different from naturally occurring DNA is eligible subject matter, even though the process of making cDNA is routine in the biotechnology art."[703] What seems to be essential is for the claims to be drafted in a way that emphasizes the difference between the claimed invention and that which naturally exists.

B. Response to guidelines

There has been criticism directed at the scope of the guidelines. First, that the USPTO's reading of the *Myriad* decision has been incorrectly applied to all natural products:

> I think horrified is a minor adjective I would use when I read those USPTO guidelines. It occurred to me that I now know how the USPTO is getting rid of its backlog, because that is pretty much everything we do at Hopkins. I don't know how the USPTO got from 'we are not going to patent a particular gene' to 'we are not going to patent any natural product.' I don't know how they went down that slope.[704]

Another grievance was a lack of discussion on the factors that should be considered in deciding whether something is eligible subject matter. In addition, although it may be recognized that the requirements for patent eligibility are made to be flexible, there is criticism directed at the multi-step examination stated in the guidance as necessary to ascertain something as patent eligible. Finally, there remains confusion

[701] Ibid.
[702] Ibid at 4.
[703] Ibid at 5.
[704] Quote from Joseph Contrera, Patent counsel, John Hopkins Technology Transfer in "IP Clinic: How is Myriad Affecting IP Practitioners?" in Managing Intellectual Property. April 2014, Issue 238 at 83.

over the 'markedly different' test. "According to the guidelines, if it is not a natural product you look at whether it is 'markedly different' from the natural product. That's the test. Of course that is clear as mud and will be defined over time in case law."[705] Therefore, despite the USPTO guidelines published after *Myriad*, there remain many more questions to be answered.

C. Continued litigation

After the US Supreme Court decision, Myriad Genetics initiated two lawsuits against Ambry Genetics Corporation (filed July 9, 2013) and Gene by Gene Limited (filed July 10, 2013). These two entities launched their own BRCA1 and BRCA2 diagnostic tests after the Supreme Court decision. Myriad maintained that there were other patent claims in its portfolio that were unaffected by the decision, and which it could assert against its rivals for the diagnostics tests, particularly its cDNA patents. Myriad sought a preliminary injunction against both Ambry and Gene by Gene, but both organizations countered the allegations by filing antitrust counterclaims against Myriad on the grounds that it had exhausted its patents via improper means to monopolize the BRCA diagnostic market. The cases were consolidated. However on February 6, 2014, Gene by Gene settled with Myriad.[706]

On March 10, 2014, Judge Robert Shelby of the Federal District Court in Salt Lake City denied Myriad Genetics' request for a preliminary injunction in its lawsuit against Ambry Genetics Corporation.[707] Ambry began offering its own breast cancer diagnostic tests for BRCA1 and BRCA2 after the Supreme Court decision in June 2013

[705] Quote from Sherry Knowles, Principal, Knowles Intellectual Property Strategies in "IP Clinic: How is Myriad Affecting IP Practitioners?" in Managing Intellectual Property. April 2014, Issue 238 at 82.
[706] "Gene by Gene Settles Lawsuit Over BRCA Patents" in Genetic Engineering and Biotechnology News. www.genengnews.com. Accessed February 8, 2014.
[707] University of Utah Research Foundation et al. vs. Ambry Genetics Corporation. United States District Court of Utah, Case No.2:13-CV-00640-RJS. March 10, 2014.

at a price of $2,200 compared to Myriad's $4000.[708] Judge Shelby acknowledged that Myriad would likely suffer irreparable harm without the injunction because it would not be able to maintain the price of its tests, but ruled that it had not established that it was likely to succeed on the merits of its argument, which is one of the legal conditions for being granted a preliminary injunction.

Recently, the *Myriad* decision was applied to a case involving a claim for mammalian products resulting from a somatic cloning method. The US Court of Appeals for the Federal Circuit (CAFC) declared mammals produced using the method which created Dolly the sheep not patent eligible.[709] The appeals court argued that while the somatic method of cloning mammals is patent eligible[710], the products of such processes are not. The patent at issue before the court was US Patent Application No. 09/225,233, or the '233 application, which claimed products of Campbell's and Wilmut's cloning method, including cattle, sheep, pigs and goats. However, the CAFC ruled that although the claimed clones may be called a composition of matter or a manufacture, they were not eligible for patenting because they comprised natural phenomena and did not possess any markedly different characteristics from those found in nature. Therefore, the products of the cloning method were deemed ineligible for patent protection because Roslin did not create or alter the genetic information for the claimed clones. Referring to *Myriad*,[711] Judge Timothy Dyk stated:

> Here, as in *Myriad*, Roslin 'did not create or alter any of the genetic information' of its claimed clones, '[n]or did [Roslin] create or alter the genetic structure of [the] DNA' used to make the clones. Instead, Roslin's chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.[712]

[708] Pollack, A. "Patentholder on Breast Cancer Tests Denied Injunction in Lawsuit," in New York Times. March 10, 2014.
[709] *In re Roslin Institute (Edinburgh)* No. 2013-1407 (Fed. Cir. May 8, 2014)
[710] Keith Henry Stockman Campbell and Ian Wilmut obtained U.S. Patent No. 7,514,258 for the somatic cell nuclear transfer cloning method used to create Dolly the sheep.
[711] *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al*. 569 U.S. 12-398 (2013)
[712] In re Roslin Institute (Edinburgh) No. 2013-1407 (Fed. Cir. May 8, 2014) at 7-8.

The decision seems to be a straightforward application of *Myriad*, in which the Supreme Court specified that Myriad did not "create or alter the genetic structure of DNA… [but] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention."[713] The Federal Circuit explained that possessing the same DNA as the donor mammal does not automatically result in patent eligibility. However, the Court pointed out that the claims did not describe the clones as having any markedly different characteristics from the donor animals. Therefore, it seems that the CAFC is reinforcing the principle that patent applications in biotechnology must ensure that the claims include the distinction between that naturally occurring entity and the claimed invention.

4.5.3. The EPO approach: limiting gene patents

In the EPO, the topic of patenting genes is less about eligible subject matter and more about the patentability requirements, particularly inventiveness and non-obviousness. As technology has progressed, identifying human genes using standard techniques has become a routine activity and no longer an inventive undertaking. The European Office stipulates two cases where the inventive step is present in a genomics claim: (i) where a "technical achievement" is attained in identifying the claimed sequence, or (ii) a new or unexpected property associated with the discovered gene is revealed**.**[714] The EPO approach seems to advocate that the threshold for claims to a gene patent is higher today merely because the exertion necessary in detecting and classifying gene sequences is no longer inventive.

The EPO granted Myriad Genetics three European patents in 2001 for the sequencing of the BRCA1 gene and the mutations practical for the diagnosis of

[713] *AMP v. Myriad* (2013) at 12.
[714] The EPO stated that claims directed at a genetic invention will be considered to possess an inventive step "if the applicant can demonstrate that obtaining the sequence was in fact a technical achievement or that they have discovered a new or unexpected property associated with the gene." European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', Press Release (Munich), 18 May 2004.

predisposition to breast and ovarian cancer in women.[715] However, these patents were contentious.[716] In August 2002, several European institutions[717] challenged Myriad's Patent EP 705 902, which was awarded for the BRCA1 gene for breast and ovarian cancer predisposition. The claims included the isolated BRCA1 gene as follows: the chemical molecule itself and the corresponding protein, all plausible therapeutic treatments like gene therapy and drug screening, and diagnostic kits, using probes or primers directed at certain mutations. The main arguments against Patent EP 705 902 were that the claimed invention lacked novelty, inventive step and industrial application and failed to the meet the written description requirement for a person skilled in the art to reproduce the invention.[718]

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[715] EP 699 754, granted on January 10, 2001, which is a use patent that asserts rights to the diagnostic use of the BRCA1 gene on any type of technique employed. EP 705 903, granted on May 23, 2001, which is a product patent and covers a series of 34 specific mutations and acts as a complement to patent EP 699 754. Finally, EP 705 902 is a product patent which covers all uses of the BRCA1 gene and proteins as a chemical product. The claims include its use in diagnostics, therapeutics, and prevention.

[716] Aside from the technical grounds for oppositions to Myriad's patents, there was inherent policy and ethical apprehension maybe reword, sounds odd. The main concern was the restrictions the patents could place on medical practice and the monopolization of genetic testing. France's Institut Curie released a press statement articulating that Myriad's broad patents would ensure monopoly position that would seriously hinder research and public health:
"Not allowing French and European laboratories to perform testing or initial family mutation searches will lead to a loss of technical and medical expertise which will probably in turn lead to a decrease in funding allocated to such laboratories. The loss of expertise and of funding would not be trivial for basic research which is critical for the future of medical genetics. It would therefore not be without repercussions either for the development of genuine preventative care for high risk women." Institut Curie, Press Office: Against Myriad Genetics's [sic] monopoly on tests for predisposition to breast and ovarian cancer. September 12, 2001. Paris. This "unacceptable monopoly" raises the question of how to balance patent law with health objectives. It cannot be denied that there are significant medical benefits to be derived from the creation of diagnostic tests like the BRCA1 and BRCA2 diagnostic kits that Myriad created. But there are various views on how the patent system should address such tools, and whether they should be protected under the patent system for the sake of promoting greater access to the technology in question, including the development of better diagnostic kits and access to testing.

[717] The challengers to the patent included three French medical institutions: Institut Curie, the Gustave Roussy Institute and the Assistance Publique Hôpitaux de Paris, along with the Belgian Human Genetics Society, the Dutch Ministry of Health, the Austrian Ministry of Health, the Swiss Social Democratic Party, Greenpeace Germany and Dr. Wilhems (Germany). Institut Curie, Press Release: Breast and Ovarian Cancer Predisposition: New European Victory in the Opposition to American Patents: the Board of Appeal of the European Patent Office Rejects the Appeal of Myriad Genetics. October 1, 2007. Paris.

[718] The opposition notices paved the way to the partial revocation of EP 699754 in January 2005, which was for a diagnosis method for detecting the BRCA1 gene. The Opposition Division of the EPO partially revoked the patent because the original patent application contained errors in the BRCA1 and encoding protein sequences. By the time they were corrected, the gene sequences were already found in the public domain. Accordingly, the BRCA1 sequence and protein were refused priority as they were incorrectly written in the first patent applications in 1994. In March 1995, Myriad amended its claims to include the correct sequence. Consequently, the actual priority date for the sequences was March 1995, and on this date, isolation of the BRCA1 gene and its complete sequence had already been published. This meant that the primary claim for the registered BRCA1 gene and the protein sequence of March 1995 did not

In 2007, the EPO Board of Appeal revoked Myriad's EP 705 902 in T1213/05 which comprised of a product claim directed at DNA sequences coding for BRCA1 coding sequence on the basis that the claims failed to fulfill the traditional criteria of patentability. The original patent claim describing the DNA sequences were incorrect as there were a total of 15 sequence deviations. After Myriad filed the application, the accurate DNA sequences were published before Myriad rectified its errors and filed the application describing the correct DNA sequences. As a result, the correct DNA sequences were in the public domain before Myriad filed the patent application containing the correct sequences. This resulted in a finding of lack of novelty. As a result, the claims were narrowed to a few small probes from the BRCA1 gene that was properly divulged in the priority document.[719]

With regards to EP 705903, the Board of Appeal upheld the method claims for diagnosing women's predisposition for breast and ovarian cancer by determining the existence of a certain mutation in the BRCA1 gene in T 666/05. The Board of Appeal held that the 15 sequence aberrations in the priority document did not have an effect on the claimed method of establishing the mutation.[720]

For the third patent EP 699754, the Board of Appeal in T80/05 upheld the broad patent claims on methods for diagnosing predisposition to breast and ovarian cancer through the identification of mutations in the BRCA1 gene. The priority document correctly pinpointed the BRCA1 reading frame which allowed the labeling of a specific group of gene mutations which were not affected by the 15 sequence deviations as disclosed in the priority document.[721]

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comply with the EPC as the invention was not novel by the time the invention was fully disclosed. However, the Opposition Division upheld Myriad's secondary claims directed to the probes and vectors of the gene sequence.

[719] See T1213/05. Decision of the Board of Appeal of the European Patent Office. September 27, 2007

[720] T 80/05. Decision of the Technical Board of Appeal of the European Patent Office. November 19 2008.

[721] Ibid.

The remaining patent rights Myriad possessed after the three decisions were fair and corresponded to a sensible recompense for their contribution to the field. The Board of Appeal limited the broad protection on the product patent due to a technicality - the loss of priority due to the 15 sequence deviations. Nevertheless, entitlement to priority was not lost on the grounds of sequence deviations in the priority document as the sequence deviations did not affect the claimed method. This is why the Board of Appeal upheld the patent coverage of the single specific cancer mutation and of the discovery of frame shift mutations in the BRCA1 gene. With respect to Myriad's product claims, however, the Board of Appeal maintained that the patent claims had to be restricted due to the patent application's failure to meet the classic patent requirements rather than any indication of an alteration in legal approach towards gene inventions. It appears that the EPO has managed gene patents reasonably well using the traditional patentability criteria, criteria which were applied to Myriad's patents and resulted in limiting the scope of patent protection.

It may seem that the issue over Myriad's gene patents in Europe has been resolved, yet the widespread discussion of gene inventions and the patent system persists. Currently, there remains a consideration of whether the next step should be to propose a control on the scope of protection which would entail a patent owner having only patent protection over the identified use of a gene.[722] In other words, third parties could identify other uses of a gene and apply for separate patent protection. Little guidance is found in Directive 98/44/EC on this matter as it was the product of several negotiated compromises and encompasses a high degree of ambiguity, particularly in

[722] Commission of the European Communities. Report from the Commission to the Council and the European Parliament: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering. Brussels. July 14, 2005. The Commission reviewed the issue of whether patents should be restricted so that only the specific use as disclosed in the patent application can be claimed. The Commission noted that Articles 8,9,10 and 11 of Directive 98/44/EC addressed the topic of scope of protection, but none addressed the concept of restricting the scope of protection relating to the specific use for the concerned gene sequence. Page 3.

key terms defining the scope of protection.[723] As a result, EU Member States and their national courts can interpret and define the scope of protection differently.

Countries like Germany[724] and France[725] have introduced legislation to restrict the scope of patent protection on DNA sequences to a specified use. This is known as 'purpose-bound' protection.[726] For instance, in Germany, §1a (4) of the German Patent Law (PatG) reflects the German Parliament's implementation of Article 5 of Directive 98/44/EC:

> [W]hen the invention is a sequence of a gene, the composition of which is identical to the composition of a natural sequence of a human gene, the use thereof, for which the industrial application is the specification according to paragraph 3 has to be included into the patent claim.[727]

Subsection 4 of §1a is based on the recommendation of the Legal Committee of the Bundestag. The German legislator merged the patentability requirement into the scope of protection, maintaining that the use described in the application should be included in the claim for genes and partial sequences of genes that are also present in humans and thereby limit the scope of such use. For such genes and partial sequences of genes the absolute protection of the patented invention should therefore be abolished -

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[723] Straus, J. The Scope of Protection Conferred by European Patents on Transgenic Plants and Methods for Their Production," in A. Bakardjieva et al. (eds.) Festschrift for Marianne Levin. Stockholm: Norstedts Juridik, 2008 at 647.

[724] §1a(4) of the German Patent Act

[725] Art. L. 613-2-1 (Loi no 2004-800 du 6 août 2004, art. 17) La partie d'une revendication couvrant une séquence génique est limitée à la partie de cette séquence directement liée à la fonction spécifique concrètement exposée dans la description. Standard>Les droits créés par la délivrance d'un brevet incluant une séquence génique ne peuvent être invoqués à l'encontre d'une revendication ultérieure portant sur la même séquence si cette revendication satisfait elle-même aux conditions de l'article L. 611-18 et qu'elle expose une autre application particulière de cette séquence. (English translation: Art. L. 613-2-1 (Act No. 2004-800 of August 6, 2004, art. 17) The portion of a claim covering a gene sequence is limited to the part of this sequence directly related to the specific function disclosed in the description. Standard> the rights created by the grant of a patent including a gene sequence cannot be invoked against a subsequent claim for the same sequence if the claim itself satisfied the requirements of Article L . 611-18 and exposes another specific application of this sequence.)

[726] For a discussion on purpose-bound protection for DNA sequences in the EU, see: Krauss, J. and T. Takenaka. "A Special Rule for Compound Protection for DNA-Sequences-Impact of the ECJ 'Monsanto' Decision on Patent Practice" in Journal of the Patent and Trademark Office Society. Vol. 93, No. 2, pp. 189-206, 2011 and Dutfield, G. "Biotechnology and IPRs in Europe," in Jensen, A and M. Pugatch (eds.) Intellectual Property Frontiers: Expanding the Borders of Discussion. London: Stockholm Network, 2005. p.49-50. Similarly: Kock, M. "Purpose-Bound Protection for DNA Sequences: In Through the Back Door?" in Journal of Intellectual Property Law & Practice. Vol. 5, No.7, Pp.495-513. 2010.

[727] §1a(4) of the German Patent Act: Ist Gegenstand der Erfindung eine Sequenz oder Teilsequenz eines Gens, deren Aufbau mit dem Aufbau einer natürlichen Sequenz oder Teilsequenz eines menschlichen Gens übereinstimmt, so ist deren Verwendung, für die ?gewerbliche Anwendbarkeit nach Absatz 3 konkret beschrieben ist, in den Patentanspruch aufzunehmen. (Original German text)

unlike for animal and plant genes. The report explained that the chosen wording takes into account the fact that human genes largely resemble animal and plant genes. Otherwise, the limitation of the absolute protection of the patented invention could be circumvented by using a matching animal gene in the patent application. Therefore, in Germany, patent applications are required to include the use or function for human gene sequences and partial sequences as such protection will be limited to the claimed use. [728]

4.6. Genes and the patentability requirements

4.6.1. Attack on Novelty

One issue that may arise involves the novelty of DNA sequences in the post-genomic era. In both the US and Europe, inventions must be new.[729] In a patent claim, novelty is assessed against the prior art which existed at the priority date of the patent application. The prior art information must include all features of an invention in clear and unequivocal terms in order for the contended invention to lack novelty.[730] It is reasonable that at the beginning of the development of a new technology patent applications will appear to be extremely innovative, but it is only as the technology

[728] "Der geltende Absatz 4 ist auf Grund der Beschlussempfehlung des Rechtsausschusses des Bundestages angefügt worden. Für Gene und Teilsequenzen von Genen, die auch beim Menschen vorkommen, sollte die in der Anmeldung beschriebene Verwendung in den Patentanspruch aufgenommen und dadurch der Schutzumfang auf diese Verwendung beschränkt werden. Für solche Gene und Teilsequenzen von Genen sollte damit – anders als für tierische und pflanzliche Gene – der absolute Stoffschutz abgeschafft werden. Die gewählte Formulierung berücksichtige die Tatsache, dass menschliche Gene weitgehend mit tierischen und pflanzlichen Genen übereinstimmten und die den Stoffschutz begrenzende Wirkung der Regelung ansonsten umgangen werden könne, indem ein übereinstimmendes etwa tierisches Gen für die Patentierung verwandt werde."
Unterrichtung durch die Bundesregierung - Bericht der Bundesregierung über die Wirkungen des Gesetzes zur Umsetzung der Biopatentrichtlinie Bundestags Drucksache 16/12809. (English translation: Report of the German Federal Government on the effects of the act to implement the Biotech Directive from 29. 04. 2009) Pg. 4.

[729] See 35 USC s 102; Patents Act 1977 (UK) s 2.

[730] It can be argued that patents on gene related inventions are not 'novel' since they naturally occur; even if the DNA sequence is isolated and purified, for example, critics maintain that this does not fulfil the novelty requirement. See Boyle, J. "Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us," in F. Scott Kieff (ed.) Perspectives on Properties of the Human Genome Project. Boston: Elsevier Academic Press, 2003 at 104.

develops over time and the techniques become recognizable that an acknowledged notion of what should be permitted begins to establish itself.[731]

In the UK, case law reveals that natural substances that have been isolated for the first time and was not known to have existed, does not lack novelty merely because it exists in nature. The novelty requirement can be satisfied for inventions covering biological materials such as genes and DNA sequences if the claimed invention is "isolated for the first time and which had no previously recognised existence."[732] For instance, in *Generics Ltd v Lundbeck A/S*,[733] the House of Lords reiterated how novelty was assessed in relation to chemical inventions. Lundbeck successfully developed a method in isolating the (+) enantiomer from its racemate citalopram. Lundbeck claimed to have created a novel method in separating the (+) and (-) enantiomers and subjected each to tests, found that the (+) enantiomer had the desired anti-depressant effect, whilst the (-) enantiomer had an inhibiting effect. As a result, a more operative anti-depressant could be attained through the isolation of the (+) enantiomer of citalopram. Lundbeck claimed to be authorized to a patent right over both the process and the product of the process. The question in relation to novelty is whether the (+) enantiomer is, for the purposes of section 1(1) of the 1977 Act, a new product.

Three manufacturers of generic citalopram challenged Lundbeck's European Patent (UK) No. 0347066 (the 'Patent') which is entitled 'New enantiomers and their isolation,' in relation to escitalopram on the grounds of lack of novelty, obviousness and insufficiency.[734] The question is whether the claim excludes the (+) enantiomer in the

[731] Cornish, W., David Llewelyn and Tanya Aplin. Intellectual Property: Patents, Copyright, Trademarks and Allied Rights. London: Sweet & Maxwell Ltd, 2010 at 935.
[732] Howard Florey Institute's Application / Relaxin OJEPO 1995, 388 (V 0008/94). The court maintained that the existence of a form of relaxin was not known until a cDNA encoding human H2-rekaxin and its precurors was isolated.
[733] Generics Ltd v Lundbeck A/S [2009] UKHL 12.
[734] 2 particular product claims were alleged to be invalid for lacking novelty. Claim 1 (US Patent number 4,136,193) is a product claim and claims the enantiomer itself: "(+) -1-(3- dimenthylaminopropyl)-1-(4'-fluorophenyl)- 1,3-dihydroisobenzofuran-5-carbonitrile . . . and non-toxic addition salts thereof." The second patent claim the appellants attacked for lacking novelty was Claim 3 (US Patent number

racemate mixture. The appellants argued that the claims lacked novelty as the racemate was already disclosed and the claim extended to the (+) enantiomer. Lundbeck maintained that claim 1 was limited to the isolated or pure (+) enantiomer and excludes the racemate. The attack on the product claims on lack of novelty failed in the lower courts. Writing for the UK Patents Court, Mr. Justice Kitchin rejected the novelty challenge.[735] Adopting the approach to novelty as set out by the House of Lords in *Synthon v SmithKline Beecham*,[736] where anticipation necessitated prior disclosure and enablement, Kitchin J. maintained that the prior art concerning the racemate did not disclose its enantiomers.

The Court of Appeal agreed with this finding in that there had been previously no disclosure found in the prior art that enabled an ordinary skilled person to make escitalopram.[737] Lord Hoffmann maintained that the "settled jurisprudence in the European Patent Office that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers."[738] Lord Justice Jacob echoed Lord Hoffman's position on novelty in this case, highlighting that the question is that of claim construction: whether the claim covers the (+) enantiomer when in the racemate. "In my opinion it obviously does not – the patentee was plainly not intending to cover the racemate. How much more than 50% of the (+) enantiomer must be present for a product to fall within the claim is simply a moot point as far as this case is concerned."[739] Therefore, both the UK Patents Court and Court of Appeal found the (+) enantiomer to be novel.

4,650,884): to a 'pharmaceutical composition in unit dosage form comprising, [as] an active ingredient, a compound as defined in claim 1.

[735] Generics (UK) Ltd v. Lundbeck A/S [2007] RPC 729. Although Kitchin J rejected the novelty and obviousness challenges, he declared that the claims of the invention were beyond its technical teaching. Therefore, the patent was held to be invalid for insufficiency.

[736] Synthon BV v. Smithkline Beecham plc [2005] UKHL 59

[737] H. Lundbeck A/S v. Generics (UK) Ltd., [2008] EWCA Civ 311 (Court of Appeal 2008).

[738] Ibid, H17.

[739] Ibid, 50.

Although the issue of novelty was not pursued on appeal in the House of Lords, it was addressed by Lord Scott, who maintained that it was a worthwhile discussion. Lord Scott deemed that the novelty involves the knowledge in separating the (+) and (-) enantiomers of citalopram and their respective roles to the anti-depressant quality of citalopram. Referencing EPO case law including T 0296/87,[740] he maintained that novelty is not destroyed even if the existence of enantiomers may be palpable from assessment of the chemical structure of the racemate of a compound, as it does not divulge them in their individualized forms. Lord Scott held that the (+) enantiomer of citalopram in its separated form, was not made available to the public prior to the priority date. Until then, it was only known as an unseparated part of the racemate that made up the citalopram molecule. "It follows, therefore, that the (+) enantiomer was "new" for the purposes of section 1(1) (a) of the Act."[741] Therefore, in the area of biotechnology inventions, novelty of a known biological product can be ascertained provided that the individual element of a compound has not been previously divulged.

4.6.2. Attack on inventive step/obviousness

In the US, it is currently expected that novel[742] genetic information must be non-obvious.[743] However, there is the view that the USPTO is lax on its interpretation of non-obviousness. In the Europe, inventions need to be differentiated from the prior art, which is known as the "inventive step" and is one of the substantial requirements of

[740] T 0296/87 (Enantiomers) of 30.8.1988 at 6.2.
[741] Generics Ltd v Lundbeck A/S [2009] UKHL 12, Para. 6.
[742] U.S. patent law requires inventions to be novel under 35 U.S.C. §102. A claimed product or process can be found to lack novelty if the claimed invention was known or used by the public in the country, already patented or described in a printed publication in the US or a foreign country (35 U.S.C. §102 (a)). To pass the novelty requirement, the claimed invention is assessed against the prior art. Section 102(b) sets the statutory bar for inventions that have been already been published in a printed publication, used by the public, or sold for more than a year prior to the patent application date. The main difference between these two subsections of §102 is that novelty is independent of the inventor's acts. However, those acts can result in a statutory bar to patentability.
[743] Cornish, W., David Llewelyn and Tanya Aplin. Intellectual Property: Patents, Copyright, Trademarks and Allied Rights. London: Sweet & Maxwell Ltd, 2010 at 936.

patentability. In the United States, this is known as non-obviousness.[744] The US Supreme Court first addressed non-obviousness in *Graham v. John Deere Co*.[745] and held that non-obviousness could be established based on three questions of fact: (i) the subject matter and scope of the prior art; (ii) the differences between the patent claims and the prior art and (iii) the level of ordinary skill possessed by a person from the relevant prior art. If a person of ordinary skill in the field who possesses the knowledge of the subject area available in the prior art, and examines the patent claims at the time the invention was produced and regards it as an obvious step, then the patent application would fail the non-obviousness requirement.[746]

In the US, the requirement of 'non-obviousness' has been applied differently pertaining to patent claims for DNA sequences. Even if the structure of a protein is known, the isolation method of a gene is in the prior art which encodes for the protein, the claimed gene sequence may still be non-obvious.[747] The United States Court of Appeals for the Federal Circuit stated in *In Re Dueul*[748] that "the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."[749] The Court articulated its reasoning by explaining that since there was nothing in the prior art which indicated the claimed DNA sequence encoded the protein, it meant that a person skilled in the art would not know the chemical structure of the DNA sequence without further research. "No particular one of these

[744] 35 U.S.C. §103(a) requires that the differences between the claimed invention and the prior art are such that the claimed invention as a whole would not have been obvious to a person who is skilled in the art the time the invention was made.
[745] *Graham v. John Deere Co.*, 383 U.S. 1 (1966).
[746] *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007)
[747] Nuffield Council on Bioethics, The Ethics of Patenting DNA (2002), 30.
[748] *In Re Dueul* 51 F 3d 1552 (Fed Cir, 1995), 1558. The patent claims were directed at DNA and cDNA molecules that encoded proteins which stimulated cell division. The patent examiner rejected the claims on the basis of obviousness. The Court of Appeals held that: (1) combination of prior art reference teaching method of gene cloning, together with reference disclosing partial amino acid sequence for a protein that stimulated cell division, did not render claims prima facie obvious; (2) conceived method of preparing some unidentified DNA does not define it with precision necessary to render it obvious over protein it encodes; and (3) patent claims generically encompassing all DNA sequences encoding human and bovine proteins to stimulate cell division were not invalidated as obvious.
[749] Ibid.

DNAs can be obvious unless there is something in the prior art to lead to the particular DNA …Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it…This is so even though one skilled in the art knew that some DNA, albeit not in purified and isolated form, did exist."[750] Additionally, the court pointed out that the existence of a general method of isolating DNA or cDNA molecules is "essentially irrelevant"[751] to the issue of whether the claimed molecules are considered obvious. This practice results in a lower threshold for the non-obviousness requirement for claims encompassing genetic sequences. This approach has been criticized by the UK-based Nuffield Council, who condemned the United States for the lower barrier for non-obviousness pertaining to genetic inventions.[752]

Particularly with gene patents, the inventive step is under great, and some commentators may say, doubtful inspection.[753] Especially genetic sequencing, which used to require extraordinary financial costs and long periods of time to do, has become significantly less difficult, in terms of time and financial resources. Due to the current state of sequencing technology, there is a higher threshold for inventive step. A patent attorney from GSK acknowledges that inventive step is judged on a case-by-case basis based on the prior art on what the skilled person would know, but a basic isolation of a simple DNA would not be considered inventive in the present day.

> DNA manipulation has moved on at a phenomenal pace. What we can do now we couldn't do in the lab ten years ago and they didn't envisage 20 years ago. I think inventive step is always judged to the priority date and that's why it's fluid. So what you have to do is take the prior art at the time. At that priority date you have to take into account the knowledge of the skilled person and who that skilled person is. In 1979, the skilled person hadn't heard about PCR and was presented with a patent application and once they saw it, went "Wow." It must have been the most clever thing they had seen. Now, the things we can do with PCR, we can read carbohydrates structures off DNA. Inventive step is judged relatively at that time. So yes, you're right, isolating DNA now, you'd be unlikely to get a patent granted for a claim to "We took some sequence, we put in a plasmid." There isn't anything inventive there. But in a case by case

[750] Re Dueul 51 F 3d 1552 (Fed Cir, 1995), 1558–1559
[751] Re Dueul 51 F 3d 1552 (Fed Cir, 1995), 1559
[752]"[T]the outcome of any complex procedure which could not have been predicted in advance, however familiar the procedure, will be judged inventive." Nuffield Council on Bioethics, The Ethics of Patenting DNA (2002), 30.
[753] Straus, J. "Product Patents on Human DNA Sequences: An Obstacle for Implementing the EU Biotech Directive?" in F. Scott Kieff (ed.) Perspectives on Properties of the Human Genome Project. Boston: Elsevier Academic Press, 2003 at 76.

> basis, if it has required innovation, or it has overcome a particular problem, or it has gone against the teaching in the prior art. If somebody says: "This gene doesn't do anything, it's not possible, it's just junk DNA," and then a group says "Well, we think it does." They work hard, they have to do something innovative to get that sequence, then it may be that particular sequence is inventive.

Genetic sequencing has become standardized and technically routine today. The increase in patent applications for genetic sequences over the years correlates with the swift developments in sequencing complete genomes like the human[754] and worm.[755] However, because the technical progress has been so considerable, the level of "inventiveness" must be scrutinized in patents that are directed at DNA sequencing in view of the fact that identifying and synthesizing DNA sequences have become a standardized routine.

In the UK, Lord Hoffman in *Biogen v Medeva* stated that the test for obviousness is 'simply a matter of degree.'[756] Sir Robin Jacob maintains that obviousness is an inherently 'woolly' test because there are various factors to consider before one can arrive to a final value judgement about whether an invention is obvious.[757]

4.6.3. Scope of protection

Aside from the matter of eligibility, another opposition against DNA patents is directed at the scope of protection. The question is whether a patent on a DNA sequence should warrant absolute protection if future functions are discovered later on. It is a scientific fact that many genes code for more than one function. [758]

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[754]Human Genome Organisation. HUGO Intellectual Property Statement on Patenting of DNA Sequences. May 1997. http://www.hugo-international.org/img/ip_sequencedata_1997.pdf. Accessed November 14, 2013.

[755]Wilson, RK. "How the Worm Was Won. The C. Elegans Genome Sequencing Project" in Trends in Genetics. Vol. 15(2):51-58. February 1999.

[756] *Biogen v. Medeva*, October 31, 1996, [1997] RPC 1 (House of Lords).

[757] Jacob, R. "Woolly Lines in Intellectual Property Law," in Patents and Technological Progress in a Globalized World. Wolrad Prinz zu Waldeck und Pyrmont et al. (eds.) Berlin: Springer, 2009 at 785.

[758]A Canadian report written for the Ontario Government emphasized that overly broad gene patents could confer control over genetic information:
Ontario Report to Premiers, Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare. Toronto: Ontario Government, 2002 at 49: " [T]he effect of fully enforced, broad scope gene patents may challenge certain principles of patent law by in effect patenting genetic information rather than simply genetic inventions, products or utilities. To remedy this problem, the scope of patents over genetic

If a sequence has a second function which was not disclosed in the patent claim nor anticipated by the inventor, then it is possible for the second invention to warrant a separate patent. This approach is consistent with the purpose of patent law, which is to compensate the inventor in exchange for disclosing valuable knowledge of the invention to the public. An unexpected result which encompasses an inventive step should not be covered by the first patent. If a patent over a genetic sequence includes protection over all future functions, then this could hinder innovation.

A good case to illustrate this issue is the dispute between Amgen and Transkaryotic Therapeutics (TKT) over the scope of Amgen's method patent of producing erythropoietin (epo).[759] Amgen's patent claim covered the gene sequence and biological function and the technique of inserting the gene as an exogenous DNA sequence into a host cell which produced significant quantities of epo. TKT created a method of producing epo which made use of the DNA sequence, but used the technique of 'gene activation,' which switched on the relevant DNA sequence in ordinary human cells rather than inserting the epo gene into a host cell. The issue was whether TKT infringed Amgen's European patent since TKT made use of the same gene sequence to produce epo, or whether TKT's method of producing epo was a novel way of producing the same hormone which does not violate the patent. The House of Lords found that Amgen's original patent claims were limited in scope and as a result, there was no infringement. Lord Hoffman argued that Amgen's patent should be construed narrowly to the use as stated in the original claim, where the DNA sequence was used to create epo in a host cell, which he says, does not include TKT's different method. Lord

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material may need to be more rigorously defined to separate the chemical or structural nature of genetic material from its informational content. Patents should only prevent the making, using, selling, and importation of genetic material when that material is used as a chemical, but should not unduly limit access and use of that particular information content of a naturally occurring sequence, regardless of whether the sequence is being used in natural or artificial form."

[759] *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.* [2004] UKHL 46 (21 October 2004). Amgen's UK patent 0148605 covered the method of using recombinant DNA technology to create EPO, a hormone that is necessary for the production of red blood cells.

Hoffman emphasized that Amgen's patent should not inhibit others from using the basic information about the DNA sequence to invent around the patented method in developing a new process to produce epo.

> Before considering any of the four objections, it is, as I indicated earlier, necessary to decide the nature of the invention which the specification had to enable. In my opinion, it was a way of making epo. For the reasons which I gave when discussing infringement, it was not and could not be the DNA sequence. It could only be a way (however broadly expressed) of making epo by the use of that information.[760]

Therefore, Lord Hoffman's statement infers that gene patents like the one Amgen possessed are not patents on the DNA sequence itself, but rather its uses. What can be derived from this outcome is the emphasis on the informational aspect of a genetic sequence, that if a sequence has a second function that was not identified at the time of the first patent application, then the second function should warrant individual protection. This line of reasoning is in line with the essence of patent protection, which is to compensate the inventor in exchange for the disclosed knowledge.

4.7. Human embryonic stem cells

Human embryonic stem cells (hESCs) are of particular interest because they have the capability to differentiate into various cell types in the body.[761] Pluripotent stem cells have the potential to develop into all of the cell types of the body.[762] Embryonic stem cells (ESCs) are the primary source of pluripotent stem cells since they hypothetically have the potential to differentiate into all possible types of cells and tissues.[763] They have significant medical value, but the way in which they are produced is surrounded by controversy based on ethical considerations. One of the methods in which they are obtained is from the inner cell mass of blastocysts.[764] This means in

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[760] Ibid at 109.
[761] Kiessling, A. and S. Anderson. Human Embryonic Stem Cells 2nd edition. Massachusetts: Jones and Bartlett Publishers, 2007 at 3.
[762] Schöler, H. "The Potential of Stem Cells: An Inventory" in Knoepffle, N. et al. (eds.) Humanbiotechnology as Social Challenge. Aldershot: Ashgate Publishing, 2008 at 28.
[763] Gottweis, H. et al., The Global Politics of Human Embryonic Stem Cell Science. New York: Palgrave Macmillan, 2009 at 10.
[764] Sullivan, S. et al. Human Embryonic Stem Cells: The Practical Handbook. Chicester: John Wiley & Sons, 2007 at 35.

practice, the derivation of embryonic stem cells results in the destruction of blastocysts. Most often, the ESCs are obtained from surplus embryos created by in vitro fertilization (IVF). Opponents of embryonic research argue that the method of obtaining hESCs is ethically immoral as it involves the destruction of a blastocyst, which, according to some religions, equates to the destruction of a human being.[765] On the other hand, advocates of embryonic research claim that unused embryos are disposed of and destroyed anyway and that it is better that they are used in research.

4.7.1. The US approach

Unlike the EU, the US does not have any legal exemptions for hESC patents. 35 U.S.C. §101 states that four categories are patentable: any new and useful process, machine, manufacture, or composition of matter.[766] In 1853 however, exceptions were articulated by the U.S. Supreme Court that included: laws of nature, natural phenomena, and abstract ideas.[767] Furthermore, 35 U.S.C. §101 does not include any exemptions on the bases of morality or the *ordre public*. This means that there are no statutory exemptions from patentable subject matter for inventions directed at stem cells.

Elsewhere, there are some clauses which may be relevant if hESCs qualify as a human organism. In the Manual of Patent Examining Procedure (MPEP), section 2105 states: "if the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. §101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."[768] Similarly, in 2011, the Leahy Smith Act revised the US patent system, which amended 35 U.S.C. §101 to include the addition of the following passage: "no patent may issue

[765] Nisbet, M. "Public Opinion About Stem Cell Research and Human Cloning" in Public Opinion Quarterly. Vol.68, No. 1, 2004 at 135.
[766] Title 35 of the United States Code §101 states: "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."
[767] O'Reilly v. Morse, 56 U.S. 62 (1853)
[768] USPTO, Manual of Patenting Examining Procedure, Ninth Edition March 2014, section 2105.

on a claim directed to or encompassing a human organism."[769] Unless hESCs are interpreted in a future court decision as human organisms, any hESC-related invention may be ineligible patent subject matter, which could result in apprehension from that biotech industry.

Less than a month after the *Myriad*, a historic patent on embryonic stem cells faced scrutiny. On July 2, 2013, three weeks after the US Supreme Court invalidated Myriad Genetics' patents on the BRCA1 and BRCA2 genes, Consumer Watchdog (CW)[770] filed a brief with the Court of Appeals for the Federal Circuit in Consumer Watchdog v. Wisconsin Alumni Research Foundation.[771] Appellant CW maintains that Wisconsin Alumni Research Foundation's (WARF) US Patent No. 7,029,913 entitled "Primate Embryonic Stem Cells" is invalid. CW's argument focuses on two main topics: the decision in *Myriad* and the issue of obviousness. CW maintained that the rationale of *Myriad* should be taken into account in respect to hESCs, which is another 35 U.S.C. §101 challenge. Rather than isolated genetic sequences, the focus is on whether an in vitro culture of human embryonic stem cells is patent eligible. CW reasoned:

> As a threshold matter, the claims of the '913 patent are invalid under 35 U.S.C. §101 for claiming subject matter that is not patent eligible. Specifically, the claimed hESC cell culture falls within the "product of nature" exception to statutory subject matter… WARF did not create or alter the properties inherent in stem cells any more than Myriad created or altered the genetic information encoded in the DNA it claimed.[772]

CW maintained that WARF's patent claims describe embryonic stem cells that are identical to embryonic stem cells inside a human embryo and the accompanying properties that are inherent in all embryonic stem cells like the potential to differentiate, refrain from differentiation when cultured on a fibroblast feeder layer. Therefore, CW argued the claims are directed at products of nature and should be invalidated under

[769] Section 33(a) of the Leahy-Smith America Invents Act.
[770] CW is a not-for-profit public charity dedicated to speaking on behalf of taxpayers and consumers in special interest-dominated public discourse, government and politics.
[771] Consumer Watchdog v. Wisconsin Alumni Research Foundation. 13-1377. U.S. Court of Appeals for the Federal Circuit. 2013.
[772] Ibid at 10-11.

section 101. CW's other point of contention was that WARF's claims were obvious under 35. U.S.C. §103(a) and that identifying human embryonic stem cells was routine because human stem cells have the same structural features as mouse embryonic stem cells and, as a result, it would have been obvious which cells to select during the stem cell derivation process.

However, on January 17 2014, the USPTO responded to the Federal Circuit panel's request regarding CW's standing in the case, maintaining that CW did not possess actual standing to bring an appeal against CW's patent.[773] On January 27, 2014, WARF issued a statement supporting the USPTO'S arguments.[774] Despite the USPTO's argument that CW did not have legal standing, CW filed a statement on the same day by re-asserting their standing.[775]

Nevertheless, CW's challenge reveals how the Supreme Court decision in *Myriad* is altering the landscape of biological patent litigation.[776] Despite the fact that the decision was restricted to isolated gene patents, the Supreme Court did not elaborate on whether other isolated natural materials fall under the same restriction of unpatentability. Yet the CW argues that stem cells falls under this area, specifically targeting WARF'S U.S. patent 7,029,913.

It is not clear whether this case will have much of an impact on hESC research. Compared to the EU, there does not seem to be great alarm over the issue. One possible explanation for this seeming lax attitude, at least within the scientific community, is that WARF has made their licensing fees and restrictions quite reasonable compared to other

[773] USPTO, Brief for the United States as Amicus Curiae. No. 2013-1377. Consumer Watchdog v. Wisconsin Alumni Research Foundation. Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Reexamination No. 95/000,154. January 17, 2014.
[774] Stoll, K.F. Correspondence to: The Honourable Daniel E. O'Toole. Re: Consumer Watchdog v. Wisconsin Alumni. January 27, 2014. http://www.laipla.net/wp-content/uploads/2014/01/CW-v-WARF-20140127-Response-to-US-by-WARF-ECF.pdf. Accessed May 22, 2014.
[775] Brief of Appellant in Response to United States 2013-1377, Consumer Watchdog v. Wisconsin Alumni Research Foundation. Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, January 27, 2014.
[776] Marshall, E. "Historic Patent on Embryonic Stem Cells Faces Scrutiny" in Science. Vol. 343, p.359. January 24, 2014.

cell lines.[777] Furthermore, with alternative research including induced pluripotent stem cells,[778] any ethical issues can be minimized:

> [M]ost research groups now emphasize or work on only reprogrammed 'adult' stem cells, not cells derived from embryos. These adult cells, also called induced pluripotent stem (iPS) cells, aren't as controversial as embryo-derived cells and don't have the same ethical and legal problems. And because they're lab-engineered, many people say iPS cells are not vulnerable to a 'product of nature' challenge.[779]

Had the CW's challenge to WARF'S patent been successful, and the court found the claims be for a 'product of nature', the ruling could have set another judicial precedent on removing patent protection for biological inventions and could lead to more extensive invalidation of other biological patents. From a law and economics perspective, this could have far-reaching consequences in the field by potentially hindering investment for potential investors who do not feel there is sufficient security for their investment, which could ultimately result in a general waning in innovation.[780]

4.7.2. *Brüstle v Greenpeace*

On October 18, 2011, the Court of Justice of the European Union (CJEU) released a decision which sent shockwaves through the biotech industry, particularly worrying for those with a focus on stem cell research. The court held that human embryo stem cells were unpatentable subject matter based on reasons related to morality. Any invention which requires the destruction of a human embryo was considered to be immoral, and therefore unpatentable. ***[781]***

In 1999, Oliver Brüstle received a German patent DE 19756864 for an invention concerning neural precursor cells, the process for producing isolated and purified neural precursor cells from hESCs and the use of neural precursor cells for therapeutic

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[777] Golden, J. "WARF's Stem Cell Patents and Tensions between Public and Private Sector Approaches to Research" in Journal of Law Medicine & Ethics. Vol. 38, Iss. 2, pp. 314–331, 2010.
[778] Takahashi K, Yamanaka S. "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors" in Cell. Vol. 126, pp. 663–676, 2006.
[779] Marshall, E. "Historic Patent on Embryonic Stem Cells Faces Scrutiny" in Science. Vol.343.p.359. January 24, 2014.
[780] Ibid.
[781] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011.

purposes.[782] His invention involved the use of cells which grew tissue for the purpose of treating injured organs for people with diseases like Parkinson's and dementia.

Greenpeace e.V. "Greenpeace" challenged the validity of Brüstle's patent and the case went through the German courts and up to the CJEU. Greenpeace challenged the German patent that was granted for the process of isolating and purifying neural precursor cells, the methods of manufacturing them from embryonic stem cells and the use of the neural precursor cells in treating neural deficiencies like Huntington's disease. Greenpeace contested the patent in the German Federal Patent Court, which ruled the grant invalid.

Brüstle then appealed to the German Federal Court of Justice, who then asked the CJEU to interpret the concept of "human embryos" and "uses of human embryos for industrial or commercial purposes," and to determine whether exclusion from patentability of human embryos covers all stages of life from fertilization. Brüstle argued that the Directive did not explicitly define what an embryo encompassed and that an "embryo" was something that existed only 14 days after fertilisation. He argued

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[782] Claim 1: Isolated, purified precursor cells with neuronal, or glial properties from embryonic stem cells, containing at most about 15% primitive embryonic and non-neutral cells obtainable by the following steps:
Cultivate of E Cells into embryoid bodies,
Cultivate of the neutral precursor cells to embryoid bodies,
...
Claim 5: Cells according to any one of claims 1 to 4, wherin the embryonic stem cells were obtained from oocytes after nuclear transfer
Claim 6: Cells according to any one of claims 1 to 4, wherin the embryonic stem cells obtained from embryonic germ cells
Claim 7: Cells according to any one of claim 1 to 6, wherin said cells are mammalian cells.
Claim 8: Cells according to claim 7, wherein the cells from the group comprising mouse, rat, hamster, pig, are bovine, primate or human been isolated.
...
Claim 12: A method for preparing purified precursor cells wiwth neuronal or glial properties, comprising the steps of
Cultivate of ES cells into embryoid bodies,
Cultivate of the embryoid bodies to neural precursor cells,
...
Claim 22: Use of the precursor cells according to any one of claims 1 to 11 for the therapy of neural defects.
These claims were translated from German to English using the Patent Translate tool powered by the EPO and Google. See http://worldwide.espacenet.com, patent DE 19756864 for more information. Last visited December 10, 2014.

that since his embryonic stem cells were obtained from five- and six-day old embryos, they should not be banned.

The CJEU ruled that any process that involved the removal of a stem cell from a human embryo at the blastocyst stage, requiring the destruction of that embryo, or its use as a base material at whatever stage the destruction occurs even if the destruction does not form a part of the claimed technical teaching, cannot be patented. The court made three main conclusions:

1. A wide interpretation of 'embryo' - "any human ovum must, as soon as fertilised, be regarded as a 'human embryo' if that fertilisation is such as to commence the process of development of a human being" (Para. 53(1)).
2. Use of human embryos for the purpose of scientific research is excluded from patentability because patents confer commercial rights. However, the use of human embryos for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it is patentable.
3. The process, including the prior destruction of a human embryo or its use as a base material, is excluded from patentability.

The CJEU's decision distinguished between the use of human embryos for industrial or commercial purposes and the use of human embryos for therapeutic/diagnostic purposes. The CJEU also held that an invention is excluded from patent protection if the invention involves the prior destruction of a human embryo. This exclusion would also apply to the use of human embryos in scientific research. However, inventions that use human embryos for therapeutic or diagnostic purposes for the benefit of the human embryo itself are patentable. It is difficult to separate even research conducted in universities since applying for a patent already signifies its intended industrial or commercial use.

After this CJEU ruling, it was up to the German Federal Court to decide on whether the original patent was permitted. In November 2012, the German Federal Court of Justice maintained that Brüstle's patent DE19756864 could be upheld in amended form.[783] The court held that in vitro cells derived from blastocysts did not have the capability of developing into human beings, and therefore do not constitute as human embryos.[784] This means that cells derived from hESCs can be patented as long as they are not harvested through the destruction of human embryos. Specifically, the court held that a common disclaimer which excluded the destruction of human embryos could be used to render inventions derived from hESCs patentable.

The CJEU decision was chosen for the case study in the next chapter as it provided the chance for participants to express their views and participate in whether the distinction by the CJEU of the uses of hESCs is correct and whether morality/ethics should be addressed by patent examiners and judges in the event of the granting or invalidation of a patent.

4.8. Comparing the European and US approaches

A comparison between the European and US contexts reveals that there are divergent approaches to the patent protection of human genetic materials. In the US, the issue seems to have been settled - it has ceased granting patent claims to isolated genes, as affirmed by the US Supreme Court in *Myriad*, holding isolated genes as 'products of nature' and no longer eligible for patent protection. This was due to a shift in understanding of isolated DNA sequences, as the US Supreme Court finally acknowledged the important role of function in a DNA sequence.[785] It is a strict departure from its previous approach, which has been to focus on the chemical structure

[783] BGH Decision of 27 November 2012, case no.: X ZR 58/07
[784] Ibid, p.14.
[785] Krauss, J. and T. Takenaka. "Construction of an Efficient and Balanced Patent System: Patentability and Patent Scope of Isolated DNA Sequences under US Patent Act and EU Biotech Directive" in Constructing European Intellectual Property. C. Geiger (ed.) Cheltenham: Edward Elgar, 2013 at 258.

instead of function in assessing patentable subject matter.[786] This means DNA sequences could be taken as means-plus-function claims under §112 of the US Patent Act to encompass the chemical structure as specified in the claims, in addition to their equivalents, provided the other DNA sequences perform the same function through the genetic information they carry.

On the other hand, in Europe, the discussion is likely to continue primarily on the patent requirement of inventiveness and the scope of protection, specifically on purpose-bound protection for patent claims on genes. The divergence occurred with the EU's enactment of Directive 98/44/EC, requiring EU Member States to adopt provisions regarding the patentability of biotech inventions. It is suggested that Directive 98/44/EC was designed to acknowledge the quality of DNA sequences as an carrier of information, which extended patent protection to include DNA sequences as long as the sequence performs a function:

> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product in incorporated and in which the genetic information is contained and performs its function.[787]

By focusing on function, it is suggested that there is no difference between an isolated DNA sequence and one in its natural form. This means that there is no infringement as long as a DNA sequence does not perform the same function as that of the patented isolated DNA sequence.[788] Krauss and Takenaka suggest by focusing on the nature of genetic information carrier, patent protection could extend to other materials regardless of the chemical structure, maintaining that this expansive protection may be too generous compared to what the inventors actually invented and disclosed. [789] Therefore, there is a constant balancing act between the state and inventors, in that an

[786] Ibid at 267.
[787] Article 9, Directive 98/44/EC
[788] Krauss, J. and T. Takenaka. "Construction of an Efficient and Balanced Patent System: Patentability and Patent Scope of Isolated DNA Sequences under US Patent Act and EU Biotech Directive" in Constructing European Intellectual Property. C. Geiger (ed.) Cheltenham: Edward Elgar, 2013 at 268.
[789] Ibid at 266.

inventor should not be overcompensated with extensive protection, because that would be to the detriment of the public good.

In the US, there is no equivalent of the Directive 98/44/EC in addressing biotech inventions. In addition, the 1952 US Patent Act does not contain any provisions that directly address the patentability of biotech inventions. Moreover, although the Supreme Court recently abandoned the chemical structural identity approach to isolated DNA sequences, it is not likely it will be replaced with the functional approach. "US courts historically disfavoured a claim defining an invention by its function."[790] Instead, case law has dictated practise and policy matters in this field. As a result, the question of whether genes may be protected under the patent legislation must now be answered differently in the two jurisdictions, combined with divergent practices gene patenting between Europe and the US.

4.9. Conclusion

The two main areas of debate in biotechnology patents concern DNA sequences and inventions derived from hESCs. In the US, the enduring exclusion of patents for "laws of nature" or "physical phenomena" and "abstract ideas" asserted in *Diamond v. Chakrabarty*[791] are recognized as the "product of nature" doctrine.[792] It is submitted that the US' continuing focus on the product of nature doctrine has largely contributed to the ongoing debate around patentable subject matter particularly in the biotechnology field. This is not aided by the longstanding convention in patent law that a natural matter can be patented as long as it is possible to physically separate it from its natural environment. American case law from the 1980s - 2010 adopted the "isolation and purification" argument as a way to differentiate isolated and purified DNA sequences from their naturally occurring counterparts and hold them patentable matter. This may

[790] Ibid, the authors cite the following case as an example: Gen. Elec. Co. v. Wabash Appliance Co., 304 U.S. 364, 37 USPQ 466 (1938).
[791] See supra note 64.
[792] Conley, J. "Gene Patents and the Product of Nature Doctrine" in Chicago-Kent Law Review.Vol.84, No.1, pp.109-132, 2009-2010 at 113.

explain why, until recently, the US legislature and courts' have refused to accept the informational quality of genetic material, for fear of disturbing expectations that isolation and purification of naturally occurring materials was sufficient for removing them from the 'product of nature' category.

However, it is submitted that the concepts of isolation and purification are inadequate. These two concepts are a legal term, an artificial construction designed to draw a line between what is and not patentable pertaining to human genetic information. The concept of isolation has been adopted by the EPO and the USPTO with a legal value. In the United States, this has taken place through case law. In the EU, this was developed through the enactment of Directive 98/44/EC. In respect to the human body, in the EU, Article 5 of Directive 98/44/EC is inadequate and outdated with the current state of biomedical research. First, the isolation technique is now a standard research tool. Second, the broad patent protection in Europe for isolated DNA sequences calls into question the balance of interests, which tends to lean towards the interests of inventors.[793] Meanwhile, by precluding isolated genes from patentable subject matter, the US has shifted the balance to protect public interests.

In regards to the patentability of hESCs, their exclusion in Europe is based on moral grounds, which a jurisdiction has a right to do. However, this thesis argued that the distinction between a therapeutic and commercial use is mistaken, and if Europe does not want hESCs to be patented, they should alter or remove Article 6(2) (c) of the Directive 98/44/EC, which allows for therapeutic or diagnostic uses that are applied to the human embryo to be patentable. Patent offices are not the appropriate arbitrators of morality and ethical questions should be decided Parliament policy makers.

[793] Krauss, J. and T. Takenaka. "Construction of an Efficient and Balanced Patent System: Patentability and Patent Scope of Isolated DNA Sequences under US Patent Act and EU Biotech Directive" in Constructing European Intellectual Property. C. Geiger (ed.) Cheltenham: Edward Elgar, 2013 at 269.

Chapter 5: Exploring perspectives of patenting human genetic materials within the business, legal and civil communities

5.1. Introduction

Both judiciaries and decision-making bodies in the US and Europe have issued judgements holding certain human biological materials as unpatentable subject matter: isolated genetic sequences and inventions derived from hESCs.[794] This has wide implications for industry looking to continue research and development in these two areas. In the US, the Supreme Court has issued a judgement which renders isolated genes unpatentable on the grounds that the act of "separating that gene from its surrounding genetic material is not an act of invention."[795] The decision was symbolic, signalling to industry that there needs to be something more involved than simply isolating a gene for a genetic sequence to qualify as an invention. Meanwhile, the CJEU ruled that a process which involved the removal of a stem cell from a human embryo at the blastocyst stage, thus, requiring the destruction of that embryo, cannot be patented.[796]

While it is known that the industry sector and legal community have various concerns about these two rulings, the evidence base is limited. Recognizing this, an empirical study was conducted to examine the perspectives of the stakeholders with regards to *Oliver Brüstle v Greenpeace e.V.* (C-34/10) (2011) and *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al.* (Fed.

[794] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al*. U.S. Supreme Court. June 13, 2013 and *Oliver Brüstle v Greenpeace e.V.* (C-34/10) (2011)
[795] *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al*. U.S. Supreme Court. June 13, 2013 at 12.
[796] *Oliver Brüstle v Greenpeace e.V.* (C-34/10) (2011)

Cir. 2011).[797] The aim of this study is to examine the stakeholders' perspectives with regards to the case rulings.

This chapter presents the results of an empirical study consisting of 43 interviews/completed surveys undertaken from March to June 2012. The purpose of conducting these interviews was to discover at a qualitative level the answer to the following question: what are the most important issues for the stakeholders regarding the eligible subject matter for patent protection pertaining specifically to isolated genetic sequences and inventions derived from hESCs? Moreover, is the patent system the appropriate forum in which to address ethical and moral considerations? If not, where should they be addressed?

Interview participants were drawn from 3 sectors of society: legal, scientific industry and civil society. As discussed over the course of this chapter, the scientific industry may need to consider what the impact of court rulings could be on their own practices, particularly whether they believe investment in R&D could continue with the knowledge that there are no patents for isolated gene sequences and inventions derived from human embryonic stem cells. In this respect, the data provided here can be used to inform future studies of how court decisions ruling isolated genes and inventions derived from hESCs as ineligible patent subject matter can alter business behaviour. In this vein, several recommendations are made in Chapter 6 with respect to the key concerns voiced by the interview participants, including whether the patent system is appropriate for protecting biotech inventions.

As discussed below, in terms of its participants the empirical study includes stakeholders based in Europe and the US, areas where there is a strong biotechnology

[797] The interviews were conducted between March and June 2012, prior to the US Supreme Court judgement which was released on June 13, 2013. Therefore, participants were asked questions based on the Federal Circuit decision*: Association For Molecular Pathology et al v. United States Patent and Trademark Office et al.* (Fed. Cir. 2011). However, follow up requests for statements were made after the US Supreme Court decision and the participants who responded did not diverge from their previous statements.

sector that will no doubt be affected by the case rulings. It is also important to make clear from the outset that this study does not provide a definitive commentary on the impact of the rulings on the business and legal communities in the two jurisdictions. The study is limited to a particular time as well as to a limited number of carefully selected participants. Nevertheless, this chapter aims to provide a snapshot of the various perspectives on the concept of a gene and the commercial use of an embryo within the scientific industry, legal communities and civil society sectors between March and June 2012, after the *Brüstle* decision but a year prior to the US Supreme Court decision in *Myriad* in 2013.

5.2. Stakeholder Analysis

This chapter will focus on prevailing attitudes of major stakeholders in biotechnology inventions by looking at landmark decisions and opinions of specialists in law and science in considering whether changes need to be made to the patent system, or whether a special set of guidelines is required to protect biotechnology developments. A method of considering intellectual property policy development is to utilise stakeholder analysis.[798] This process encompasses the recognition of key stakeholders, which include the various interests and institutions with a concern with the undertaking of policy. According to R. Edward Freeman, the definition of stakeholder analysis consists of "any group or individual who can affect or is affected by the achievement of the organization objectives."[799] A straightforward stakeholder-derived reasoning for patent policy is that patented products require government control to

[798] For more on stakeholder theory, see: Fletcher, A., et al. "Mapping stakeholder perceptions for a third sector organization." in Journal of Intellectual Capital Vol. 4 Iss. 4, pp. 505 – 527, 2003.Mitchell, R. K., B. R. Agle, and D.J. Wood. "Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts" in Academy of Management Review. Vol. 22, Iss. 4, pp. 853 – 888, 1997 and
Savage, G. T., T. W. Nix, Whitehead and Blair. "Strategies for assessing and managing organizational stakeholders," in Academy of Management Executive. Vol. 5, Iss. 2, pp. 61 – 75. (1991).

[799] Freeman, R.E. Strategic Management: A Stakeholder Approach. Boston: Pitman, 1984 at 46.

establish stability between the competing interests of the main stakeholders in this area: (i) inventor, (ii) investor/producer and (iii) others (i.e. NGOs, consumers).[800]

Defining stakeholder groups

Stakeholder analysis involves identifying primary, secondary and key stakeholders and assessing their interests.[801] Once those interests are identified, conflicts of interests can be ascertained, and interests can be assessed based on influence and importance.

Primary stakeholders are those individuals whose ongoing involvement is vital to an establishment's survival.[802] This group is usually comprised of inventors and investors, along with what is known as the public stakeholder group, which consists of the governments and communities that arrange the economic and legal infrastructures.[803] This primary stakeholder group comprises those who are affected positively or negatively by the establishment's actions. The organization's survival is dependent on its ability to create adequate wealth, value or satisfaction for those belonging to the stakeholder groups.[804] Members of these groups are ultimately affected by legal decisions regarding the patentability of biotech inventions in the following case studies. The scientific and research community and biotech industry members are primary stakeholders in the following case studies.

Secondary stakeholders are agents who are indirectly affected by an establishment's actions, in that they may influence or be affected by the establishment's operations.[805] This group may include special interest groups, and groups who have the ability to

[800] Dutfield, G. and U. Suthersanen. Global Intellectual Property Law. United Kingdom: Edward Elgar Publishing Limited, 2008 at 51-52.
[801] Clarkson, M. "A Stakeholder Framework for Anlayzing and Evaluating Corporate Social Performance," in Academy of Management Review. Vol. 20, No. 1, pp. 92-117, 1995.
[802] Ibid, 106.
[803] Ibid.
[804] Ibid, 107.
[805] Ibid.

activate public judgement in favour of, or in opposition to, an establishment's performance.[806]

External participants: This group includes individuals who inform the debate with their expertise.

The various stakeholders who participated in the debate include:

1. **Inventors, investors and the scientific and research community**: This group includes the researchers, inventors, their funding bodies and employers, which can include academic institutions and industry bodies. These are primary stakeholders. There were a total of 7 participants in this category.
2. **Legal actors**: The second group comprises patent attorneys who arrange patent applications or prosecute and defend them on a regular basis. It also includes judges who make decisions in litigation whilst deciding patent validity and interpreting whether the claimed invention meets the requirements of patentability. These are external participants. There were 20 interviewees in this category.
3. **Civil Society:** This group consists of non-governmental organizations (NGOs) and ethical actors. It includes advocates working on behalf of NGOs who highlight their causes and shed light on the issues, which they may feel the system is not addressing sufficiently. In addition, this group consists of the individuals who comment on the ethics of patenting human genetic materials, many of whom are on ethical committees or are advisors to policy-making bodies. These are external participants. There were 10 interviewees in this category.

[806] Ibid.

An institutional stakeholder map

	Interests	Capacities/Resources	Philosophical/jurisprudential rhetoric
Primary stakeholders			
Inventors and corporate investors	Remuneration Access to patented inventions/knowledge	Financial resources	Property rights, right to equitable remuneration
Scientific community	Access to patented inventions/knowledge	Scientific know-how	Public domain, access to knowledge
Secondary stakeholders			
Consumers	Access to and affordability of scientific technology Enforceable and state-sponsored regime to protect investment/capital	Buying power	Public domain, public interest, access to essential healthcare
External participants			
Legal analysts	Legal certainty	Legal compliance	Property rights, right to equitable remuneration
Ethical analysts	Represent the ethics of a community	Moral regulation	Moral underpinnings in conjunction with practical ethics
NGOs	Access to information	Power to advocate	Public domain, public interest, access to essential healthcare

As a result of the different interests and values each group represents, it is difficult to expect all of the stakeholders to possess the same view on questions relating to this topic area. The next section will focus on the first case study, in which the scientific industry and legal participants' answers to three questions regarding the patent eligibility of isolated genetic sequences, looking at both the US District and Federal Circuit rulings pertaining to Myriad's BRCA1 and BRCA2 patents.[807] This will be followed by the second case study, which is centred on the commercial exploitation of inventions concerning the uses of human embryos in *Oliver Brüstle v Greenpeace*

[807] *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al (2010)* and *Association for Molecular Pathology v United States Patent and Trademark Office et al (2011)*

e.V.[808] Both proponents and opponents of patenting inventions arising from the commercial and therapeutic uses of hESCs will be presented.

The following two cases are selected to demonstrate and deliberate some facets and difficulties of patenting human genetic inventions. The core of the dispute is a debate over whether patenting human genetic materials should occur at all. Despite the fact that thousands of gene sequences have been patented, part of the reason the debate persists is because genes are recognized more as programmed information than mere chemical substances.[809] In addition, patents on inventions derived from hESCs are another heavily disputed area, which stems from a combination of political, economic and legal factors. In Europe, it has encountered opposition from an ethical and political standpoint, whilst in the US, there is a challenge based on the notion that a human embryo is a 'product of nature.'

There are two main practical issues with gene patenting. First, granting companies patents on genes can lead to abusive behaviour. The case *Association for Molecular Pathology v. U.S. Patent and Trademark Office (2010)* highlighted the issue with granting gene patents related to instances of breast cancer to Myriad Genetics, which was criticized for monopolizing the industry and engaging in abusive behaviour. A UK cancer company uploaded the genetic sequence of BRCA2, one of the genes associated with breast cancer, to the Internet. Myriad Genetics downloaded the information, and received a patent for the gene.[810] The second argument against patenting genes is that they will hinder research and development, where researchers

[808] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011.
[809] The Nuffield Council on Bioethics states DNA sequences "are the body's way of carrying information as to how proteins are to be constructed. But this kind of information, it will be said, cannot be properly patented. It may be discovered and stored on a database which carries a charge for access; but it is simply not eligible for patenting." Nuffield Council on Bioethics. The Ethics of Patenting DNA: A Discussion Paper, at 27.
[810] Myriad Genetics' behaviour had several effects on how certain countries implemented EU law. For instance, France's rules on gene patenting are stricter, given how Myriad Genetics acted upon receiving the patents.

need to obtain many licenses from patent holders before a product can be developed, and lead to a "tragedy of the anticommons."[811]

5.2.1. Myriad's BRCA1 and BRCA2 patents

The debate surrounding whether or not DNA sequences should be patentable has largely been centred on one particular set of patents which relates to what has been termed the "BRCA1" and "BRCA2" patents owned by Myriad Genetics, Inc. (Myriad). Myriad received patents on BRCA1 and BRCA2 in the US and the EU and litigated in both jurisdictions, although with different outcomes. Myriad obtained patents on the *BRCA1* and *BRCA2* genes after discovering their precise location and sequence, which claimed mutations that are associated with increased risk of breast and ovarian cancers. Once Myriad determined the genes' characteristic nucleotide sequence, they were able to develop diagnostic tests for the detection of mutations in the genes to assess a patient's cancer risk. These patents gave Myriad the exclusive right to isolate BRCA1 and BRCA2 genes and also the right to synthetically create BRCA cDNA.[812] Myriad was the exclusive provider of BRCA1 and BRCA2 testing.[813] However, Myriad's patents did not deter some institutions from developing their own tests and in response, Myriad sent out cease and desist letters.[814]

5.2.2. Ethical Objections to Myriad's Gene Patents

Aside from the technical grounds (which will be discussed below) for oppositions against Myriad's patents, there was inherent policy and ethical

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[811] Heller, M. and R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science. Vol. 280, pp. 698-701, 1998 at 3

[812] *AMP v Myriad* (2013) at 1.

[813] Myriad did license 13 laboratories in the United States to provide single mutation testing, which applied in instances where a woman whose test discovered a mutation and her female relatives wanted to be tested for the same mutation. Instead of undergoing the full BRCA1 and BRCA2 test, the relatives could instead opt to test their gene against the discovered mutation, which was one-tenth of the cost. Myriad only licensed this single mutation follow-up testing after a woman had paid for and undergone Myriad's own genetic testing kit. See Gold, R. and J. Carbone, "Myriad Genetics: In the eye of the policy storm" in Genetics in Medicine. Vol.12, No.4, S39–S70. April 2010 Supplement.

[814] See La Belle, M. "Standing to Sue in the Myriad Genetics Case" in California Law Review Circuit.Vol.2, November 2011 at 77-78.

apprehension. The main concern was the restrictions the patents could place on medical practice and the monopolization of genetic testing. France's Institut Curie released a press statement articulating that Myriad's broad patents would ensure a monopoly position that would seriously hinder research and public health:

> Not allowing French and European laboratories to perform testing or initial family mutation searches will lead to a loss of technical and medical expertise which will probably in turn lead to a decrease in funding allocated to such laboratories. The loss of expertise and of funding would not be trivial for basic research which is critical for the future of medical genetics. It would therefore not be without repercussions either for the development of genuine preventative care for high risk women.[815]

This "unacceptable monopoly" raises the question of how to balance patent law with health objectives. It cannot be denied that there are significant medical benefits with the creation of diagnostic tests like the BRCA1 and BRCA2 diagnostic kits that Myriad created. But there is still debate about how the patent system should address such tools, and whether they should be protected under the patent system for the sake of promoting greater access to the technology in question, including the development of better diagnostic kits and access to testing. However, it is difficult to strike the right balance. As long as the private sector is the primary body for investing in and developing genetic therapeutics, biotech companies will continue to need some level of exclusive control over the developed technologies to recoup on their investment.

5.2.3. The US patent

A. The District Court's invalidation of Myriad's gene product patents:

In March 2010, Myriad Genetics lost aspects of its patent rights to two breast cancer genes after civil rights groups legally challenged the validity of their patents. [816] The American Civil Liberties Union filed the case against Myriad Genetics on behalf of many different groups including doctors, scientists, cancer patients, and non-profit research groups. The plaintiffs sued to nullify the patents held by Myriad Genetics and

[815] Institut Curie, Press Office: Against Myriad Genetics's [sic] monopoly on tests for predisposition to breast and ovarian cancer. September 12, 2001. Paris.
[816] *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, No. 09-cv-4515, 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010).

the University of Utah Research Foundation for two human genes related to breast and ovarian cancer. Myriad had prohibited anyone else from performing diagnostic tests and conducting research. This case provided the first opportunity to test the legal validity of gene patents, which have been subject to controversy since the completion of the Human Genome Project, yet the USPTO has continued to grant gene patents. Genomes of genetically-engineered organisms have long been rendered patentable because they are something new and an invention. Other patents in this case include those for the methods of isolating segments of DNA, deemed to be purified genes that are claimed not to be found in nature, and methods or processes that *make use of* DNA segments.

The claim in the composition patent reads as follows: “An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”

The key statutory provision applied in the case was section 101 of Title 35 of the US Code, which provides as follows: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

Consequently, the court had to determine whether the relevant segments of DNA and the processes used to test for them could be classified as a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." In the past, scientific principles, laws of nature, things occurring in nature and abstract ideas were deemed to be outside the realm of patentable subject matter.

In the past, there was an exception to the ‘product of nature’ doctrine if the subject matter was purified. In *Parke-Davis*, it was held that the ban on patenting ‘products of nature’ did not apply to purified substances that were of practical, commercial, and therapeutic value. This ruling established that purified DNA was

eligible for patenting. However, this exception was considered to be inapplicable by Judge Sweet, holding that the isolated DNA contained sequences that were found in nature, and therefore unpatentable under 35 U.S.C §101.[817]

Myriad claimed that they had "isolated" and "purified" the DNA segments in question, and that these had markedly different characteristics, or were fundamentally distinct from, what was found in nature. But Sweet held that the composition patents were invalid and the DNA segments were products of nature, and not an 'invention.' Sweet held that isolated DNA was the same as naturally occurring DNA in cells.

> Indeed, the relationship between a naturally occurring nucleotide sequence and the molecule it expresses in a human cell - that is, the relationship between genotype and phenotype, is simply a law of nature. The chemical structure of native human genes is a product of nature, and it is no less a product of nature when that structure is 'isolated' from its natural environment than are cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth.[818]

The case established that mere extraction and purification of a naturally-occurring chemical element or compound would not be patentable (the process for doing this might be, but not the extracted and purified substance itself). Myriad argued that a purified substance not found in nature in pure form was patentable, but this was rejected.

Thus, the question was whether Myriad had patented something with markedly different characteristics from naturally-occurring DNA. On this, it failed. Assessing whether the isolated DNA was "markedly different" from its naturally occurring form on the basis of its genetic information, Judge Sweet reasoned, "[b]ecause the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter under 35 U.S.C. §101."[819] As a result, claims for isolated DNA are not eligible subject matter for patenting under s.101. Unlike the genetically engineered microorganisms in *Chakrabarty*, the unique chain of chemical

[817] Association for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181,186–89 (S.D.N.Y. *2010).*
[818] Ibid at 10-11.
[819] Ibid at 135.

base pairs that induces a human cell to express a BRCA protein is not a "human-made invention." Nor is the fact that particular natural mutations in that unique chain increases a woman's chance of contracting breast or ovarian cancer.

In sum, the District Court invalidated Myriad's two composition of matter gene patents on the basis that the patented DNA sequences resembled the equivalent naturally-occurring DNA in encoding the same genetic information. "The USPTO and the courts, including the Federal Circuit...have uniformly acquiesced. Now a federal court has said that, no, genes aren't just chemicals - precisely because they carry information."[820] This approach was not adopted by the Federal Circuit, choosing to assess whether the claimed DNA sequences were "markedly different" from their natural counterpart on the basis of whether they possessed a distinctive chemical identity. The decision was appealed and heard by the Court of Appeal for the Federal Circuit (CAFC) in 2011,[821] which overturned the District Court's ruling that the isolated gene sequences were invalid.

B. Federal Circuit decision: isolated genes are eligible for patent protection

In July 2011, the US Court of Appeals for the Federal Circuit restored the law to its prior status before the District Court's invalidation of Myriad's patents on BRCA1 and BRCA2 genes in March 2010 and verified the patentability of isolated DNA molecules that included short primer and probe sequences, longer DNA sequences and cDNA sequences.[822]

The panel consisted of three judges: Lourie, Moore and Bryson. The majority, consisting of Judges Lourie and Moore, held that all isolated DNA was patentable subject matter. Bryson dissented, claiming that although cDNA sequences were

[820] "Federal District Judge in Manhattan Says That Isolated and Purified Genes Are Not Patentable Because They Are Products of Nature" in Biotechnology Law Report, 29, 307, Nov 3, 2010
[821] *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed.Cir. 2011).
[822] Ibid.

patentable because they were not found in nature, DNA was not because there were no "marked differences" between the isolated DNA and natural DNA found in chromosomes.

Like the District Court, the Federal Circuit relied on the standard set out by *Chakrabarty* and *Funk Bros*. In *Chakrabarty*, a genetically engineered bacterium was held to be patentable because it possessed "markedly different characteristics"[823] from other naturally occurring bacteria. However, in *Funk Bros*., six bacteria strains with new behaviour were held to be unpatentable because none of the bacteria had achieved a new use. [824] Writing for the majority, Judge Lourie merged these two decisions and wrote that the issue was whether the invention had 'markedly' different characteristics from what exists in nature.

Both Judges Lourie and Moore emphasized that Myriad's claimed cDNA sequences did not exist in nature, were created by man and were patentable subject matter. In regards to isolated DNA, Judge Lourie maintained that isolated DNA sequences were different from naturally occurring DNA because they had different chemical structures, and that this chemical difference between the isolated DNA and naturally occurring DNA was sufficient to make isolated DNA sequences patentable.

> *BRCA 1* and *BRCA2* in their isolated state are not the same molecules as DNA as it exists in the body, human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a *distinctive chemical identity* from that possessed by native DNA.[825]

In arriving at this conclusion, Judge Lourie utilized the "breaking covalent bonds" test:

> Isolated DNA has been cleaved (i.e. Had covalent bonds in its backbone chemically severed?) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. For example, the BRCA1 gene in its native state resides on chromosome 17, a DNA molecule of around 80 million nucleotides. Similarly, BRCA2 in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast, isolated BRCA1 and BRCA2, with introns, each consist of just 80,000 or so nucleotides...Accordingly, BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in

[823] *Chakrabarty*, 447 U.S. at 310
[824] *Funk Bros*., 333 U.S. at 129-130.
[825] *Association for Molecular Pathology v US Patent and Trademark Office et al653* F.3d 1329 (Fed. Cir. 2011) at 42.

> cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA.[826]

Judge Lourie's employment of the "cleaving covalent bonds test" enabled him to come to the conclusion that Myriad's isolated BRCA1 and BRCA2 gene sequences were markedly different from their larger natural state. Yet, this position has been met with mixed reactions.[827]

Although Judge Moore agreed with Judge Lourie that isolated DNA was patentable, Moore's interpretation differed from Lourie's claim that isolated DNA was patentable simply because of its differing chemical structure from naturally occurring DNA. In fact, Judge Moore rejected Judge Lourie's approach: "Although the different chemical structure does suggest that claimed DNA is not a product of nature, I do not think this difference alone necessarily makes isolated DNA so 'markedly different.'"[828] In her concurring opinion, Judge Moore focused on the function and informational content between natural and isolated DNA sequences. Isolated DNA sequences had to have a "significant new utility as compared to nature"[829] for them to be patentable. She noted that short, isolated DNA sequences could be useful as primers and probes, which could satisfy the "markedly different" test as they were (1) chemically different from naturally occurring DNA and (ii) possessed a "different and beneficial utility."[830]Judge Lourie however, did not address whether the claimed isolated DNA sequences had new functions, only their chemical structure.

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[826] Ibid at 17

[827] Interview with Tim Roberts on February 7, 2012: "I would agree with Judge Lourie when he says these are chemical compounds having particular sequences. I think where I disagree with him, is where he says they're best described in patents by their structures rather than by their functions. That's quite frequently true. It's not always true, I don't feel. The point of an invention is probably best described by structure, usually. But sometimes putting two functions together will produce a novel effect and can be a proper way of distinguishing and I would regard that as generally applicable across patents, not specifically applicable solely in this area. With DNA, you can produce the same protein, I think, from more than one DNA sequence...the novel point of the invention is producing a particular protein and it may even be possible to make small changes within that protein without affecting its function. If it's producing a new protein with a particular function, then it may be proper to describe the DNA in terms of its function in producing that protein."

[828]Moore concurrence at 14.

[829] Ibid at 7.

[830] Ibid at 14.

Judge Moore considered policy implications of invalidating Myriad's patents on the claimed DNA sequences, emphasizing the impact of disturbing thirty years of patent practise and "settled expectations and extensive property rights."[831]Moore decided to leave it to Congress to decide whether DNA sequences and genes should be patented and was not comfortable with having a lower court enlarge the scope of patentability exceptions. This concern about retroactive impact can create a "one-way ratchet in patent law."[832]

Like Judges Moore and Lourie, Judge Bryson also applied the *Chakrabarty* test, although reaching an entirely different result than his two colleagues. Judge Bryson dissented, rejecting the importance of the different chemical structure between isolated DNA and its natural counterpart.[833] He also dismissed the utility of isolated DNA, maintaining that the mere fact that DNA was isolated and purified from its natural state did not garner it patentability status, writing "there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is altered or broken."[834] Since Judge Bryson found no significant differences between the isolated form and naturally occurring form, he held that isolated DNA was not patentable subject matter. The case was appealed and went to the Supreme Court. In 2012, the Supreme Court granted *writ of certiorari* and remanded the case back to the United States Court of Appeals for the Federal Circuit for further deliberation in light of *Mayo v. Prometheus.*[835]

[831] Ibid at 19.
[832] Rai, A. "Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development," in Duke Law Journal. Vol. 61, 2012 at 149.
[833] Bryson dissent at 6.
[834] Ibid at 7.
[835]*Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc. 566 , 132 S.Ct. 1289, 101 USPQ2d 1961 (2012)*

C. US Supreme Court invalidates gene patents

The US Supreme Court reversed the Federal Appeal Court's ruling on June 13, 2013[836] and invalidated Myriad Genetics' product claims for the BRCA1 and BRCA2 genes on the basis that the patent claims were directed at products of nature. The Supreme Court's approach to the isolation of DNA was that isolating genes from their surrounding naturally occurring environment was not enough to warrant a patent: "genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."[837]

The issue was determining whether Myriad's patent claimed a "new and useful composition of matter" according to §101 or naturally occurring phenomena.[838] The court reiterated the essential purpose of the patent system, which was to strike a balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention."[839] The decision is remarkably similar to the amicus curiae brief submitted by the US Department of Justice, on behalf of the US government.[840] The US government acknowledged that the USPTO's practise of granting patents for isolated genes and DNA sequences is wrong as these are still products of nature:

> The district court correctly held, however, that genomic DNA that has merely been isolated from the human body, without further alteration or manipulation, is not patent-eligible. Unlike the genetically engineered microorganism in Chakrabarty, the unique chain of chemical base pairs that induces a human cell to express a BRCA protein is not a human-made invention…The chemical structure of native human genes is a product of nature and it is no less a product of nature when that structure is 'isolated' from its natural environment than are cotton fibres that have been separated from cotton seeds or coal that has been extracted from the earth.[841]

[836] *AMP v Myriad (2013)*
[837] Ibid at 18.
[838] Ibid at 11
[839] Ibid.
[840] No. 2010-1406.Brief for the United States as Amicus Curiae in Support of Neither Party, written by the Assistant Attorney General in The Association for Molecular Pathology et al. v. United States Patent and Trademark Office and Myriad Genetics, Inc. (2010).
[841] Ibid at 10-11.

The Court applied the reasoning in *Chakrabarty* to the case, holding that the scientists in *Chakrabarty* added four plasmids to the claimed bacterium which resulted in its ability to break down crude oil, which was why the bacterium was found to be new with markedly different characteristics. In contrast, the Court acknowledged that Myriad had found an important and useful gene, but had not created anything, because "separating that gene from its surrounding genetic material is not an act of invention."[842] Therefore, the important criterion is that there is a marked difference between the claimed product and the naturally occurring one.

> It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create? or alter the genetic structure of DNA.[843]

The Court maintained that the value of Myriad's claims was directed at the information contained within the claimed nucleotides rather than at the chemical composition itself.

> Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.[844]

Perhaps the most striking part of the Supreme Court's decision was to differentiate between isolated DNA and cDNA, holding that a "naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."[845] The decision echoes sentiments contained in the amici brief pertaining to cDNA molecules, maintaining that it is patent eligible subject matter because they are:

> synthetic molecules engineered by scientists to incorporate, in a single contiguous DNA segment, only the exons (i.e. protein-coding sequences) of a naturally occurring gene?…such molecules do not occur in nature, either in isolation or as contiguous sequences contained within

[842] *AMP v. Myriad* (2013) at 12.
[843] Ibid at 11-12.
[844] Ibid at 14.
[845] Ibid at 2

> longer natural molecules, but instead must be synthesized by scientists in the laboratory from other genetic materials.[846]

The Court chose to emphasize that synthetically engineered products that do not naturally exist in the human body are patentable subject matter, which reflects the Court's concern over the impact of the decision on other genetically derived inventions. As a result, the focus now shifts from isolated genes to cDNA, which challenges the normal gene approach with two questions: whether it naturally occurs in nature, and also the question of the utility/industrial application of cDNA. cDNA does not naturally exist in the human body, but can be naturally produced through the processes of certain retroviruses.[847] cDNA is also more useful for researchers who seek to study diseases associated with a particular gene because it is shorter than natural DNA which makes several laboratory operations achievable that could not be done with natural DNA.[848] Although the Supreme Court's decision pertained to isolated and purified products generally, it limited the decision to DNA.

The case highlights the issues associated with how patent law should address inventions encompassing informational content. The issue will persist with the growth of personalized medicine.[849] Part of the difficulty with genetically derived inventions can be traced to confusion about the nature of genes and the language that is expressing the content of genes.[850] The question that needs to be answered is whether a DNA sequence represents one of the building blocks of scientific exploration, and whether a patent for a DNA sequence will obstruct scientific exploration by suppressing an elementary idea. By declaring isolated DNA sequences as 'products of nature' and not

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[846] No. 2010-1406. Brief for the United States as Amicus Curiae in Support of Neither Party, written by the Assistant Attorney General in The Association for Molecular Pathology et al. v. United States Patent and Trademark Office and Myriad Genetics, Inc. (2010) at 15.
[847] Feldman, R. "Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law" in Stanford Law Review. Vol. 63, 2010-2011 at 1388.
[848] Ibid.
[849] "Personalized medicine is an area of applied research devoted to developing tests that operate on biological and clinical data from a patent (e.g., protein levels, genetic mutations, medical history) to provide diagnoses, prognoses, and treatment regimens specific to the patient." Feldman, R. Rethinking Patent Law. Cambridge: Harvard University Press, 2012 at 128.
[850] Ibid at 131.

markedly different from their naturally occurring counterparts to be considered a "new composition of matter within the context of 35 U.S.C §101," the decision could have significant importance to industry. This is because the courts can be interpreted as expanding the natural product exception to patent eligibility whilst simultaneously narrowing the areas of biotechnology inventions that can be patented in the country. Moreover, the decision enlarges the gap between US patent law and EU patent law.

5.3. *AMP v. Myriad* Case Study- Biotech and Legal Stakeholders

A set of three questions were posed to the scientific industry and legal stakeholder participants about the case to discover whether participants agreed with the main lines of reasoning adopted by the US judiciary regarding patenting isolated genomic sequences.

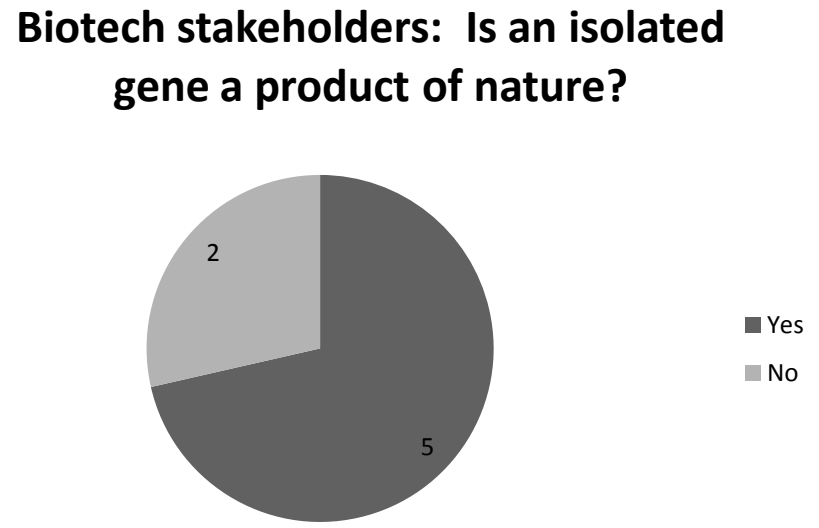
1. In March 2010, the District Court invalidated Myriad's BRCA1 and BRCA2 patents, declaring the isolated gene sequences to be "products of nature."[851] Do you agree with this?
2. Do you think isolating and purifying a naturally occurring gene makes the claimed matter 'markedly different' from a naturally occurring form?
3. Judge Sweet held that DNA sequences should not be treated the same as other chemicals in regards to patenting because of their "information rich quality." However, Judge Lourie took a different approach, stating: "genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions." Who is right?

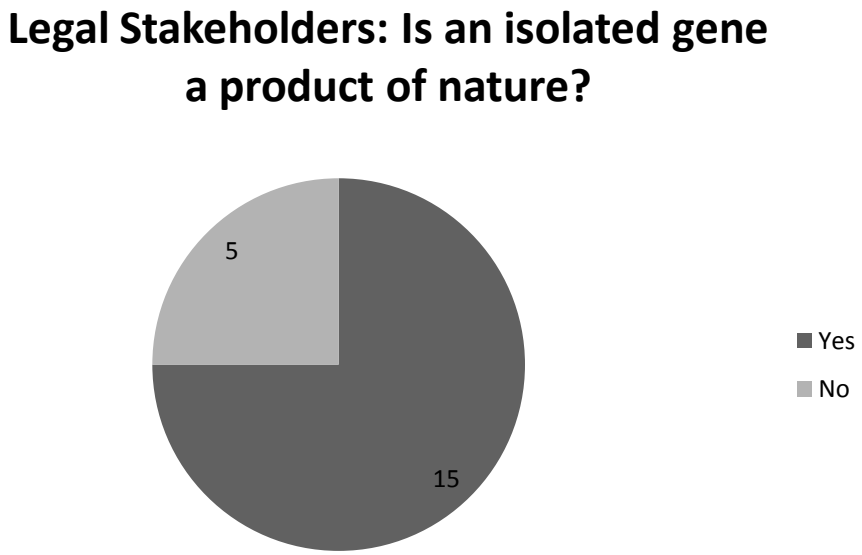
5.3.1. Is an isolated genomic sequence a product of nature?

Most respondents from both the biotechnology and legal sectors believed that an isolated genomic sequence is a product of nature. 5 out of 7 biotech respondents and 15 out of 20 legal respondents maintained that District Court Judge Sweet was correct in

[851]The product of nature doctrine is prominent in the distinction between discovery and invention in the United States patent case law.

maintaining that Myriad's isolated BRCA1 and BRCA2 genomic sequences were products of nature.[852]





This line of reasoning is tied to the invention/discovery dichotomy, in that a product of nature is seen as a discovery and not an invention. [853] The reason for this position is that genes already exist in the world and they are not invented *per se*.

[852] Frequencies are shown rather than percentages due to low sample size.

A German-based lawyer argued that merely isolated genetic resources should not be eligible for patent protection because they are found in nature and not inventive:

> Genetic resources are normally not invented, they're just found in nature and should not be protected by patents...It's a way how [sic] genetic resources come into the biosphere, it's not by invention, but by evolution.

He argued that if companies start patenting those blocks of information, then they can extend their intellectual property to whole living beings which are not created by an invention, but by evolution. Consequently, he maintains that this can be quite detrimental to the medical area for all research and innovation if human gene sequences are patented, pointing to the example of the *Myriad* case:

> The function was known before, and they were simply looking for the DNA structure, which is related to the function, so what was surprising in that case? It is like you have a map, and treasure is hidden, and you follow this map and then go to the treasure. You did not invent the treasure, but you found it. That's very similar in most cases, [to] patents for human gene sequences. I think this judgement goes in the right direction. But from a European perspective, you have to take a different argument.

As illustrated above, there is some difficulty with the idea of a gene as an invention since it already exists in nature. The counter-argument to this is of course that isolated genes are not found in nature and thus different from naturally occurring genes. Lord Hoffman claims:

> Isolated genes are not products of nature. In nature, there are no isolated genes wandering about. They're in people. Its absolute nonsense, isn't it? Because if you take a gene in nature, one of the characteristics of that gene is it's got a lot of other things attached to it. If you take an isolated one, it hasn't got a lot of the things attached to it. And that is the difference between them. They're not identical. I mean, what of course you can say, and it may be that by now, the method of isolating the gene makes it obvious and therefore, the isolated gene although it is patentable, fails because there is no inventive step in producing it. But that's a question of fact. Maybe it is, maybe it isn't. But if it is inventive to find a way of isolating the gene, then I can't see why it shouldn't be patentable.

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[853] When patent applications for products of biotechnology are submitted, and patent offices must determine which side of the line the claimed invention falls on, be it a discovery or an invention before an application can advance this sentence is not complete/needs rewording. This issue is well demonstrated by the following statement:
"DNA is a polymer which is a natural product, and most, but not all, sequences of interest in DNA are present somewhere in nature. It is worth recognizing explicitly that most of what recombinant DNA methodology is doing at the present time is taking genes out of one genetic context in nature where, at least for our immediate purposes, they are not directly useful to us, and putting them in another genetic context where they are more useful. To what extent the Patent Office and the Courts will hold that a pre-existing sequence of base pairs which has been isolated and amplified by gene splicing methods is a "product of nature" and therefore not patentable remains to be determined." Jackson, "Patenting of Genes: Ground Rules in ASM, Forum on Patentability of Micro-organisms" 17 (1981) at 25 In: Cooper, I.P., "*Biotechnology in the Law - 1995 Revision*" v. 1 (Clark, Boardman, Callaghan: New York, N.Y., 1995).

In a similar vein, a Justin Turner, a UK barrister provided an example of an instance where something which naturally existed, when isolated, qualified as an invention. He emphasized that antibiotics were an "unexpected" invention and warranted patent protection:

> The nature of the patent is you cannot define what people will do. They are always doing the unexpected. A patent should be something unexpected. To be able to find a gene that was not obvious, that no one else was able to find, and to be able to isolate and produce proteins from it, to produce things that treat diseases will do...Look at antibiotics. Antibiotics were isolated from soil samples, from Venetian sewers. You take a bug, and it produces an antibiotic. I mean, at some point you can say you have not invented anything. But get real; at the end of it, you have got a medicine that is stopping people of [sic] dying from suffocating sores. Where before, you have not. Of course, you can argue philosophically that it is different, it is materially different from a machine that you have built."

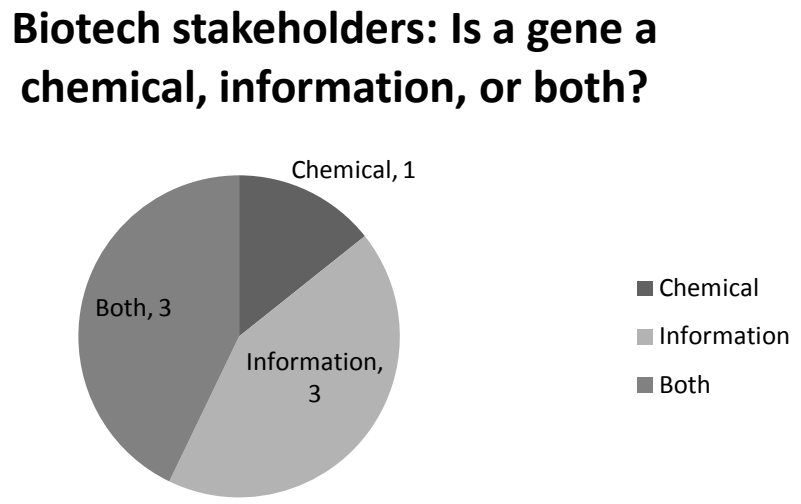
This comment highlight that in the case of gene patents, this issue is whether the isolation and purification of the naturally occurring substance is obvious. In other words, where a product of nature has been discovered, the issue is rather a question of obviousness, rather than whether it is a product of nature. In the case that the gene is isolated and an unexpected or non-obvious/inventive practical application has been identified that serves a useful function, this strongly points to the justification of a patent provided it fulfils the other criteria of an invention.

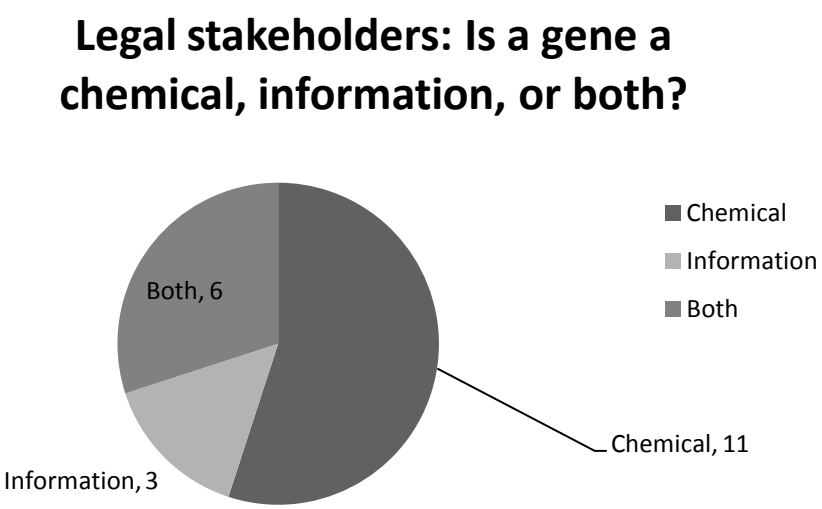
In light of this, and the comments made above, it is reasonable to summarize that any product of biotechnology which qualifies as an artificial replica of a product which occurs in nature faces the question of patent eligible subject matter in the United States.

5.3.2. What is a gene: chemical, information or both?

The question of "what is a gene" was addressed in *Myriad*. Both the District and Federal Circuit courts addressed the issue in different ways. The District Court placed a deep emphasis on the notion of genes as information, which allowed it to come to the conclusion that the claimed isolated gene sequences were equivalent to the naturally occurring genomic DNA as they encoded the same genetic information, and therefore the isolated gene sequence was not "markedly different" and should not be granted a

patent. The Federal Circuit, however, adopted a different stance, opting to assess whether the claimed isolated DNA sequences were "markedly different" from their natural counterparts on the basis of chemical-structural difference rather than their informational difference. The interview participants were asked whether they agreed with the District Court judge or with the Federal Circuit decision. As will be shown in the next section, attitudes are nuanced over whether a gene is a 'carrier of information,'[854] a chemical, or both.





[854] Rai, A. "Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials" in Washington University Journal of Law and Policy. Vol. 2, pp. 199-227, 2000. The article discusses the relationship between the USPTO and the Court of Appeals for the Federal Circuit (what is now known as the US Federal Circuit).

Several legal interviewees argued that isolated genomic sequences are merely chemicals. Julian Cockbain, a UK-based patent attorney remarked:

> They are chemicals, simple as that. They are chemicals that carry information. But they're chemicals. It's a bit like a computer program on a disk. It's still a disk, even though it carries information.

Another UK-based patent attorney, Nick Bassil, reiterated this position:

"Genes are just polymers of chemical compounds."

By contrast, UK scientist Tim Hubbard, Head of Informatics at the Wellcome Trust Sanger Institute emphasized that it is an isolated gene's function that is important in patenting:

> The position for a patent for a composition of matter must be linked to a function - you have to show that it has some novelty, that's a principle of patenting, isn't it? Just saying what it does is not enough. You have to show an application.

Another argument comes from a GlaxoSmithKline patent attorney, who emphasized that it is both:

> I think chemically, a DNA molecule, you can describe it chemically and you can describe the sequence of A, G, T, C. You can describe and modify bases and what you have is information. The EU has an extra layer of information on that, that if you know what the sequence does and what it encodes for and the downstream processes and the subsequent proteins that are involved as you go along. So for me, they're both right. You can describe DNA chemically and you can say it is a source of information.

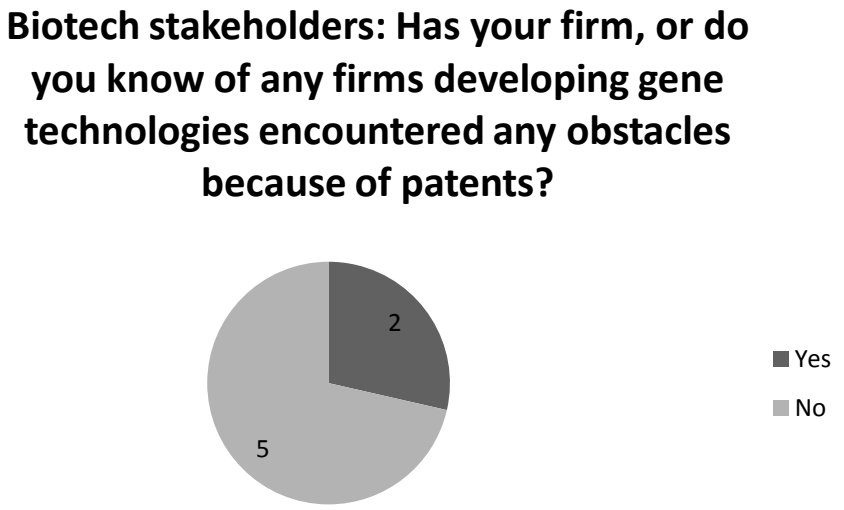
This comment highlights that isolated genomic sequences are chemicals and also carriers of information. Similarly, Justin Turner stated that EU law requires that gene patents be described by its function in addition to its chemical sequence:

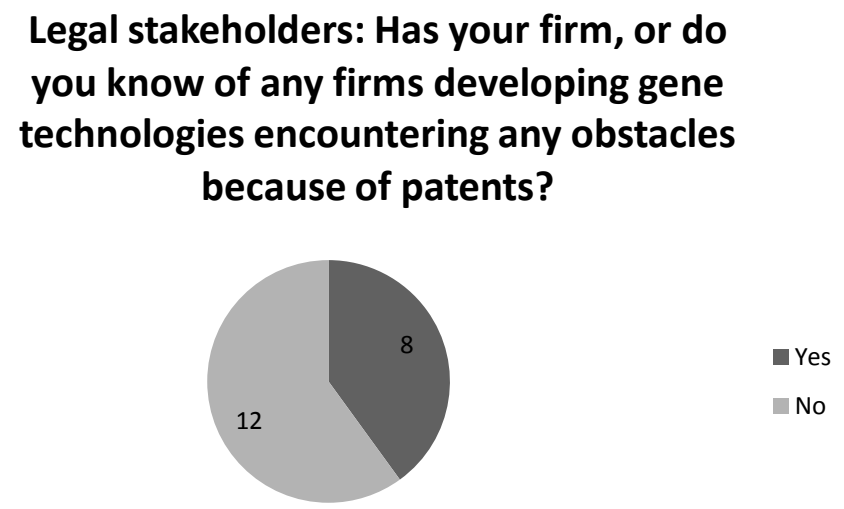
> Particularly under the Biotech Directive, and this is what HGS was all about, that yes, you need to describe a gene. Usually, you won't get a patent unless you describe it by reference to its structure, its sequence. You can't get a patent on a gene unless you also describe its function, its industrial application. One has to look at context, but I think they need to be described by their structure and their function.

The responses here suggest that it is difficult to articulate exactly what a gene is, and how an isolated gene should be assessed in comparison with a naturally occurring gene - whether chemically, if there is a functional difference, or both.

5.3.3. Gene patents as roadblocks?

The question of whether gene patents have impeded research is of legitimate concern both in the legal community and in industry. For potential researchers, there may be concern that gene patents can obstruct research. However, more than half of the respondents said they have not encountered or know of anyone who has encountered any obstacles whilst developing gene technologies because of patents. On this issue, Yen Choo, founder and executive chairman of Plasticell commented that any blocking effect from a patented invention was expected, stating that: "any genetic research will be held up" as a result of patents on genetic sequences.





Interestingly, some of the interviewees admitted that they have encountered obstacles as a result of patents, but noted that this is a justified effect of and part of the nature of the patent system. Justin Turner stated:

> Patents are obstacles all the time. I mean patents form webs of complexity and so yes, absolutely. And that's pretty common, that sort of situation where an early innovator gets broad protection and people are always working within that protection. Subsequently, they are nesting within each other. And they always have to go to the person next up in line. So I've got a case at the moment, which is by a way of making antibodies, and manipulate the genes to make an antibody, and several patents in this area and that anyone who makes artificial antibody has to pay royalties to these people. So I think it's a real problem, it's a problem which is justifiable I mean, it's a nature of monopolies. People are going to infringe them. In an ideal world, you can negotiate a royalty. And in a non-ideal world, the government may be able to get a compulsory license.

In this vein, Trevor Cook noted that there are various mechanisms in place within the EU patent system which allows non-commercial use of patented information pertaining to protected genetic sequences:

> In relation to research in the area to the extent research may be divorced from any commercial outcome. We have in Europe a very broad experimental use defence. Now I don't think that extends to the use of an established unknown linkage between a gene and a condition, like doing tests to people if you know the linkage or condition extends to finding your understanding, whether it has a commercial outcome.

Turning to the US, Cook pointed to the Bolar exception which in effect narrowed the experimental use defence, but stated that the Merck/Integra[855] decision broadened the defence for downstream and upstream applications.

> From the point of view of research, I don't think in fundamental research in improving something, or understanding something, I don't see patent claims will impede that in whatever sense whatsoever. Where they might impede it is in a commercial sense because do you want to work in an area which is already patented or where you may be paying tribute to some dominant patentee? Then you'll be doing work to commercialize it anyway. If there's a significant obstacle for the next generation of innovation is probably not having patents.

On this point, there is the view that not granting patents for genetic sequences could be more harmful in the long run compared to granting them in the present and experiencing some obstacles as a result.

[855] *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193 (2005). This US Supreme Court decision holds that the research exemption or "FDA safe harbor" (§ 271(e) (1) applies to (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA.

5.4. Brüstle case study (civil society stakeholders)

The patenting of particular inventions in the field of the life sciences has raised questions of an ethical nature. Stem cell-related technologies have been a primary area for condemnation by certain social groups, and the patent system is an easy target compared to science itself. Attention is then directed towards patent law to seek answers to questions of ethics. It should be remembered that a patent provides the patent holder the right to exclude others from practising the invention. Whether a patent is granted or not does not determine whether an activity is legal or not. In other words, if a society wants to ban a certain type of invention which is perceived to be ethically unsuitable from entering the marketplace, then excluding it from patent eligibility is inadequate.[856]

This section will examine and analyse the various objections to patents directed at hESCs and possible defences as well. IVF procedures have been popular and widely accepted in several countries as a positive practice in helping women get pregnant. The debate arises from deciding what should happen to the spare embryos which remain after IVF procedures.

The case study focused on the CJEU's decision in *Brüstle.*[857] This case stirred a vast amount of discussion about whether inventions related to hESCs should be excluded from patentability on the basis of morality considerations. Coordinators of multinational European stem cell projects who work with both adult and embryonic stem cells wrote a letter to *Nature* on behalf of 12 signatories in response to the recommendation of Yves Bot, [858] the Advocate-General the European Court of Justice to prohibit patents involving human embryonic stem cells on ethical grounds:

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[856] Directive 98/44/EC is a prime example of a special regulation which the European Parliament enacted as a means to answer some of those questions.

[857] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011.

[858] Bot, Yves. Opinion of Advocate General. Case C‑34/10: Oliver Brüstle v. Greenpeace Ev. Delivered on March 10, 2011. It should be noted that the Advocate General's Opinion is non-binding on the European Court of Justice. As Advocate General, Bot's role was to propose an independent legal solution to the case.

> We write to express profound concern over this recommendation…Embryonic stem cells are cell lines, not embryos. They are derived using surplus in vitro fertilized eggs donated after fertility treatment and can be maintained indefinitely. As more than 100 established lines are now supplied through national and international cell banks, concern about commercialization of the human embryo is misplaced.[859]

The above quote illustrates that there is debate over what an human embryonic stem cell consists of. Whilst the CJEU has treated it as an actual embryo, one can argue that it is actually a cell line; the rationale being that since cell lines are eligible patent subject matter, embryos should be as well since they are cell lines.

The following section provides some significant viewpoints from the civil society interviewees.

5.4.1. What is the definition of a "human embryo"?

Some of the interviewees remarked that the definition of 'embryo' is not clear. First, there is no definition of an "embryo" in Directive 98/44/EC, which has created some uncertainty as to what an embryo is.[860] The scope of the definition is contingent on either a narrow or broad interpretation of embryo. A narrow interpretation of the term means that hESCs derived from embryos created by artificial means like IVF are not barred by Directive 98/44/EC and are patentable since they are neither intended to nor possess the capacity to develop into human beings.[861] The CJEU in *Brüstle* adopted a broad concept of 'human embryo' which rendered all embryos unpatentable no matter their source of origin and their future capacities:

> The context and aim of the 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 wide sense.[862]

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[859] Smith, A. "'No' to ban on stem-cell patents" in Nature. Vol. 472, April 28, 2011.
[860] See 4.4.4 for more on the Directive 98/44/EC. Directive 98/44/EC states explicitly that patents cannot be granted if the claimed subject matter and its commercial exploitation would be contrary to 'ordre public' or morality. Specifically, the use of human embryos is banned from patenting in Article 6(2) (c): "[I]nventions requiring the prior destruction of human embryos or their prior use as base material [are] not patentable even if process descriptions do? not refer to use of human embryos." However, Recital 42 in the preamble to the Directive makes an exception: if human embryos are used for therapeutic or diagnostic purposes, then the patent exclusion no longer applies.
[861] Laurie, G. "Patenting Stem Cells of Human Origin," in European Intellectual Property Review. Vol. 59, 2004 at 62.
[862] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011. Paragraph 34.

One interviewee suggested this interpretation of an embryo is overly broad and should apply to a more developed embryo that was not produced from IVF:

> Define an embryo? I think I'd define it as being something where it was sufficiently developed that it would amount to an abortion to terminate the pregnancy. Certainly, I would confine it to embryos in the body and not sort of in vitro fertilization.

With respect to defining an embryo, one interviewee stated that the CJEU's ruling is scientifically flawed and experts should have been consulted, specifically directing his criticism to Yves Bot, who was in charge of looking at the issue and determined that a parthenote was 'capable of commencing the process of development of a human being' based on the available technical information provided to him.[863]

Bot's views on hESC research was met with spirited dissent from those in industry and patients who could benefit from using stem cell technology, as he proposed that hESC-based medicine should be prohibited from patents in the name of preserving human dignity.[864] Bot maintained that totipotent cells should be legally classified as human embryos because they have the capacity to develop into a complete human being, and as a result should be excluded from patentability:

> Science teaches us – and it is now universally accepted, at least in the Member States – that development from conception begins with a few cells, which exist in their original state for only a few days. These are totipotent cells whose main characteristic is that each of them has the capacity to develop into a complete human being. They hold within them the full capacity for subsequent division, then for specialisation, which will ultimately lead to the birth of a human being. The full capacity for subsequent development is therefore concentrated into one cell. Consequently, in my view totipotent cells represent the first stage of the human body which they will become. They must therefore be legally categorised as embryos.[865]

Bot's recommendation is deemed by another interviewee to be a menace to the continued European funding and investment in this area and the subsequent risk to the wellbeing of those suffering from illnesses that could be treated with stem cell-based medical products.

The CJEU's reliance on Bot's opinion is clear from its account that parthenotes:

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[863] Ibid.
[864] Palmer, Alasdair. "Should the European Court be allowed to dash my hopes of a cure?" in The Daily Telegraph. London. April 30, 2011. Print.
[865] Bot, Yves. Opinion of Advocate General. Case C‑34/10: Oliver Brüstle v. Greenpeace Ev. Delivered on March 10, 2011. Paragraph 84 and 85.

> have not, strictly speaking, been the object of fertilisation, [and,] due to the effect of the technique used to obtain them they are, as apparent from the written observations presented to the Court, capable of commencing the process of development of a human being, just as an embryo created by fertilisation of an ovum can do so.[866]

From this observation, the CJEU concluded that parthenotes are a type of totipotent cell, which have the capacity to develop into a human being. The CJEU reliance on Bot's proposal and definition of the human embryo has been criticized as being scientifically flawed. One interviewee maintained:

> The fact that no scientists were even asked for an opinion to a point where he is now defining the beginning of life as a pluripotent state which is quite a bizarre definition of life. What I'm amazed about is the European Court of Justice didn't take any scientific advice on the particular issue which the German court asked the European Court to rule on. So I find it startling, if not amazed that they could go forward with the decision they've made. The issue here with human embryonic stem cells is whether you are actually killing a person? And that is where Bot comes in: You are killing what is an existing person. But it's not an existing person; it's a group of cells.

The decision was criticized by some interviewees based on a lack of scientific knowledge on the part of the CJEU, particularly the inadequate quality of the scientific information noted in *Brüstle.* For example, one interviewee noted that the CJEU should have been sensitive to the distinction between parthenotes and non-fertilized ova derived from somatic-cell nuclear transfer.

5.4.2. Impact on future innovation

This ruling is divisive in nature, drawing opinions from both sides of the debate. Members from the biotechnology industry have strongly condemned the decision. There were two major concerns regarding the impact of the decision. The first one is the impact the case will have on the continued European funding and investment in this area from both governmental and commercial sources. There is a fear that there are no exclusions for inventions regarding hESCs in other biotech-rich jurisdictions like Canada and the US, and consequently that the absence of patent protection in the EU will mean that the R&D for hESCs will leave the EU and go to jurisdictions where hESCs-related inventions are eligible for patentability. A consequence of this could be

[866] *Oliver Brüstle v Greenpeace e.V.*, Case C-34/10, decision of 18 October 2011.

that European companies are less likely to invest in R&D involving the use of hESCs. If pharmaceutical companies need a stable environment where they feel they are likely to recoup on their investments, then patents may be the best solution.

Others maintain that the decision will not likely have any practical effect on research and development, as the exclusion of hESCs from being inventions does not impinge on their use in the research and development of processes and products using hESCs. One interviewee noted, "I am unaware of a single project that has been cancelled or suspended as a result of this decision, or the WARF decision in 2008 for that matter." If the very threat of entering litigation for patent infringement does not thwart research, what is the point of a patent? This means that the biotech community investing in this type of research will have to adopt new business models to recoup on their R&D.

5.4.3. Categorization of ethics pertaining to human embryonic stem cells

With respect to the debate over inventions derived from hESCs, there are two main questions regarding their ethics: whether research on hESCs is acceptable and whether inventions derived from hESCs are patentable. The civil society interviewees did not object to research on hESCs taking place or to the associated technology as such. However, Donald Bruce, managing director of the ethics consultancy Edinethics, noted that their use should be limited to necessity: "I would prefer it they were not used at all, but if there are no other alternatives, and there is a really good medical case, then it would be okay." This interviewee stressed that there is an obligation to look for alternatives such as induced pluripotent cells. As such, there was no overwhelming objection to research on hESCs as such from the interviewees.

Regarding the second issue, although the respondents considered that hESC research and the technology itself may be acceptable, many had concerns over the patenting of inventions derived from hESCs. Moreover, one member of the EPO

Enlarged Board of Appeal (EBOA) compared the patenting of hESCs with the patenting of human organ transplantation.

> You can say under very restricted conditions, it is okay that someone donates his kidney to someone else. But if there is money involved, which is something we do not want to have at all, and it is punished by criminal law. So if you read the general provision here, commercial exploitation, you could argue that the commercial thing is that which at the end turns out to be the problem. And the technology itself, you may allow to practise.

This statement illustrates a position adopted by other respondents, in that research conducted on hESCs should not be primarily for commercial gain, but for the benefit of the embryo itself. The legal system permits certain technologies in a restricted way under particular conditions, such as not being able to patent that technology. The law clearly says that no commercial profit can be made on embryos, despite research being allowed.

The civil society stakeholders, composed of ethical analysts, religious figures and representatives from various non-governmental organizations, were asked the following set of questions about the case:

1. Is the use of hESCs for commercial purposes justified?
2. Is the use of hESCs for therapeutic purposes justified?

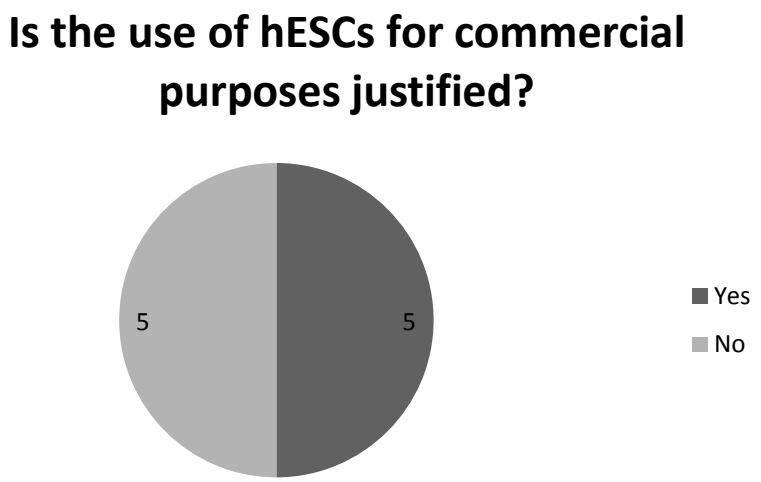
5.4.4. Is the use of hECSs for commercial purposes justified?

Three important findings emerged from the interviews. The first is that there is a clear divide amongst civil society stakeholders over whether the commercial exploitation of hESCs is justified. The definition of "commercial exploitation" is found in Article 6(2) (c) of Directive 98/44/EC.[867] Half of the respondents stated that it is not, whilst the other half maintained that it is. For those respondents who maintained that the

[867] Article 6(2)(c) Directive 98/44/EC:
1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;

use of hESCs for commercial purposes is justified, one argument for this position is that if research on hESCs is permissible, then its commercialization should be permissible as well. Roger Brownsword, a retired law professor commented:

> There is no categorical reason for why we shouldn't use human embryos for research and this applies to commercialization of the research, and there is no categorical reason why that shouldn't happen either.



On the other hand, the other half of the civil society interviewees adopted the opposite view, stating that research on hESC should not be conducted primarily for commercial purposes. Legal academic Margaret Llewelyn argued that inventions derived from hESCs should not be banned from patentability, but distinguishes between research for research's sake, or "pure research" and research for the sole purpose of commercial gain:

> I am not of the order that believes the human embryo has a special status as such but I do draw the line at over instrumentalising the uses of the embryo where that use is primarily for commercial gain rather than scientific/medical advancement.

Llewelyn maintained that it is acceptable to reward subsequent uses which might be commercial in application with a patent. Although she acknowledged that there is a fine distinction between research and commercial uses, in reality, it is highly difficult to separate the two. Based on this argument, it can be said that universities, as

research-based institutions, which invent a product using hESCs that could be commercial, could patent the product because the intention of the first use of the hESCs was for research. Yet, any for-profit organization like a pharmaceutical company, which has a commercial interest, would not be eligible for patent protection if they produced any invention using hESCs because they would be conducting research on hESCs for the purpose of finding a commercial application. The assumption that there is a clear separation of using hESCs solely for research and using hESCs for research with the intention of commercialization is flawed. Additionally, it is difficult to completely separate research from commercial purposes because in the field of biotechnology, commercial interests are present in educational institutions.

> Financial relationships among industry, scientific investigators, and academic institutions are pervasive. About one-fourth of biomedical investigators at academic institutions receive research funding from industry.[868]

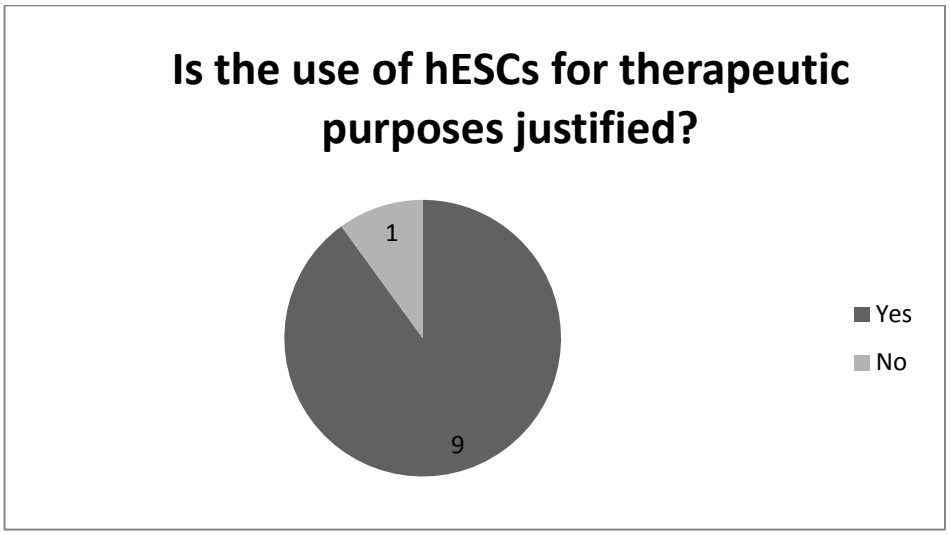
As a result, the entrance of commercial forces into academia further complicates the issue in that the research itself may not be perceived as non-commercially driven. In other words, academic institutions with any funding from industry are not entirely free from commercial interests.

Although these considerations were not distinguished in the *Brüstle* decision, most of the interviewees agreed with the argument that hESCs cannot be patented, because they objected to their commercialization. On the whole, they maintained that the research is acceptable but that no one should commercially profit from it. Given the wide interpretation of "human embryo" adopted by the CJEU, this means that inventions which involved the prior destruction of human embryos or their prior use as base material, even if no reference is given to their prior destruction or use in the patent application, are not patentable.

[868]Bekelman J., Li Y., "Gross C. Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review" in The Journal of the American Medical Association. Vol. 289. 2003 at 463.

5.4.5. Is the use of hESCs for therapeutic purposes justified?

The majority of the interviewees noted that research involving hESCs for therapeutic purposes is justified. Amongst those who agreed that the therapeutic use of hESCs is justified, some respondents noted that it was only justified if there is no other alternative than using embryonic stem cells.



One UK-based scientist participant was concerned about the meaning of 'therapeutic benefit' for the blastocyst, maintaining that the law is not unclear:

> It's just completely blurring the lines. They also talk about therapeutic benefit for the blastocyst. So again, it gets very confused, so it's not just therapeutic use as in for any patient who has a disease. The actual therapeutic has to benefit the blastocyst which you've just killed, which is just not going to happen. So it's completely screwed up. That's just bad law.

In addition, there were many critical comments directed at the differentiation between the commercial and therapeutic use of the blastocyst as stated in Directive 98/44/EC. On this point, a German interviewee argued that the distinction between commercial and therapeutic use is incorrect:

> The distinction between therapy and commercial use is completely absurd because of course under Article 53(c) of the EPC; it says therapeutic and diagnostic methods cannot be patented. Only commercial purposes can be patented so it takes us nowhere. And of course, there's always some therapeutic purpose behind the issue, and also if you go to the patent office, there's always a commercial purpose. So there is no possibility to have a distinction.

Article 53(c) of the EPC maintains that European patents shall not be granted for methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. However, this provision

does not apply to products (in particular substances or compositions) for use in any of these methods. Indeed, a method for the treatment of the human embryo is not patentable under Article 53(c) EPC. For him, the crucial issue that policy-makers must take into account is "what is patentable and what is not."

Another reason why the distinction between a "commercial" use and "therapeutic" use is difficult is because the two can be interconnected. Organizations are unlikely to conduct research solely for the creation of therapies without expecting to commercialize it, as argued by an ethical analyst:

> I think if you allow stem cell derivation at all, I can't see that it makes any sense to say, for instance if you can use it for basic research, but you can't use it commercially. And clearly, any development of stem cell therapies would be very, very expensive and it's not going to happen outside of the commercial sector. So if we have stem cells, I can't see any argument that, and I think it would counterproductive to say, "Well, you can't use them for commercial purposes."

This comment highlights the fact that even if a society decides that the research is beneficial and should continue, it may not endorse the commercialization of that research. The distinction is arbitrarily drawn and difficult, and the real question is whether the research should continue to exist at all. However, the same interviewee argued that as long as the invention is not directed at a frivolous commercial use, and the product has serious implications for human welfare, there is very little argument for why the commercialization of the invention is forbidden when the research of embryonic stem cells is accepted.

5.5. Core questions regarding patenting human biological materials

Each of the primary stakeholders (members of the biotech research industry) was asked a set of 3 questions. However, for the purposes of developing a broader analysis of the issues, legal stakeholders who are well-versed in the field of biotech and law also contributed. The purpose was to discover how participants perceived the patenting of human biological materials. The key questions explored below include:

1. Is there something about the life sciences that raises unique issues that other pioneering technologies in the past did not raise?
2. What specific issues concerning the patenting of human biological materials are of concern to you?
3. Do you think patents will be problematic for the biotech industry in the future?

5.5.1. Is there something about the life sciences that raises unique issues that other pioneering technologies in the past did not raise?

The purpose of this question was to discover whether the participants perceived biotech inventions as the equivalent of a 'problem child' for the patent system.[869] Interpretations differed over whether there is an intrinsic quality to this area of research that precludes it *a priori* from the patent system. There were three general approaches to this question. First, some of the participants acknowledged that there is something exceptional about the life sciences, but there is no need to approach patenting differently. The second position is that there is something distinctive about this field and something should be done to address this reality, such as the implementation of Directive 98/44/EC by the European Parliament and Council. The third type of response was that there is nothing inherently special about the life sciences and that the focus should not be on *ex ante* policy questions but on *ex post* mechanisms.

A. Biotechnology inventions are unique but should be patented

The first position is that there is something unique about the life sciences, but this uniqueness does not make biotech inventions unsuitable for patenting, just difficult. One of the arguments why biotech inventions are unique is that the claimed product can self-replicate, as Julian Cockbain noted:

[869] Burk, D. "Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context" in Patent Law in Global Perspective. R. Okediji and M. Bagley (eds.). Oxford: Oxford University Press, 2014 at 187-212.

> The problem is with patenting life, the product replicates itself. And hence, you end up with patent claims for the product of the product of the product. So you get companies like Monsanto claiming seeds and suing people.

That being said, even though biotech inventions are generally seen as different from other technologies, several interviewees argued that the patent system can still incentivize and protect biotech inventions, notwithstanding the reality of the self-reproducibility quality of most life science inventions.

Tim Roberts, a UK based patent attorney, maintained that inventions in biotechnology raise different legal issues from other pioneering technologies, but this does not mean that they warrant a different approach to patenting, unless one could demonstrate that biotech inventions raise different legal issues from other pioneering technologies.

> Whether that means we would need to approach patenting differently, I am not sure about. My immediate reaction is that it would require to be demonstrated that biotech raises different legal issues from other pioneering technologies. At least in the area of patenting I am thinking about.

Despite this, he argued that there are two main concerns. The main issue with patenting life science inventions was the subject matter's ability to replicate. This is linked to the second issue, which is the environmental impact if the self-replicating entities were ever released outside the lab into the world.

> I mean, there is always the question of releasing things into the environment, particularly releasing self-reproducing things into the environment; you do need to think a little carefully about this. The inheritability of the thing being loose in the environment and self-replicating does raise, I think different legal issues.

Also noting the speculative nature of biotech inventions, a member of the Enlarged Board of Appeal of the European Patent Office maintained that this issue is highlighted in biotechnology:

> I would not say it is totally unique, you could imagine also before the arrival of biotech, certain inventions which were quite speculative. Maybe the inventor had already an idea, which at the end, ten years after he made that invention, was reproducible. And the key idea was already there ten years before, but there was no real way of doing it. You could imagine before the arrival of biotech, early inventions also could have a blocking effect on future innovators. But nevertheless, as the case law shows, certain problems have really been focused on because of biotech inventions.

The same interviewee explained that due to the nature of the invention, there are actually various stages of the invention and that there is a tendency for there to be concerns surrounding patents that are granted for 'speculative inventions,' like an invention which was filed too early, or a precursor to an invention of greater social worth. However, this phenomenon is not particular to the biotechnology industry, but can happen in other fields. The European Patent Office acknowledged that biotechnology does raise distinguishing issues, but can and should be protected under the patent system, albeit with additional specifications.

> Biotechnology inventions have to meet the same criteria as those in any other technical field. But given the nature of biotechnology and its socio-political implications, various other rules also apply, in particular those of Directive 98/44/EC which were incorporated into the EPC.

Interestingly, a relatively large number of interviewees stated that biotech patents raise challenges that can occur in all areas of technology, but for some reason, appear habitually in biotechnology. However, they maintained that biotech inventions could still be protected under the patent system.

B. Biotechnology inventions are unique and should be excluded from patent protection

The second position is that there is something inherently different about biotechnology, which is problematic for the patent system and, as a result, some life science developments should be precluded from patent protection.

Joshua Sarnoff, a US-based law professor, argued that "Patenting DNA (like patenting any other product or process that is discovered in nature and only minimally altered) raises both deontological and utilitarian ethical concerns. It is also bad social policy."

Ideas about ownership towards naturally occurring organisms affect attitudes to whether they can be patented - it is argued that they are already owned and no one should be able to patent them. Jonathan Wolff, a UK philosophy professor and a member of the Nuffield Council on Bioethics, argued that things that already exist in

nature are problematic to patent, noting that patents should only be granted to new inventions which are not found in nature:

> It's like trying to patent gold, who are you to take that for yourself when it already belongs to everyone? I think if someone comes up with a completely new invention like an industrial process, then it's perfectly reasonable to say that's something they've added to the world, it wouldn't have existed without them. But the gene sequence would have existed without them. All they have done is isolated it and discovered it.

Indeed, this position was reiterated by an experienced Germany-based lawyer:

> There are various aspects which are quite specific to biological material like the access to genetic resources. Genetic resources are normally not invented; they're just found in nature and should not be protected by patents. If it comes to whole animals, you never invent a whole animal; you always introduce a technical trait, so you should not in the end own the whole animal and all the following generations.

The same respondent criticized Directive 98/44/EC, which he argued was written in favour of industry and fails to address the underlying issues related to the nature of the subject matter, and that there should be a balance between the benefits of granting patents in the area and the negative effects that could arise.

> And this balancing was not done in the European Patenting Directive 98. For biotechnology, let us have innovation come in, and then we have patents, which were? created by biotechnology companies and I think this was a very naive approach and very much in favour of a few companies. Because the other companies are not having a benefit if seed biological resources are patented. Later on, pharmaceutical companies come in and say I am no longer free to use the human genome sequence. It was very specific for industry, and the overall approach was quite naive and not really being aware of the nature of biology, which is completely different. As described in the patent Directive, as soon as you isolate part of the human body, the gene sequence and describe a function or commercial purpose, then you have all kinds of attached uses are owned by the person who described the gene sequence. And it is simply stupid.

Meanwhile, the question of determining patentable subject matter should consider the distinction between the animate vs. inanimate. The importance of this consideration was emphasized in the writings of one of the interviewees:

> Despite the hype coming from certain quarters, we are simply not there yet. When we are, the engineering analogy presumably will finally fit perfectly, thereby ceasing to be an analogy. Synthetic biology will be a form of engineering. Life forms will truly become manufactured mechanical devices at least in the artificial environments in which they will be placed…Life is different from non-life, and that is relevant for patent law.[870]

[870] Dutfield, G. "'The Genetic Code is 3.6 Billion Years Old: It's Time for a Rewrite' Questioning the Metaphors and Analogies of Synthetic Biology and Life Science Patenting" in Annabelle Lever's (eds.) New Frontiers in the Philosophy of Intellectual Property. Cambridge: Cambridge University Press, 2011 at 21.

From the information gathered from the stakeholders, there seem to be a consensus that there is something about inventions derived from naturally occurring entities that proliferate some issues more when compared to other fields of technology. It is plausible to claim that there is something different about the field of biotechnology and its subsequent inventions can create difficulties for the patent system.[871]

C. There is nothing special about the life sciences

The third response is that there is nothing special about the life sciences and that patenting a biotech invention is like patenting any other. A UK-based barrister stated, "I do not see the issue of genes as any different to the issue of anything else. I mean, are patents good at all? I think that is a big question."

In a similar vein, a UK-based solicitor stated outright that there is nothing special about the life sciences, and that the focus on the eligibility issues overshadows what he argued is the real issue in the area:

> I don't think there's anything special about the life sciences in general. Clearly, it attracts a vast amount of rhetoric and high degree of academic interest, a high degree of rather naïve academic interest because these sort of issues are not actually the main problems that one encounters in biotechnology. Normally, there are much more conventional issues you get in patentability such as obviousness and sufficiency.

When asked whether there was something unique about the life sciences which made them problematic for patenting, Tim Hubbard stated that patents are a mechanism designed to protect inventors and their inventions and while a discovery is not an invention, he acknowledges that the biotechnology industry wants to have some sort of protection.

> I think patents were meant to protect inventors who have invented something. And there really isn't any invention in the discovery of things, it's not an invention. But the problem is that the structure of the industry wants to have some protection.

[871]It is not improbable to claim that the courts have recognized this reality and made judicial decisions in favour of finding DNA sequences and transgenic organisms patentable.

Another interviewee noted that biotech patents have been granted since the 19th century and that the patent system is built to address all forms of technology, which is reflected in the WTO TRIPS Agreement:

> The patent system inherently deals with so far unknown technology. This is not an expansion of the system, but its very nature. Is the question useful towards the background of Article 27 TRIPS, which does not distinguish between different technologies?

5.5.2. What specific issues concerning the patenting of human biological materials are of concern to you?

The major issue raised by the participants in regards to patenting human genetic material was the scope of protection. The crucial importance of the scope of patent claims issue was emphasized by the interviewees, noting that it is a constant problem that is always being addressed by the courts and that technically, it is a legal barrier. Tim Roberts, a UK-based patent attorney stated that the issue of scope tends to involve the grant of overly broad patents rather than overly narrow claims:

> It is possible to get unreasonably broad claims which are a problem from the point of view of competitors and other people reasonably entitled to do?, and also a situation where you get a claim to exactly what you've done, and anybody can get variants of it which produce the same advantages, so you don't get any reward for your invention. There can be a problem in two senses, mainly the issue of too broad rather than too narrow.

However, Justin Turner highlighted the fact that the scope of claims is always going to be a problem, particularly for DNA claims. In fact, he argued that the major pharmaceutical companies would prefer not to own a broad patent due to the associated problems that come with the territory:

> Mostly, they don't like broad patents. 'Course, they're schizophrenic when they've got one. They love it. But all the time, I'm having conversations with drug companies and they're going like, you know, we've got some real problems and of course they're horribly tactical and financial. They need to be sensible.

While it can be observed that the scope of patent claims is a persistent problem, Turner acknowledged that as DNA technology becomes routine, patents will be narrower in scope compared with when gene sequencing first developed:

> The first person ever to sequence a piece of DNA could have asked for a patent claim to any DNA ever sequenced, ever, ever, ever. And the first person ever to take a gene and put it in a recombinant system and express a protein could have said: "I want a royalty for anyone ever to express as a protein again." They didn't, they weren't that ballsy. But it would have been a really

> interesting debate. It would have made Bill Gates look like a poor person if they had gotten patents that broad.

Therefore, it appears that the majority of research/industry and legal interviewees were of the opinion that patenting genetic material would not constitute a major problem for patent law, with one exception: the breadth of claims.

5.5.3. Do you think patents will be problematic for the biotech industry in the future?

With respect to this question, most of the legal and research/industry stakeholders maintained that based on the business model of innovation in biotechnology, the patent system is the ideal incentive regime. US attorney Rick Henschel stated: "Patents are probably the best proxy out there that there is as an incentive to innovate." He maintained that not having patents could be an obstacle for innovation. However, Tim Roberts stated that obtaining patents is a more difficult process due to the rapid advances in science which can make inventions more obvious and anticipated:

> In the early days, everybody was amazed you could isolate a gene at all. In those circumstances, they were ready to accept that the invention lay not in what you've done, but in the fact that you succeeded in doing it at all. But these days, the technology is much more systematized and generally you're going to have to demonstrate something unexpected and, generally speaking, you're going to have to demonstrate something unexpected about your result.

With respect to the point that patents are problematic, some interviewees acknowledged that this may be true, but this does not mean they should not be removed. Justin Turner stated:

> It [the patent system] is incredibly sophisticated; it's been around for hundreds of years. Constantly, people are trying to find a balance that is good for innovation and good for freedom to operate. The system inherently is checking that it's in the right place because as I say, GSK and Lilly are defendants in patent actions. So yes, of course, they're problematic, but they're meant to be problematic.

With respect to the fact that there is a constant balance between freedom to operate and incentivizing innovation, another interviewee from industry remarked that on balance, patents on the whole are not problematic for the biotechnology industry. The reason for this is that for practical reasons, investors want patent protection. The

same interviewee noted that investors are required and if investors think patents are important, they will not invest if they do not believe patent protection is available at the end of the process.

5.6. Conclusion

Interview data revealed the overall general support of the patent system by the primary stakeholders (inventors and companies investing in R&D), accepting that the patent system incentivizes the production of inventions that ultimately benefit society at a cost of temporal exclusion. They emphasized that the bargain was 'worthwhile' and necessary given the financial realities of the business model in biotechnology. Ultimately, it is a constant balancing test and up to the society and legislature to decide whether research in genes and hESCs is worthwhile and necessary through the clarification of patent law. Whilst all participants acknowledged the blocking effects of patents, the general opinion was that if innovation is to continue in biotechnology, patents for human genetic materials were necessary given the high costs required to bring a product to market.

One issue that was frequently brought up was the scope of the patent claim on genes, in which overly broad patents were more of a concern than narrow patent claims. The civil society stakeholders were split in regards to the patenting of inventions derived from hESCs. Whilst the general attitude towards the research on hESCs was positive, there were some negative responses over the patenting a commercial use derived from hESCs. Biotech industry members stressed that funding would likely be halted in the area as result of the CJEU decision, and admonished the court's distinction between a 'therapeutic' and a 'commercial use,' holding that there is no clear line.

6: Conclusion and Policy Recommendation

6.1. Introduction

This thesis set out to explore the patent protection of human genetic materials and has identified the nature of a patent right, the reasons and goals for its existence, and the role and impact it can impose on innovation in the biotechnology industry. This research has also sought to reveal whether granting patents for genetic materials is justified, particularly considering the dual nature of DNA sequences.

The thesis answered four sub-questions:

(i) Whether gene patents create a *de facto* tragedy of the anti-commons?

(ii) Can a temporary exclusive right over human genetic materials be justified?

(iii) How have Europe and the US addressed human genetic materials in determining patent eligibility and the scope of protection?

(iv) Do the current statutory regimes in Europe and the US need to be amended in the name of the public interest with regards to human genetic inventions?

6.2. Theoretical Implications

The findings in the comparative review of the European and the US approach towards patenting isolated DNA sequences, combined with stakeholder responses provided a practical perspective on the impact of patents on innovation in biotechnology. The data corresponds with the theoretical underpinnings of patent law: particularly, the notion of the social contract.

Chapter 2 explored the development of biotechnology and situated modern biotechnology products and processes within the patent system along with a brief insight into the science of genes and hESCs and their international legal governance.

The chapter examined the nature of genetic material and challenged the proposition that patent protection on genes will inevitably lead to an tragedy of the anticommons. However, the research found that although the nature of genes and inventions can create conditions that can lead to the development of an anticommons, there is a lack of empirical data that proves the presence of patent thickets in biotechnology. Therefore, the answer to the first subquestion: "Whether gene patents create a de facto tragedy of the anti-commons" is no, not necessarily given the practical reality of patent holders' willingness to reasonably license with one another.

Chapter 3 analysed the theoretical justifications for patents on human genetic materials. Patents are put forward as a social contract in which there is a bargain between the inventor and society. It maintained that a patent right is a socially constructed right to exclude but is limited. With the above analysis as a foundation, this study can now answer the second question: Can a temporary exclusive right over human genetic materials be justified? This chapter concludes "yes," that in order for useful products and processes to come to market, there needs to be the incentive to innovate and develop products. Using the prospect theory, biotechnology requires patents due to the realities of the industry development process, which can justify strong patent rights over inventions. Inventors and their financial backers require adequate control over the invention due to the indefinite route towards commercial development. This could also assist in minimizing the anticommons issue (where too many narrow patents are granted resulting in too many licenses to create a feasible product). To combat the issue of access, a strong research exception can be used to ensure that patented knowledge can be accessed and applied in a non-commercial manner and does not interfere with future inventors' ability to patent improvements on the original protected invention.

6.3. Empirical Findings

Chapter 4 assessed how Europe and the US have addressed human genetic materials in determining their patent eligibility status and their scope of protection. In the US, the 'product of nature' principle and the role it plays in §101 patent eligibility holds strong. In Europe, the invention/discovery ensures that entities that should not be granted exclusive rights are not patented.

An analysis of Myriad's BRCA gene patents through a comparative study of how Myriad's gene patents were addressed by both systems, reached the following conclusion: Whilst the US opted to abolish the practice of patenting of genes by tackling the question of patentable subject matter, Europe engaged in narrowing of scope of protection for gene patents. As a result, in the US, isolated genes cannot qualify as an 'invention' because it is a product of nature. In declaring isolated genes as products of nature, the US Supreme Court essentially opened up the field for research as there is no longer any need to obtain a license on a patented gene.

But, for the matter of isolated genes, it is submitted that given that function plays a more important role in patentability and infringement for isolated DNA sequences and science is rapidly evolving. Thus, treating genes as inventions based on just one disclosed function can be viewed as over-generous, especially if routine isolating and purification techniques were used to obtain the sequence. Because DNA sequences are carriers of information, it is possible that a sequence can code for two separate products. Taking this into account, if any patent protection is to be granted by the state to incentivize for innovation purposes, it is suggested that purpose bound protection is justified. This approach acknowledges that such a discovery may have been expensive and difficult, but there may well be more to be discovered, which may be even more important and should remain accessible to other researchers.

This chapter also revealed that the ongoing uncertainty and ambiguity as to the patentability of hESCs in Europe can only be resolved by separating from a semantic approach, i.e. by no longer debating about the meaning of the words 'human embryo' in Rule 28 of Article 53(a) of the EPC[872] and Article 6(2) (c) of the Directive 98/44/EC,[873] but instead by scrutinizing the intrinsic arguments to justify the patentability of hESCs. The definition of an embryo will likely be determined on a case by case basis. However, the CJEU in *Brüstle* significantly widened the definition of 'human embryo' and essentially maintained that the commercial exploitation of inventions derived from the destruction of a human embryo is immoral and therefore not patentable. Without the promise of a patent, investment will likely be reduced unless institutions can recoup on the investment with the promise of patent protection.

Chapter 5 included empirical data from stakeholder interviews. Despite some criticism directed at the patent system, it was upheld as the most ideal system to promote innovation in the area. Access to human genetic material and the privatisation of inventions derived from these biological materials can coexist harmoniously under the patent system. Based on two case studies, human biological materials should not be excluded from patentability *per se*. Specifically, isolated biological materials falls within the definition of an 'invention' provided there is a *technical* difference between the claimed invention and its naturally occurring counterpart. It also appears that the majority of stakeholders are not in favour of abolishing patents for human genetic inventions.

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[872] Rule 28-Exceptions to patentability. Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a)processes for cloning human beings;
(b)processes for modifying the germ line genetic identity of human beings;
(c)uses of human embryos for industrial or commercial purposes;
Implementing Regulations to the Convention on the Grant of European Patent of 5 October 1973. Available at http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma2.html (Accessed July 24, 2011).

[873] Article 6 (2) (c) of the Directive 98/44/EC specifies that, on the basis of paragraph 1, the following, in particular, shall be considered unpatentable: 'uses of human embryos for industrial or commercial purposes'.

Therefore, the answer to the fourth subquestion: "Do the current statutory regimes in Europe and the US need to be amended in the name of the public interest with regards to human genetic inventions?" is "not necessarily."[874] The patent system is still the most suitable mechanism to promote the public interest for the following three reasons:

1. Despite *Myriad,* which ruled isolated genes ineligible subject matter and cDNA eligible subject matter, the decision has not had a detrimental effect on scientific inquiry. While isolated DNA is particularly useful for research and diagnostic endeavours and no longer patentable, cDNA (which is relevant to commercial therapeutic activities), remains eligible. On the whole, the result is not doctrinally or scientifically accurate, particularly its decision in drawing the distinction between isolated DNA and cDNA. But since the US Supreme Court held that cDNA remains eligible subject matter for patent protection, *Myriad* ultimately maintained the status quo.
2. Despite the ruling in *Brüstle* and the effect the decision could have on research directed to hESCs, there has been no detrimental effect on the patent research incentive. The decision affects hESCs that have been granted in EU Member States, yet researchers based in the EU can continue to apply for patents outside the EU where comparable limitations do not exist. Moreover, the decision may actually speed up hESC related research as the research community does not have to worry about infringing patents on hESCs.

[874] It must be emphasized again that intellectual property rights perform a social function and "under no circumstances be allowed to benefit the few to the detriment of the many, that on the contrary they are closely linked to the interests of society, a fact that ultimately can only contribute to restoring their acceptance." Geiger, C. "The Social Function of Intellectual Property Rights, or how Ethics can Influence the Shape and Use of IP Law" in Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, 2013 at 175-176.

3. There is no evidence of a patent hold up in the sense of research deterrence caused by the patenting of human genetic material. Empirical studies reveal that initial fears over the development of an anticommons and 'chilling' effect on research have not manifested in practice. One of the strongest arguments against patents on human genetic materials is that it can affect further innovation due to licensing issues that can obstruct progress and lead to an anticommons.[875] However, industry members are generally optimistic about their ability to license with their competitors. As part of the qualitative study, a total of 5 out of the 7 interviewees from industry (primary stakeholders) maintained they did not: (i) know of a product or process that had been kept from the market and (ii) any research that was blocked due to patents. This claim was also reflected in the academic literature.[876] This suggests that the patent eligibility of isolated DNA has minimal effect on the patent research incentive. Although from a doctrinal perspective, it may suggest that more cumulative research would be executed by the wider scientific community free from patents, the available evidence suggest that gene patents may not be a hindrance in incentivizing initial examination or essential in creating practical applications.

[875] Heller, M. and R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science. Vol. 280, 1998. Pp. 698-701.
[876] Epstein, R. "Steady the Course: Property Rights in Genetic Material" (University of Chicago Law School, John M. Olin Law and Economics Working Paper No.152 [2d Ser.], Revised March 2003) at 18.

A Draft Manifesto: Policy Guidelines for the US and EPO

PREFACE

Conscious of the societal goal of patents to promote innovation and of the social value of promoting human welfare.
Affirming that the promotion of human health is a common concern of humankind.
Aware of the urgent need to develop scientific and technical capacity to provide further therapies.
Noting the starting point should be in a favour of a regime of strong property rights unless there is a clear evidence of necessitating the switch to a regime that requires forced purchases.
Acknowledging that the current patent system is imperfect.
Emphasizing that the current legal structure, despite its shortcomings, has promoted a huge expansion in biotechnology in the past few decades.
Reaffirming that states have sovereign rights over whether to implement exemptions for certain patented inventions.

AIMS: PATENTABILITY OF HUMAN GENETIC MATERIALS

Concerned that the human genome possesses a fine number of genes and that patenting a genetic sequence could hinder further research and development in the field.
Acknowledging that genetic sequences are not created, but found; even if the process used to find the sequence was laborious, time consuming and costly, ultimately, the sequence already existed.
Observing that some human substances should be left in the public domain like ESTs and unmodified genetic sequences, whilst others should be governed by patent protection.
Discerning that the special nature of biological inventions does present some difficulties for the patent system, but this does not necessitate their removal from patent eligibility.
Noting that the protection of the human genome accords with the broader objectives of patent law

CONSIDERATIONS

1. Noting that systematic efforts should be made to ensure that basic information about the genome is placed into a public domain database available for public use.
2. Recommending that genetic material that meets the criteria of novelty, non-obviousness and utility is recognized as patent eligible.
3. Noting further that the in-built mechanisms within the patent system have an important role to play

   a. Recognizing that there is a real question about the optimal patent scope (i.e. patent holder cannot claim future uses to a genetic sequence that was not in the original patent claim)
   b. Granting a patent over the claimed use in a genomic invention may be the most appropriate solution. (i.e. only for commercialization, but not for basic research)
4. Recommending that patent examiners should assess the utility or industrial application requirement more strictly for genomic inventions
5. Highlighting the necessity for a more stringent test for inventive step
6. Stating the importance of identifying the function of a genetic sequence in a patent claim
7. Noting that claimed inventions must be sufficiently specific in view of the state of the art and must be credible and non-speculative, supported by empirical evidence

RESEARCH AND EXPERIMENTAL USE EXCEPTION

8. Patent legislation should include a research and experimental use exception which includes the following statement:
   It is not an infringement of a patent to use a patented process or product either:

   (a) Privately and for non-commercial purposes, or
   (b) To study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.

MORALITY IS A LEGISLATION ISSUE

9. Noting that morality should be construed narrowly in the EU
10. Perceiving the need to clarify exactly whether it is the invention or the patenting of the invention and its potential commercialization that is immoral.
11. Observing if the invention is deemed to be immoral, then it should left to national legislation to ban it.
12. Stressing that the patent system is not a regulatory tool.

Bibliography

Journal articles and book chapters

Abramowicz, M. "Perfecting Patent Prizes" in Vanderbilt Law Review. Vol.56, No.1 pp. 114-236, 2003.

Alexander, G. "Property as Propriety" in Nebraska Law Review. Vol. 77, pp.667-702, 1998.

Alexander, G. "The Social-Obligation Norm in American Property Law" in Cornell Law Review. Vol. 94, pp.745-819, 2008-2009.

Amani, B. & R. Coombe. "The Human Genome Diversity Project: The Politics of Patents at the Intersection of Race, Religion, and Research Ethics," in Law and Policy. Vol. 27, No. 1 pp. 152-188, January 2005.

Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain Part 1" in Columbia-VLA Journal of Law & the Arts. Vol. 18, Issues 1 & 2, pp. 1-74, 1993-1994.

Aoki, K. "Authors, Inventors and Trademark Owners: Private Intellectual Property and the Public Domain-Part II" in Columbia-VLA Journal of Law & the Arts. Vol. 18, Issues 3 & 4, pp. 191-268, 1993-1994.

Atkinson, R. "Mixed Messages: Canada's Stance on Patentable Subject Matter in Biotechnology," in Intellectual Property Journal. Vol. 19, pp.1-27, 2005-2006.

Barrad, C. "Genetic Information and Property Theory" in Northwestern University Law Review. Vol. 87, pp. 1037-1086, 1992-1993.

Beauchamp, C. "Patenting Nature: A Problem of History," in Stanford Technology Law Review. Vol. 16, pp. 257-312, 2013.

Becker, L. "Deserving to Own Intellectual Property" in Chicago-Kent Law Review. Vol. 68, pp. 609-629, 1993.

Beier, F-K. & J. Strauss. "The Patent System and its Information Function-Yesterday and Today," in International Review of Industrial Property and Copyright, Vol. 8, 1977.

Beier, F.-K. and Rainer Moufang. "Patentability of Human Genes and Living Organisms: Principles of a Possible International Understanding" in F. Vogel and R. Grunwald. Patenting of Human Genes and Living Organisms. Pp.205-219.Heidelberg: Springer, 1994.

Bekelman J. & Y. Li. "Gross C. Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review" in The Journal of the American Medical Association. Vol. 289, pp. 454-465, 2003.

Bessen, J., M. Meurer & J. Ford. "The Private and Social Costs of Patent Trolls" in Boston University School of Law, Law and Economics Research Paper. No. 11-45, September 19, 2011.

Bittlingmayer, G. "Property Rights, Progress, and the Aircraft Patent Agreement," in Journal of Law & Economics. Vol.31, pp. 227-247, 1988.

Björkman, B. & S. Hansson. "Bodily Rights and Property Rights" in Journal of Medical Ethics. Vol. 32, pp. 209-214, 2006.

Bonner, C., F. Cohn & C. Schneider. "Patenting Life: A View From the Constitution and Beyond," in Whittier Law Review. Vol. 24, pp.385-416, 2002-2003.

Boyle, J. "Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us," in Perspectives on Properties of the Human Genome Project. F. Kieff (ed.) Pp.97-122. Boston: Elsevier Academic Press, 2003.

Buchanan, J. & Y. Yoon. "Symmetric Tragedies: Commons and Anticommons" in Journal of Law & Economics. Vol. 43, 2000.

Burk, D. "Patent Law's Problem Children: Software and Biotechnology in Transatlantic Context" in Patent Law in Global Perspective R. Okediji and M. Bagley (eds.). Oxford: Oxford University Press, 2014. pp.187-212.

Burk, D. & M. Lemley. "Is Patent Law Technology-Specific?" in Berkeley Technology Law Journal. Vol. 17, 2002. p. 1155-1206.

Burk, D. & M. Lemley. "Policy Levers in Patent Law" in Virginia Law Review. Vol.89, No.7, pp.1575-1696. November 2003

Burk, D. "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective" in Houston Law Review. Vol. 30, pp. 1597-1668. 1993-1994.

Calvert, J. "Patenting Genomic Objects: Genes, Genomes, Function and Information" in Science as Culture. Vol. 16, No. 2, pp. 207-223. 2007.

Calvert, J. and P-B. Joly. "How Did the Gene Become a Chemical Compound? The Ontology of the Gene and the Patenting of DNA" in Social Science Information. Vol. 50, Iss.2, pp 1-21. 2011.

Cassier, M. and M. Correa. "Scaling-up and Reverse Engineering: Acquisition of Industrial Knowledge by copying drugs in Brazil" in Benjamin Coriat (ed.) The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems and Free Access. Pp.130-149.Cheltenham: Edward Elgar, 2008.

Chavez, M. "Gene Patenting: Do the Ends Justify the Means?" in Computer Law Review & Technology Journal. Vol. 7 pp.255-272, 2002-2003.

Clarkson, M. "A Stakeholder Framework for Anlayzing and Evaluating Corporate Social Performance," in Academy of Management Review. Vol. 20, No. 1, pp. 92-117, 1995.

Claude, H. and J. Stiglitz. 'Intellectual Property, Dissemination of Innovation and Sustainable Development," in Global Policy. Vol 1. Iss 3. October 2010.

Cohen, F. "Dialogue on Private Property" in Rutgers Law Review. Vol. 9, No.2, Pp.357-387. 1954.

Cohen, L. "Holdouts and Free Riders," in Journal of Legal Studies. Vol. 20, pp. 351-362. 1991.

Cohen, M. "Property and Sovereignty" in Cornell Law Quarterly. Vol.13, 1927. Pp.8-30.

Conley, J. “Gene Patents and the Product of Nature Doctrine” in Chicago-Kent Law Review. Vol.84, No.1, pp.109-132, 2009-2010.

Conley, J. and R. Makowski. “Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents,” in Journal of the Patent and Trademark Office Society. Vol.85, pp.301-334, 2004.

Coombe, R. “Objects of Property and Subjects of Politics: Intellectual Property Laws and Democratic Dialogue,” in Texas Law Review, Vol. 69, 1991, pp. 1853-1883.

Crespi, S. “Biotechnology Patenting: The Wicked Animal Must Defend Itself,” in European Intellectual Property Review. Vol. 17, Iss.9, pp.431-441. 1995.

Crucible Group. People, Plants, and Patents: The Impact of Intellectual Property on Biodiversity, Conservation, Trade and Rural Society. Ottawa: International Development Research Centre, 1994.

Dam, K. “The Economic Underpinnings of Patent Law” in The Journal of Legal Studies. Vol. 23, No. 1, pp.247-271. 1994.

Dastgheib-Vinarov, S. “Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill” in Marquette Intellectual Property Law Review. Vol. 4, pp.143-180, 2000.

Day, M. “Patents: Patentable Subject Matter: Living Man-Made Organisms Held to Be Patentable Subject Matter Under 35. U.S.C. Sec. 101 (Diamond v. Chakrabarty)” in Marquette Law Review. Vol.63, Iss.4, 1980. Pp.711-730.

DeBeer, J. “Reconciling Property Rights in Rights” in The Journal of World Intellectual Property. Volume 8, Issue 1, pp. 5–31, January 2005.

Demaine, L. & A.Fallmeth. “Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent” in Stanford Law Review. Vol.55, 2002.

Demsetz, H. ‘Toward a Theory of Property Rights,” in The American Economic Review. Vol. 57, No. 2, Papers and Proceedings of the Seventy-ninth Annual Meeting of the American Economic Association. May 1967. Pp. 347-359

Drahos, P. “Biotechnology Patents, Markets and Morality,” in E.I.P.R. Iss. 9, Pp.441-449. 1999.

Dreyfuss, R. “Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein’s Steady Course” (NYU Law School, Public Law Research Paper No. 59, April 2003).

Duncan, M. “Reconceiving the Bundle of Sticks: Land as a Community-Based Resource. Environmental Law. Volume 32, 2002. Pp. 773-807.

Dutfield, G. “Biotechnology and IPRs in Europe,” in Jensen, A and M. Pugatch (eds.) Intellectual Property Frontiers: Expanding the Borders of Discussion. pp.49-50.London: Stockholm Network, 2005

Dutfield, G. and U. Suthersanen, “DNA Music: Intellectual Property and the Law of Unintended Consequences,” in Science Studies. Vol. 18, No. 1, 5-29, 2005.

Dutfield, G. “DNA patenting: implications for public health research”, in Bulletin of the World Health Organization. Vol. 84, Iss. 5, pp. 388-392, 2006.

Dutfield, G. “Patents on Steroids: What Hormones tell us about the Evolution of Patent Law and the Pharmaceutical Industry” in Intellectual Property Law Journal. Vol. 23, pp 249-66. 2011.

Dutfield, G. “‘The Genetic Code is 3.6 Billion Years Old: It’s Time for a Rewrite’ Questioning the Metaphors and Analogies of Synthetic Biology and Life Science Patenting” in A.Lever (ed.) New Frontiers in the Philosophy of Intellectual Property. Cambridge: Cambridge University Press, 2011.

Dutfield, G. “Who Invents Life: Intelligent Designers, Blind Watchmakers, or Genetic Engineers?” in Journal of Intellectual Property Law & Practice. Vol 5. No. 7, 2010.

Eisenberg, R. “How Can you Patent Genes?” in David Magnus, A. Caplan and G. McGee (eds) Who Owns Life? New York: Prometheus Books, 2002.

Eisenberg, R. “Patents and the Progress of Science: Exclusive Rights and Experimental Use” in University of Chicago Law Review. Vol. 56, pp. 1017-1086, 1989.

Eisenberg, R. “Proprietary Rights and the Norms of Science in Biotechnology Research,” in Intellectual Property Law Review, pp.29-83 (1989).

Eisenberg, R. & R. Merges. “Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of the Partial cDNA Sequences,” in American Intellectual Property Law Association Quarterly Journal. Vol.23, pp.1-52, Winter1995.

Eisenberg, R. “Re-examining the Role of Patents in Appropriating the Value of DNA Sequences” in Emory Law Journal . Vol. 49, pp783-800. 2000.

Eisenberg, R. “Why the Gene Patenting Controversy Persists” in Academic Medicine. Vol. 77, No.12, December 2002. Pp. 1381-1387.

Epstein, R. & B. Kuhlik, “Is There a Biomedical Anticommons?” in Regulation. Vol. 27, No. 2, pp. 54-58, Summer 2004.

Epstein, R. “Steady the Course: Property Rights in Genetic Material” (University of Chicago Law School, John M. Olin Law and Economics Working Paper No.152 [2d Ser.], Revised March 2003).

Epstein, R. “The Property Rights Movement and Intellectual Property” in Regulation. Vol. 30, No. 4, Winter 2007-2008.

Evans, B. “Mining the Human Genome After Association for Molecular Pathology v Myriad Genetics” in Genetics in Medicine. Vol. 16, pp.504-509, 2013.

“Federal District Judge in Manhattan Says That Isolated and Purified Genes Are Not Patentable Because They Are Products of Nature” in Biotechnology Law Report, 29, pp. 303-307, Nov 3, 2010

Feldman, R. “Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law” in Stanford Law Review. Vol. 63, pp.1377-1402, 2010-2011.

Fellmeth, A. Book Review of David Koepsell's "Who Owns You? The Corporate Gold Rush to Patent Your Genes" (2009) in Bioethical Inquiry (2010) 7:129-131.

Fisher, W. "Reconstructing the Fair Use Doctrine," in Harvard Law Review, Vol. 101 June 1988, pp. 1659-795.

Fletcher, A., et al. "Mapping stakeholder perceptions for a third sector organization." in Journal of Intellectual Capital. Vol. 4 Iss. 4, pp. 505 – 527, 2003.

Forman, J. "Timing Perspective on the Utility Requirement in Biotechnology Patent Applications" in Albany Law Journal of Science & Technology. Vol.12. pp. 647-682. (2001-2002).

Gallini, N. "The Economics of Patents: Lessons from Recent U.S. Patent Reform" in Journal of Economic Perspectives. Vol. 16, No. 2, pp 121-154. Spring 2002.

Geiger, C. "'Constitutionalising' Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union" in International Review of Intellectual Property and Competition Law. Vol. 37, No.4, 2006. Pp. 371-500.

Geiger, C. "Implementing Intellectual Property Provisions in Human Rights Instruments: Towards a New Social Contract for the Protection of Intangibles," Max Planck Institute for Innovation and Competition Research Paper No. 14-10. 2014.

Goeddel, D. et al. "Expression in Escherichia coli of chemically synthesized genes for human insulin" in Proceedings of the National Academy of Sciences. Vol. 76, No. 1, pp. 106-110, January 1979.

Gold, R. "Biomedical Patents and Ethics: A Canadian Solution," in McGill Law Journal. Vol. 45, pp. 413-435, 2000.

Gold, R. & J. Carbone, "Myriad Genetics: In the eye of the policy storm" in Genetics in Medicine. Vol. 12, No.4, S39–S70. April 2010 Supplement.

Golden, J. "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System" in Emory Law Journal. Vol.50, pp.101-191, 2001.

Golden, J. "WARF's Stem Cell Patents and Tensions between Public and Private Sector Approaches to Research" in Journal of Law Medicine & Ethics. Vol. 38, Iss. 2, pp. 314–331, 2010.

Gottweis, H. et al., The Global Politics of Human Embryonic Stem Cell Science. New York: Palgrave Macmillan, 2009.

Gray, K. "Property in Thin Air" in The Cambridge Law Journal. Vol. 50, pp 252-307. 1991.

Guenin, L. "Norms for Patents Concerning Human and Other Life Forms" in Theoretical Medicine. Vol. 17, pp.279-314, 1996.

Harkness, J. "Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in Parke-Davis v. Mulford" in Journal of Patent & Trademark Office Society. Vol. 93, 2011

Hayden, E. 'Patent Trolls' Target Biotechnology Firms in www.nature.com. Vol. 477, September 28, 2011. Accessed October 18, 2013.

Heller, M. "The Tragedy of the Anticommons: Property in the Transition from Marx to Markets," in Harvard Law Review. Vol. 111, pp. 621–88, 1998.

Heller, M. & R. Eisenberg. "Can Patents Deter Innovation? The Anticommons in Biomedical Research," in Science. Vol. 280, 1998. Pp. 698-701.

Helmers, C., B. Love & L. McDonagh. "Is There a Patent Troll Problem in the U.K.?" in Fordham Intellectual Property Media and Entertainment Law Journal. Vol. 24, pp.509 -553. 2014.

Henry, C. & J. Stiglitz. "Intellectual Property, Dissemination of Innovation and Sustainable Development" in Global Policy. Volume 3, Iss. 3, Pp.237-251, October 2010.

Henry, C., M. Trommetter & L. Tubiana. "Innovations et droits de propriété intellectuelle: quels enjeux pour les biotechnologies." Rapport du Conseil d'Analyse Economique. Paris: La Documentation Français, 2003.

Herper, M. "The Cost Of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change" in Forbes. www.forbes.com. August 11, 2013. Accessed October 14, 2013.

Hohfeld, W. Fundamental Legal Conceptions as Applied in Judicial Reasoning. David Campbell and Philip Thomas (eds). Aldershot: Ashgate Publishing Limited, 2001.

Honoré, A. "Ownership" in Oxford Essays in Jurisprudence. Guest, A.G. (ed.). Oxford: Oxford University Press, 1961. Pp.107-147.

Holman, C. "Clearing a Path Through the Patent Thicket," in Cell, Vol. 125, pp. 629-633, 2006.

Holman, M. & S. Munzer. "Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags" in Iowa Law Review. Vol. 85, No.3, Pp. 735-848, March 2000.

Hubbard T. & J. Love. "A New Trade Framework for Global Healthcare R&D" in PLoS Biology. Vol. 2, Iss.2, pp.147-150, 2004.

Hubbard, F. "'Do Androids Dream?: Personhood and Intelligent Artifacts." Draft Text, April 22, 2010.

Hughes, J. "The Philosophy of Intellectual Property" in Georgetown Law Journal. Vol. 77, pp.287-367, 1988.

Hughes, S. "Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980" in The History of Science Society. Vol. 92, No. 3, pp. 541-575, Sep. 2001.

Hunkapiller, T. et al. "Large-scale and automated DNA sequence determination" in Science. Vol.254 no. 5028, pp. 59-67, October 4, 1991.

Ilag, L., L. Ilag & L. Ilag. "From Patenting Genes to Proteins: The Search for Utility via Function" in TRENDS in Biotechnology. Vol. 20, No.5, Pp197-1999. May 2002.

Iwasaka, R. “From *Chakrabarty* to Chimeras: The Growing Need for Evolutionary Biology in Patent Law,” in Yale Law Journal. Vol 109. Pp 1505-1534. 1999-2000.

Jacob, R. “IP Law: Keep Calm and Carry On?” in Current Legal Problems. Vol. 66, pp. 379-399, 2013.

Jacob, R. “One Size Fits All?” in Perspectives on Properties of the Human Genome Project. S. Kieff (ed.) San Diego: Elsevier Academic Press, pp. 449-458, 2003.

Jacob, R. “Patent Thickets: A Paper for the European Patent Office Economic and Scientific Advisory Board Meeting,” in Journal of Intellectual Property Law & Practice. Vol. 8, No.3, pp.1-4, 2013.

Jacob, R. “Woolly Lines in Intellectual Property Law,” in Patents and Technological Progress in a Globalized World. Wolrad Prinz zu Waldeck und Pyrmont et al. (eds.) Berlin: Springer, pp. 781-791, 2009.

Jackson, M. “How Gene Patents are Challenging Intellectual Property Law: The History of the CCR5 Gene Patent” in Perspectives on Science.. Vol. 22, No. 3, pp.1-12. Fall 2014

Jacobs, P. & G. Van Overwalle. “Gene Patents: A Different Approach” in European Intellectual Property Review. Vol. 23, Iss. 11, pp. 505-506, 2001.

Jay Dratler, Jr. “Alice in Wonderland Meets the U.S. Patent System,” in Akron Law Review, pp299-336, 2005.

Jefferson, T. “The Invention of Elevators,” (Letter, 1813), in Saul K. Padover, ed., The Complete Jefferson. New York: Dell, Sloan & Pearce, 1943.

Jensen, K. & F. Murray. “Intellectual Property Landscape of the Human Genome,” in Science. Vol. 310 no. 5746 pp. 239-240. October 14, 2005.

Jewkes, J., D. Sawers & R. Stillerman. The Sources of Invention. London: Macmillan, 1958.

Karp, L. Genetic Engineering: Threat or Promise? Chicago: Nelson-Hall, Inc., 1976.

Joyner, C. “Legal Implications of the Concept of the Common Heritage of Mankind,” in International and Comparative Law Quarterly. Vol 35, Iss. 1. Pp.190-1999. 1986.

Katz, L. “Exclusion and Exclusivity in Property Law,” in University of Toronto Law Journal. Vol. 58, No.3, 2008. Pp.275-315.

Kaul, I., I. Grunberg & M. Stern (eds.). Global Public Goods: International Cooperation in the 21st Century. Oxford: Oxford University Press, 1999.

Kevles, D. & A. Berkowitz. “The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics,” in Brooklyn Law Review. Vol. 67, pp. 233-248, 2001.

Kevles, D. "From Eugenics to Patents: Genetics, Law, and Human Rights," Annals of Human Genetics, forthcoming, late summer, 2010

Kevles, D. "Genes, Railroads, and Regulation: Intellectual Property and the Public Interest," in Mario Biagioli and Jessica Riskin, eds., Worldly Science: Instruments, Practices, and the Law (forthcoming: New York: Palgrave MacMillan, 2010)

Kevles, D. "Genes, Disease, and Patents: Cash and Community in Biomedicine," in Caroline Hannaway, ed., Biomedicine in the Twentieth Century: Practices, Policies, and Politics. (Amsterdam: IOS Press, 2008), pp. 203-216

Kevles, D. Living Properties: Making Knowledge and Controlling Ownership in the History of Biology, coeditor with Jean-Paul Gaudilliere and Hans-Joerg Rheinberger (Preprint No. 382; Berlin: Max Planck Institute for History of Science, 2009)

Kevles, D. "Of Mice & Money: The Story of the World's First Animal Patent" in Daedalus. pp. 78-88, Spring 2002.

Kieff, F. "Property Rights and Property Rules for Commercializing Inventions" in Minnesota Law Review. Vol. 85, pp. 697-754. 2001.

Kitch, E. "The Nature and Function of the Patent System" in Journal of Law and Economics. Vol. 20, pp. 265-290, 1977.

Ko, Y. "An Economic Analysis of Biotechnology Patent Protection" in Yale Law Journal. Vol. 102. Pp.777-804, 1992-1993.

Kock, M. "Purpose-Bound Protection for DNA Sequences: In Through the Back Door?" in Journal of Intellectual Property Law & Practice. Vol. 5, No.7, Pp.495-513. 2010.

Kohler, P. "The Death of Ownership and the Demise of Property" in Current Legal Problems. Vol. 53, Iss. 1, p 237-282, 2000.

Krauss, J. & T. Takenaka. "A Special Rule for Compound Protection for DNA-Sequences-Impact of the ECJ 'Monsanto' Decision on Patent Practice" in Journal of the Patent and Trademark Office Society. Vol. 93, No. 2, pp. 189-206. 2011.

Krauss, J. & T. Takenaka. "Construction of an Efficient and Balanced Patent System: Patentability and Patent Scope of Isolated DNA Sequences under US Patent Act and EU Biotech Directive" in Constructing European Intellectual Property. C. Geiger (ed.) Cheltenham: Edward Elgar, Pp.255-270, 2013.

Kuhn, J. "Patentable Subject Matters: New Uses for an Old Doctrine," in Berkeley Technology Law Journal. Vol. 22.pp 89-114, 2007

La Belle, M. "Standing to Sue in the Myriad Genetics Case" in California Law Review Circuit. Vol.2, pp. 68-94. November 2011.

Lametti, D. "Laying Bare an Ethical Thread: From IP to Property to Private Law?" in Intellectual Property and the Common Law. S. Balganesh (ed.). Cambridge: Cambridge University Press, 2013. pp.353-381.

Lametti, D. "The Concept and Conceptions of Intellectual Property as Seen Through The Lens of Property" in Science and Law in the Prism of Comparative Law. G. Comandé, G. Ponzanelli,(eds.). Torino: Giappichelli, 2004, pp. 265-291.

Lametti, D. "The Concept of Anticommons: Useful, or Ubiquitous and Unnecessary?" in Concepts of Property in Intellectual Property Law. Howe, H. and J. Griffiths (eds.). Cambridge: Cambridge University Press, 2013. Pp.232-257.

Lametti, D. "The Concept of Property: Relations Through Objects of Social Wealth," in University of Toronto Law Journal. Vol. 53, pp.325-378. 2003.

Lametti, D. “The Morality of James Harris’s Theory of Property” in The Properties of Law: Essays in Honour of James Harris. T. Endicott, J. Getzler and E. Peel, (eds.). Oxford: Oxford University Press, 2006. pp. 138-165

Laurie, G. “Patenting Stem Cells of Human Origin,” in European Intellectual Property Review. Vol. 59, pp. 59-66, 2004.

Lemley, M. “Ex Ante versus Ex Post Justifications for Intellectual Property” in UC Berkeley Public Law Research Paper No. 144. 2004.

Lemley, M. & D. Burk. “Policy Levers in Patent Law,” in Virginia Law Review. Vol. 89, pp. 1575-1696, 2003.

Lemley, M. “Property, Intellectual Property, and Free Riding,” in Texas Law Review. Vol. 83, Pp.1031-1075, 2005.

Lemley, M. “Reconceiving Patents in the Age of Venture Capital” in Journal of Small and Emerging Business Law. Vol. 4, pp.137-148, 2000.

Leung, S. “The Commons and Anticommons in Intellectual Property” in UCL Jurisprudence Review. Vol. 16, pp.16-28, 2010.

Litman, M. “The Legal Status of Genetic Material” in B. Knoppers et al (eds.) Human DNA: Law and Policy: International and Comparative Perspectives. Pp. 17-32. The Hague: Kluwer Law International, 1997.

Llewelyn, M. “The Patentability of Biological Material: Continuing Contradiction and Confusion,” in E.I.P.R. Issue 5, pp.191-197, 2000.

Looney, B. “Should Genes Be Patented-The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement,” in Law & Policy in International Business. Vol 26. Pp.231-272 (1994-1995).

Machlup, F. & E. Penrose, “The Patent Controversy in the Nineteenth Century” in Journal of Economic History. Vol. 10, No.1, pp. 1-29, 1950.

Mayor, S. “First UK patents for cloning issued to creators of Dolly the sheep” in BMJ. Vol. 320, p.270. January 29, 2000.

McBride, M. “Patentability of Human Genes: Our Patent System Can Address the Issues Without Modification” in Marquette Law Review. Vol. 85, pp. 511-535, 2001.

Marden, E. “The Neem Tree Patent: International Conflict over the Commodification of Life,” in Boston College International & Comparative Review. Vol 22, 1999.

Martinez, J. “Reconstructing the Takings Doctrine by Redefining Property and Sovereignty” in Fordham Urban Law Journal. Vol.16, Iss.2, pp.157-194, 1987.

Merges, R. & R. Nelson, “Market Structure and Technical Advance: The Role of Patent Scope Decisions,” in Thomas M. Jorde David J. Teece (eds.) Antitrust, Innovation and Competitiveness. Oxford: Oxford University Press, 1992. pp.185-232.

Merges, R. The Concept of Property in the Digital Age. UC Berkeley, 2008. Retrieved from: http://escholarship.org/uc/item/142112hd. Accessed October 23, 2013.

Mazzoleni, R. & R. Nelson. “The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate” in Research Policy. Vol. 27, 1998.

Miller, J. "Sealing the Coffin on the Experimental Use Exception" in Duke Law and Technology Review. Vol. 2, Iss. 1, 2003.

Mireles, M. “An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation,” in University of Michigan Journal of Law Reform. Vol. 38, pp.141-235, 2004.

Mitchell, R. K., B. R. Agle, & D.J. Wood. "Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What really Counts" in Academy of Management Review. Vol. 22, Iss. 4, pp. 853 – 888, 1997.

Moga, T. “Transgenic Animals as Intellectual Property (or the Patented Mouse That Roared)” in Journal of Patent & Trademark Office Society. Vol 76,1994. Pp 511-545.

Morris, C. “Property and Sovereignty” in Cornell Law Quarterly. Vol.13, 1927. Pp.8-30

Nisbet, M. “Public Opinion About Stem Cell Research and Human Cloning” in Public Opinion Quarterly. Vol.68, No. 1, pp. 131-154, 2004.

Ohly, A. “Reverse Engineering: Unfair Competition or Catalyst for Innovation?” in Wolrad Prinz zu Waldeck und Pyrmont et al. (eds.) Patents and Technological Progress in a Globalized World. Pp. 535-552. Munich: Springer, 2009.

Onwuekwe, C. “Plant Genetic Resources and the Associated Traditional Knowledge: Does the Distinction between High and Lower Life Forms Matter?” in Johanna Gibson’s (ed.) Patenting Lives: Life Patents, Culture and Development. England: Ashgate Publishing Limited, 2008.

Ossorio, P. “Property Rights and Human Bodies,” in Magnus, D., Arthur Caplan and Glenn McGee (eds.) Who Owns Life? Pp.223-243. New York: Prometheus Books, 2002.

Ossario, P. “The Human Genome as Common Heritage: Common Sense or Legal Nonsense?” in Genetics and Group Rights. Pp. 425-439. Fall 2007.

Padron, Miguel Sanchez and Mikel Gomez Uranga. “Protection of Biotechnological Inventions: A Burden Too Heavy for the Patent System” in Journal of Economic Issues. Vol. XXXV No. 2 June 2001 pp.315-322.

Penner, J. “Hohfeldian Use-Rights in Property” in Property Problems: From Genes to Pension Funds. J.W. Harris (ed.) London: Kluwer Law International, 1997. Pp.164-174.

Penner, J. “The Bundle of Rights Picture of Property” in UCLA Law Review. Volume 43, 1995-1996. Pp.711-820.

Penner-Hahn, J. & J. Shaver. "Does international research and development increase patent output? An analysis of Japanese pharmaceutical firms" in Strategic Management Journal. Vol. 26, no. 2, pp.121-140, 2005.

Pila, J. “Isolated Human Genes: The Patent Equivalent of a Non-Copyrightable Sound Recording” in Law Quarterly Review (forthcoming) 2014.

Pila, J. “Patent for Human Genes and Methods of Analysis and Comparison,” in Law Quarterly Review. Vol. 126, pp. 534-538, 2010.

Pila, J. “The Future of the Requirement for an Invention: Inherent Patentability as a Pre- and Post-Patent Determinant,” in Arezzo, E. and Gustavo Ghidini (eds.) Biotechnology and Software Patent Law: A Comparative Review of New Developments. Cheltenham: Edward Elgar Publishing Limited, 2011.

Plant, A. “The Economic Theory Concerning Patents for Inventions,” in Economica, New Series, Vol. 1. Pp. 30-51. 1934.

Poland, S. “Genes, Patents and Bioethics-Will History Repeat Itself?” in Kennedy Institute of Ethics Journal. Vol. 10, No. 3, 265-381. 2000.

Priest, G. “What Economists Can Tell Lawyers About Intellectual Property: Comment on Cheung” in Research in Law and Economics. Vol. 8, pp.19-24, 1986.

Quigley, M. “Property and the Body: Applying Honoré” in Journal of Medical Ethics. Vol.33, 2006. Pp.631-634.

Ramirez, H. “Defending the Privatization of Research Tools: An Examination of the Tragedy of the Anticommons in Biotechnology Research and Development” in Emory Law Journal. Vol. 53, pp.359-389, 2004.

Rai, A. “Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials” in Washington University Journal of Law and Policy. Vol. 2, pp. 199-227, 2000.

Rai, A. “Intellectual Property Rights in Biotechnology: Addressing New Technology,” in Wake Forest Law Review. Vol. 34. Pp.827-847, 1999.

Rai, A. “Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development,” in Duke Law Journal. Vol. 61, pp. 101-160, 2012.

Rai, A. “Regulating Scientific Research: Intellectual Property Rights and the Norms of Science,” in Northwestern University Law Review. Vol. 94, No.1, pp.77-152, 1999.

Ravenshear, A. The Industrial and Commercial Influence of the English Patent System. London: T. Fisher Unwin,1908.

Resnik, D. “A Biotechnology Patent Pool: An Idea Whose Time Has Come?” in The Journal of Philosophy, Science & Law. Vol.3, 2003.

Restaino, L., S. Halpern & E. Tang. “Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?” in UCLA Journal of Law and Technology, 2003.

Robinson, D. and N. Medlock. “Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents” in Intellectual Property & Technology Law Journal. Vol. 17, No. 10, October 2005.

Romano, R. “‘Ownership and Provenance’ of Genetic Material in the Rules on Biotechnological Patents” in Bin, Roberto, Sara Lorenzon and Nicola Lucci (eds.) Biotech Innovations and Fundamental Rights. pp.69-76. New York: Springer, 2012.

Rogers, E. “Can You Patent Genes? Yes and No” in Journal of the Patent and Trademark Office Society. Vol 93. Pp 19-56. 2010.

Samuelson, P. "The Pure Theory of Public Expenditure" in Review of Economics and Statistics. Vol. 36. Iss. 4, 1954. Pp. 387–389.

Savage, G., T. Nix, Whitehead & Blair. "Strategies for assessing and managing organizational stakeholders," in Academy of Management Executive. Vol. 5, Iss. 2, pp. 61 – 75. (1991).

Schöler, H. "The Potential of Stem Cells: An Inventory" in Knoepffle, N. et al. (eds.) Humanbiotechnology as Social Challenge. pp.27-56. Aldershot: Ashgate Publishing, 2008.

Shapiro, C. "Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting," in Jaffe, A., Joshua Lerner, and Scott Stern (eds.) Innovation Policy and the Economy. Cambridge: The MIT Press. 2001.

Shiffrin, S. "Lockean Arguments for Private Intellectual Property," in Stephen Munzer (ed.) New Essays in the Legal and Political Theory of Property. Cambridge: Cambridge University Press. 2001. Pp.138-167.

Singer, J. "Legal Theory: Sovereignty and Property" in Northwestern University Law Review. Vol.86, No.1 1991-1992. Pp.1-56.

Smith, H. "Intellectual Property as Property: Delineating Entitlements in Information," in Yale Law Journal. Vol. 116, pp. 1742-822. 2007.

Stadler, W. (ed). Cancer Biology Review: A Case-Based Approach. Demos Medical Publishing, 2014.

Storz, U., W. Flasche & J. Driehaus. Intellectual Property Issues: Therapeutics, Vaccines and Molecular Diagnostics. Springer: Heidelberg, 2012.

Straus, J. An Updating Concerning the Protection of Biotechnological Inventions Including the Scope of Patent Genes-An Academic Point of View. Official Journal of the European Patent Office Special Issue. pp. 155-189, 2003.

Straus, J. "Ordre Public and Morality Issues in Patent Eligibility" in Takenaka, Toshiko (Ed.). Intellectual Property in Common Law and Civil Law. Cheltenham: Edward Elgar Publishing, p. 19-49. 2013

Straus, J. "Product Patents on Human DNA Sequences: An Obstacle for Implementing the EU Biotech Directive?" in F. Scott Kieff (ed.) Perspectives on Properties of the Human Genome Project. Boston: Elsevier Academic Press, 2003. Pp.65-78.

Straus, J. The Scope of Protection Conferred by European Patents on Transgenic Plants and Methods for Their Production," in A. Bakardjieva et al. (eds.) Festschrift for Marianne Levin. pp. 643-657. Stockholm: Norstedts Juridik, 2008.

Takahashi, K. & S. Yamanaka. "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors" in Cell. Vol. 126, pp. 663–676, 2006.

Underkuffler, L. "Tahoe's Requiem: The Death of the Scalian View of Property and Justice," in Constitutional Commentary. Vol. 21, pp. 727-755, 2004.

Van Overwalle, G. "Patent Protection for Plants: A Comparison of American and European Approaches," in IDEA-Journal of Law and Technology, pp. 143-194, 1999.

Van Overwalle, G. et al. 'Models for Facilitating Access to Patents on Genetic Inventions' in Nature Reviews Genetics. Vol. 7, 2006

Van Zimmeren, E. & G. Van Overwalle. "A Paper Tiger? Compulsory License Regimes for Public Health in Europe" in International Review of Intellectual Property and Competition Law. Vol. 4, pp. 4-40, 2011.

Walsh, P. et al. "Effects of Research Tool Patenting and Licensing and Biomedical Innovation" in Patents in the Knowledge-Based Economy. Cohen, W. and S. Merill (eds.) Washington: National Academies Press, pp.285-340, 2002.

Walsh, T. et al. The Journal of the American Medical Association. Vol. 295, 1379-1388, 2006.

Walsh, T. et al. Detection of Inherited Mutations for Breast and Ovarian Cancer Using Genomic Capture and Massively Parallel Sequencing. Proceedings of the National Academy of Science. Vol. 107, No. 28, 12629–12633, 2010.

Wang, R. "Biomedical Upstream Patenting and Scientific Research: The Case For Compulsory Licenses Bearing Reach-Through Royalties" in Yale Journal of Law and Technology. Vol. 10, Iss. 1, Article 7, 2008.

Warren-Jones, A. "Patenting DNA: A Lot of Controversy Over a Little Intangibility," in Medical Law Review. Vol. 12, pp. 97-124, Spring 2004.

Whitehill, J. "Patenting Human Embryonic Stem Cells: What is so Immoral?" in *Brooklyn Journal of International Law.* Vol. 34, Issue 3, pp. 1045-1080 (2009).

Wilson, R. "How the Worm Was Won. The C. Elegans Genome Sequencing Project" in Trends in Genetics. Vol. 15, Iss.2, pp.51-58. February 1999.

Wolf, L. "Advancing Research on Stored Biological Materials: Reconciling Law, Ethics and Practice" in Minnesota Journal of Law, Science and Technology. Vol. 11, pp.99-156. 2010.

Woollett, G. & O. Hammond. "An Industry Perspective on the Gene Patenting Debate" in Perspectives on Gene Patenting (Ed.: A. Chapman) American Association for the Advancement of Science. pp.43-50. Washington,1999.

Wilson, J. "Patenting Organisms: Intellectual Property Law Meets Biology," in D. Magnus, A. Caplan & and G. McGee (eds.). Who Owns Life? New York: Prometheus Books, Pp. 25-58, 2002.

Yu, A. "Why It Might Be Time to Eliminate Genomic Patents, Together with the Natural Extracts Doctrine Supporting Such Patents," in IDEA: The Intellectual Property Law Review. Vol.47, No.5, pp.659-755. 2006-2007.

Books

Alexander, G. Commodity & Propriety: Competing Visions of Property in American Legal Thought 1776-1970. Chicago: The University of Chicago Press, 1997.

Amani, B. State Agency and the Patenting of Life in International Law. Surrey: Ashgate

Publishing Limited, 2009.

Aristotle. Aristotle in 23 Volumes, Vol. 21, translated by H. Rackham. Cambridge, MA, Harvard University Press; London, William Heinemann Ltd. 1944.

Barnes, R. Property Rights and Natural Resources. Oxford: Hart Publishing, 2009.

Bentham, J. Principles of the Civil Code. Edinburgh: The Works, published under the superintendence of John Bowring. 1843.

Bentham, J. Theory of Legislation: Being Principes de legislation, and Traites de legislation, civele et penale. Volume 1. London: Humphrey Milford, 1914.

Bentham, J. The Works of Jeremy Bentham/Published Under the Superintendence of His Executor, John Bowring Vol. III. Edinburgh: William Tait, 1843.

Bernier, L. Justice in Genetics: Intellectual Property and Human Rights from a Cosmopolitan Liberal Perspective. Cheltenham: Edward Elgar, 2010.

Beyleveld, D. & R. Brownsword. Mice, Morality and Patents: The Oncomouse Application and Article 53(a) of the European Patent Convention. London: The Common Law Institute of Intellectual Property, 1993.

Black's Law Dictionary (8th ed). Bryan A. Garner (Editor in Chief). Minnesota: Thomson West, 2004.

Boyle, J. The Public Domain: Enclosing the Commons of the Mind. New Haven: Yale University Press, 2008.

Bud, R. The Uses of Life: A History of Biotechnology. Cambridge: Cambridge University Press, 1993.

Chemtob-Concé M. C. et Gallochat A., Le Brevetabilité des inventions technologiques appliquées à l'homme. (Ed. Lavoisier, Tech & Doc, Paris 2ème ed., 2004).

Cicero, M. (May, J.M. & Wisse, J. trans.), Cicero on the Ideal Orator (De Oratore), Oxford University Press, (Oxford), 2001.

Chisum, D. Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement. New York: Matthew Bender, 1978-, Release 140, 2013.

Cooter, R. and T. Ulen. Law & Economics. Boston: Pearson Educational International, 2003.

Cornish, W., D. Llewelyn and T. Aplin. Intellectual Property: Patents, Copyright, Trademarks and Allied Rights. London: Sweet & Maxwell Ltd, 2010.

Correa, C. Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement. Oxford: Oxford University Press, 2007.

Daintith, J. and E. Martin (eds.) A Dictionary of Science. Oxford: Oxford University Press, 2010.

Davies, M. & N. Naffine. Are Persons Property?: Legal Debates about Property and Personality. Aldershot: Ashgate, 2001.

Dawkins, R. The Selfish Gene. Oxford: Oxford University Press, 2006.

De Robbio, A. Biobanks: Patents or Open Science? Oxford: Woodhead Publishing Limited, 2013.

Devaney, S. Stem Cell Research and the Collaborative Regulation of Innovation. London: Routledge, 2014.

Dickenson, D. Property in the Body: Feminist Perspectives. Cambridge: Cambridge University Press, 2007.

Dinwoodie, G. Methods and Perspectives in Intellectual Property. Cheltenham: Edward Elgar, 2013.

Drahos, Peter. A Philosophy of Intellectual Property. Aldershot: Dartmouth Publishing Company, 1996

Dutfield, G. Intellectual Property Rights and the Life Science Industries: Past, Present and Future 2nd Edition. London: World Scientific Publishing Co. Ptc Ltd, 2009.

Dutfield, G. and U. Suthersanen. Global Intellectual Property Law. United Kingdom: Edward Elgar Publishing Limited, 2008.

Dybdahl, L. European Patents. Cologne: Carl Heymanns Verlag KG, 2001.

Ebermann, P. Patents as Protection of Traditional Medical Knowledge? A Law and Economics Analysis. Cambridge: Intersentia, 2012.

Ereky, K. Biotechnologie der fleisch, fett und milcherzeugung im landwirtschaft- lichen grossbetriebe Biotechnology of Meat, Fat and Milk Production in an Agricultural Large-Scale Farm (English translation) Berlin, 1919.

Feldman, R. Rethinking Patent Law. Cambridge: Harvard University Press, 2012

Fiechter, A. (Ed.) History of Modern Biotechnology I. Berlin, Springer, 2000.

Fisher, M. Fundamentals of Patent Law: Interpretation and Scope of Protection. Oxford: Hart Publishing, 2007.

Freeman, R. Strategic Management: A Stakeholder Approach. Boston: Pitman, 1984

Gibson, J. (ed.) Patenting Lives: Life Patents, Culture and Development. England: Ashgate Publishing Limited, 2008.

Gold, R. Body Parts: Property Rights and the Ownership of Human Biological Materials. Washington: Georgetown University Press, 2008.

Gribbin, J. Introducing Genetics. Cambridge: Icon Books Ltd, 2005.

Gulick, G. and R. Kimbrough (eds.). American Jurisprudence 2nd edition. Volume 1. San Francisco: Bancroft-Whitney Company, 1962.

Hardcastle, R. Law and the Human Body: Property Rights, Ownership and Control. Oxford: Hart Publishing, 2007.

Harris, J. Property & Justice. Oxford: Oxford University Press, 1996.

Hegel, G.W.F. Elements of the Philosophy of Right. Allen Wood (ed.) Cambridge: Cambridge University Press, 1991.

Hobbes, T. Leviathan: Or the Matter, Forme, & Power of a Common-wealth Ecclesiasticall and Civill. Edited by I. Shapiro. New Haven: Yale University Press, 2010

Hughes, S. Genentech: The Beginnings of Biotech. Chicago: The University of Chicago Press, 2011.

Jacob, R., D. Alexander and M. Fisher. Guidebook to Intellectual Property-6th edition. Oregon: Hart Publishing, 2013.

Keller, E. Making Sense of Life: Explaining Biological Development with Models, Metaphors and Machines. Cambridge: Harvard University Press, 2003.

Kiessling, A. & S. Anderson. Human Embryonic Stem Cells 2nd edition. Massachusetts: Jones and Bartlett Publishers, 2007.

King, R., P. Mulligan & W. Stansfield. A Dictionary of Genetics (8 ed.) Oxford: Oxford University Press, 2014.

Landes, W. and R. Posner. The Economic Structure of Intellectual Property Law. Cambridge: Belknap Press, 2003.

Locke, J. Two Treatises of Government [1698] New Jersey: Lawbook Exchange Edition, 2010.

Lodish, H. et al. Molecular Cell Biology, 7th edition. New York: W.H. Freeman and Company. 2012.

Macfie, R. The Patent Question under Free Trade: A Solution of the Difficulties by Abolishing or Shortening the Inventor's Monopoly and Instituting National Recompenses 2nd edition. London: W Johnson, 1863.

Macpherson, C. The Political Theory of Possessive Individualism: Hobbes to Locke. Oxford: Oxford Paperbacks, 1962.

Martin, E. & R. Hine. A Dictionary of Biology (6 ed.) Oxford: Oxford University Press, 2008.

Martens, J. Secret Patenting in the U.S.S.R. and Russia. Sante Fe: Deep North Press, 2010.

Mattei, U. Basic Principles of Property Law: A Comparative Legal and Economic Introduction. London: Greenwood Press, 2000.

Mazzucato, M. & G. Dosi. Knowledge Accumulation and Industry Evolution: The Case of Pharma-Biotech. Cambridge: Cambridge University Press, 2006

McGloughlin, M. The Evolution of Biotechnology: From Natufians to Nanotechnology. Dordrecht: Springer, 2010.

Mercuro, N. & S. Medema. Economics and the Law: From Posner to Post-Modernism. Princeton: Princeton University Press, 1997.

Merges, R. Justifying Intellectual Property. Cambridge: Harvard University Press, 2011.

Merges, R. & J. Duffy. Patent Law and Policy: Cases and Materials, 5th Ed. Lexis Nexis, 2011.

Mill, J. Principles of Political Economy: With Some of Their Applications to Social Philosophy Vol. 1. New York: D. Appleton and Company, 1864.

Mill, J. Principles of Political Economy, Vol.2. London: Green & Company, 1929.

Mill, J. Utilitarianism. Chicago: University of Chicago Press, 1906.

Miller, A. and M. Davis. Intellectual Property. Minnesota: West Publishing, 2000.

Mills, O. Biotechnological Inventions: Moral Restraints and Patent Law. England: Ashgate Publishing Limited, 2010

Mitchell, H. The Intellectual Commons: Toward an Ecology of Intellectual Property. New York: Lexington Books, 2005.

Mossoff, A (ed.). Intellectual Property and Property Rights. Cheltenham: Edward Elgar, 2013.

Mueller, J. Patent Law 4th edition. New York: Wolters Kluwer Law & Business, 2013.

Munzer, S. A Theory of Property. Cambridge: Cambridge University Press, 1990.

Nwabueze, R. Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information. England: Ashgate Publishing Limited 2007.

Palombi, L. Gene Cartels: Biotech Patents in the Age of Free Trade. Cheltenham: Edward Elgar Publishing Ltd., 2009.

Parry, B. Trading the Genome: Investigating the Commodification of Bio-Information. New York: Columbia University Press, 2004.

Paterson, G. The European Patent System: The Law and Practice of the European Patent Convention. London: Sweet & Maxwell, 2001.

Penner, J. The Idea of Property in Law. Oxford: Clarendon Press, 1997.

Pila, J. The Requirement for an Invention in Patent Law. Oxford: Oxford University Press, 2010.

Plomer, A and P. Torremans. Embryonic Stem Cell Patents: European Law and Ethics. Oxford: Oxford University Press, 2009.

Posner, R. Economic Analysis of Law 5th edition. New York: Aspen Law and Business. 1998.

Rhodes, C. Governance of Genetic Resources: A Guide to Navigating the Complex Global Landscape. Cheltenham: Edward Elgar, 2013.

Rimmer, M. Intellectual Property and Biotechnology. Cheltenham: Edward Elgar, 2008.

Ritchie, J. et al. Qualitative Research Practice. 2nd edition. Los Angeles, Sage Publications Inc., 2014.

Robinson, W. The Law of Patents For Useful Inventions. Boston: Little, Brown and Company, 1890.

Roughton, A., P. Johnson & T. Cook (eds.) The Modern Law of Patents (2nd edition). UK: Lexis Nexis, 2010.

Samuelson, P. and W. Nordhaus. Economics. London: McGraw-Hill, 1989.

Schumpeter, J. Business Cycles I. New York: McGraw Hill, 1939.

Schumpeter, J. Capitalism, Socialism and Democracy. New York: Harper & Row, 1950.

Schumpeter, J. The Theory of Economic Development, 1983. London: Transaction Publishers, 2008.

Shmaefsky, B. Biotechnology 101. London: Greenwood Press, 2006.

Skloot, R. The Immortal Life of Henrietta Lacks. London: Macmillan Publishers, 2010.

Smith, A. The Wealth of Nations. New York: The Modern Library, 1937.

Sullivan, S. et al. Human Embryonic Stem Cells: The Practical Handbook. Chicester: John Wiley & Sons, 2007.

Sulston, J. and G. Ferry. The Common Thread: Science, Politics, Ethics and the Human Genome. Great Britain: Bantam Press, 2003.

Swanson, J. Scientific Discoveries and Soviet Law. Gainesville: University of Florida Press, 1984.

Taussig, F. Inventors and Money-Makers. New York: 1915.

Taylor, C. & A. Silberston. The Economic Impact of the Patent System. Cambridge: Cambridge University Press, 1973.

The Shorter Oxford English Dictionary on Historical Principles Part II 3rd edition. C.T. Onions (Ed). Oxford: Clarendon Press, 1987.

Underkuffler, L. The Idea of Property: Its Meaning and Power. Oxford: Oxford University Press, 2003.

Vogel, F. and R. Grunwald (eds.). Patenting of Genes and Living Organisms. New York: Springer, 1994.

Waldron, J. The Right to Private Property. Oxford: Clarendon Press, 1988.

Wei, G. An Introduction to Genetic Engineering, Life Sciences and The Law. Singapore: Singapore University Press, 2002.

Westerlund, L. Biotech Patents, Equivalency and Exclusions Under European and US Patent Law. New York: Kluwer Law International, 2002.

Westerlund, L. Life Science Inventions. Uppsala: Iustus Forlag, 2004.

Wilkinson, S. Bodies for Sale: Ethics and Exploitation in the Human Body Trade. London: Routledge, 2003.

Verma, A. et al. "Biotechnology in the Realm of History," in Journal of Pharmacy & Bioallied Sciences. Vol. 3, Iss.3, pp. 321–323, Jul-Sep 2011.

Zweigert, K. and H. Kötz. An Introduction to Comparative Law. Oxford: Clarendon Press, 1992.

Reports

American Jurisprudence 2nd edition. Volume 63C, 2009 revision.

Australia Government. Genes and Ingenuity Report: Gene Patenting and Human Health. Australia Law Reform Commission. Report 99, June 2004.

Beier, F-K, R. Crespi & J. Straus. Biotechnology and Patent Protection: An International Review. Paris: OECD, 1985.

Belcher, Brian and Geoffrey Hawtin. A Patent on Life: Ownership of Plant and Animal Research International Development Research Centre, Ottawa, Canada. 1991

Brief of Appellant in Response to United States 2013-1377, Consumer Watchdog v. Wisconsin Alumni Research Foundation. Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, January 27, 2014.

Brief of James D. Watson, as Amicus Curiae in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013.

Brief for Amicus Curiae Eric S. Lander in Support of Neither Party. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013.

Brief of the American Bar Association as Amicus Curiae in Support of Respondents. The Association of Molecular Pathology, et al., v. Myriad Genetics, Inc., et al., No. 12-398. 2013.

Canadian Biotechnology Advisory Committee. Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee. June 2002. www.publications.gc.ca/collections/Collection/C2-598-2001-2E.pdf. Accessed May 27, 2012.

Commercial Biotechnology: An International Analysis (Washington, D. C.: U.S. Congress,

Office of Technology Assessment, OTA-BA-218, January 1984)

Council of Europe, Committee of Ministers. Recommendation Rec (2006)4 of the Committee of Ministers on Research on Biological Materials of Human Origin. (Adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies).

Decision G 1/07 of February 15, 2010, Reasons 3.3.6.

Decision T 154/04 of November 15, 2006, Reasons 6, Official Journal of the European Patent Office.

European Commission. The Contribution of Biotechnology to Europe's Industry Sectors. May 2, 2013. http://ec.europa.eu/enterprise/sectors/biotechnology/what-is-biotechnology/contribution/. Accessed June 14, 2013.

European Patent Office, Decision of the Technical Board of Appeal. 3.3.2 of 3 October 1990.

European Patent Office. Guidelines for Examination in the EPO Part C Guidelines for Substantive Examination Chapter IV Patentability 3. Biotechnological Inventions. www.epo.org/law-practice/legal-texts/html/guiex/e/c_iv3_2.htm. Accessed August 10, 2011.

European Patent Office, Press Release 3/92, European Patent for Harvard's Transgenic Mouse.

European Patent Office. Guidelines for Examination in the EPO Part C Guidelines for Substantive Examination Chapter IV Patentability 3. Biotechnological Inventions. www.epo.org/law-practice/legal-texts/html/guiex/e/c_iv3_2.htm. Accessed August 10, 2011.

European Patent Office Economic and Scientific Advisory Board. Report of Workshop on Patent Thickets. March 2013. Available at: http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/workshop_patent_thickets_en.pdf. Accessed October 3, 2013.

European Patent Office. Travaux Préparatoires EPC 1973. Available at: http://www.epo.org/law-practice/legal-texts/archive/epc-1973/traveaux.html. Accessed November 8, 2013.

European Patent Application No. 863044907, President and Fellows of Harvard College, Response to the Official Letter of 11th December 1990.

Evangelischen Kirche in Deutschland (EKD). The Earth is the Lord's and all That is in It: Biopatents and Food Security from a Christian Perspective. April 2013. www.ekd.de. Accessed April 30, 2013.

Federal Trade Commission. To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy. www.ftc.gov.os/2003/1110/innovationrpt.pdf. October 2003. Accessed January 4, 2014

Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries. World Health Organization, 2005.

In the Canadian Patent Office-The Decision of the Commissioner of Patents, Harvard Oncomouse Case. August 4, 1995.

Kevles, D. A History of Patenting Life in the United States with Comparative Attention to Europe and Canada . January 12, 2002. http://ec.europa.eu/bepa/european-group-ethics/docs/publications/study_kevles_en.pdf. Accessed June 8, 2013.

Machlup, F. An Economic Review of the Patent System. 65th Congress 2d Session. United States Printing Office Washington: 1958.

Max Planck Institute for Innovation and Competition. Declaration on Patent Protection: Regulatory Sovereignty under TRIPS. http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm. Accessed on April 15, 2014.

National Academy of Sciences, Committee on Intellectual Property Rights in the Knowledge-Based Economy. A Patent System for the 21st Century. www.nap.edu/catalog.php?record_id=10976. 2004. Accessed January 4, 2014.

National Bioethics Advisory Commission. Ethical and Policy Issues in Research Involving Human Participants. Vol 1. Report and Recommendations of the NBAC. August 2001. Bethesda, Maryland. www.bioethics.georgetown.edu/nbac/human/overvol1.pdf . Accessed July 9, 2013.

National Cancer Institute (NCI). Office of Biorepositories. Best Practices for Biospecimen Resources. 2011. www.biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf. Accessed July 10, 2013.

National Institutes of Health. National Human Genome Research Institute. www.genome.gov. Accessed June 27, 2013.

National Research Council (US) Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. Reaping the Benefits of Genomic and Proteomic Research. S. Merrill & A. Mazza (eds.). Washington (DC): National Academies Press (US), 2006.

Glossary of Industrial Organisation Economics and Competition Law, compiled by R. S. Khemani and D. M. Shapiro, commissioned by the Directorate for Financial, Fiscal and Enterprise Affairs, OECD, 1993.

OECD. "Biotechnology" in OECD Factbook 2011-2012: Economic, Environmental and Social Statistics. OECD Publishing. 2011.

OECD. Future Prospects for Industrial Biotechnology OECD Publishing. 2011.

OECD. Genetic Inventions, Intellectual Property Rights and Licensing Practices, Report of a Workshop Organized by the OECD Working Party on Biotechnology. www.oecd.org/dataoecd/42/21/2491084.pdf. Accessed February 5, 2012.

Official Journal of the European Patent Office. Special Edition 4, 2007.

Ontario Report to Premiers, Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare. (Toronto: Ontario Government, 2002).

Bot, Yves. Opinion of Advocate General. Case C- 34/10: *Oliver Brüstle v. Greenpeace Ev* .Delivered on March 10, 2011.

Quigg, D.J. "By the Commissioner of the United States Patent and Trademark Office, Policy Statement on Patentability of Animals" in Official Gazette Patent Office. Vol. 24, April 7, 1987.

Commission of the European Communities. Report from the Commission to the Council and the European Parliament: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering. Brussels. July 14, 2005.

Report of the National Institutes of Health (NIH) Working Group on Research Tools. June 4, 1998. http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm. Accessed September 23, 2013.

Subcommittee on Patents, Trademarks, and Copyrights of Senate Committee on the Judiciary, 85th Congress., An Economic Review of the Patent System 80 (Comm.Print 1985) (Fritz Machlup)

The Law of the Twelve Tables, Table VI, Law I .c.450 B.C. Project Gutenberg. www.gutenberg.org. Accessed Aug 29, 2013.

The Nuffield Council on Bioethics. Human Tissue, Ethical and Legal Issues. 1995. www.nuffieldbioethics.orgsites/default/files/Hurnan%20tissue.pdf. (Accessed April 2, 2013).

The Nuffield Council on Bioethics. The Ethics of Patenting DNA. London: Nuffield Council, 2002.

UK Intellectual Property Office, "Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the Intellectual Property Office" (April 2011).

United Kingdom Human Tissue Act. 2004. Chapter 30. www.opsi.gov.ac. Accessed July 9, 2013.

United States Patent and Trademark Office. Memorandum: Guidance For Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena. March 4, 2014.

United States Patent and Trademark Office. Memorandum: Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc. June 13, 2013.

United States Patent and Trademark Office. "Revised Utility Examination Guidelines, Requests for Comments" in Federal Register. Vol.64, Iss. 224. Pp. 71440-71442. December 21, 1999.

United States Patent and Trademark Office. "Utility Examination Guidelines" in Federal Register. Vol. 66, No.4, Friday, January 5, 2001. Pp.1092-1099. http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf. Accessed October 18, 2012.

Unterrichtung durch die Bundesregierung - Bericht der Bundesregierung über die Wirkungen des Gesetzes zur Umsetzung der Biopatentrichtlinie Bundestags Drucksache 16/12809. (English translation: Report of the German Federal Government on the effects of the act to implement the Biotech Directive from 29. 04. 2009)

UK Intellectual Property Office. A Study of Patent Thickets. July 30, 2013. www.ipo.gov.uk/ipresearch-thickets.pdf. Accessed November 19, 2013

World Intellectual Property Organization Secretariat. CDIP/13/10. Patent-Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels-Part III. March 27, 2014.

World Health Organization, Genomics and World Health (Geneva: WHO, 2002)

World Intellectual Property Organization. WIPO Intellectual Property Handbook: Policy, Law and Use. 2004. Available at: http://www.wipo.int/about-ip/en/iprm. Accessed June 3, 2011.

World Intellectual Property Organization. World Intellectual Property Indicators, 2012 Edition. WIPO Economics & Statistics Series. http://www.wipo.int/ipstats/en/wipi/ Accessed July 24, 2013.

News Articles

Angier, N. “Fierce Competition Marked Fervid Race for Cancer Gene” in New York Times. September 20, 1994. www.nytimes.com . Accessed July 23, 2013.

“Bioethics and Patent Law: The Case of the Oncomouse” in WIPO Magazine. Issue 3, pp.16-17, June 2006

Check, E. “Canada Stops Harvard's Oncomouse in its Tracks” in Nature. Vol. 420, December 12, 2000.

“Genes and Patents: More Harm Than Good?” The Economist. April 15, 2010. New York. Print.

Gilbert, N. “Case studies: A hard look at GM crops” in Nature. Vol. 497, Iss. 7447, pp. 24–26, May 2013.

“IP Clinic: How is Myriad Affecting IP Practitioners?” in Managing Intellectual Property. Issue 238, pp.82-83, April 2014.

Ledford, H. “Myriad Ruling Causes Confusion: Change to Gene Patents Leaves US Biotech in a Lather” in Nature. 498, 281–282 (June 20 2013) www.nature.com. Accessed June 21, 2013.

Krauthammer, C. “A Special Report on Cloning” in Time. March 10, 2007. Print.

Makin, Kirk. “Canada Rules in Favor of Monsanto over Seed Saving Farmer Percy Schmeiser” in Globe and Mail Update (Canada). May 21, 2004. Accessed November 3, 2013.

Marshall, E. "Historic Patent on Embryonic Stem Cells Faces Scrutiny" in Science. Vol. 343, p.359. January 24, 2014.

Marshall, E. “HIV Experts vs. Sequencers in Patent Race” in Science. Vol. 2.75. 28.2. 1997.

Palmer, Alasdair. "Should the European Court be allowed to dash my hopes of a cure?" in The Daily Telegraph. London. April 30, 2011. Print.

Park, A. “The Perils of Cloning” in Time Magazine. July 5, 2006. www.time.com. Accessed July 23, 2013.

Pearson, H. "Genetics: What is a Gene?" in Nature Vol. 441. Pp. 398–401. 2006.

Plecash, C. “Canada’s Life Sciences Industry Split on Canada-EU Free Trade Agreement” in The Hill Times. September 10, 2012. Accessed July 22, 2013.

Pollack, A. “Patentholder on Breast Cancer Tests Denied Injunction in Lawsuit,” in New York Times. March 10, 2014.

Pray, L. “Discovery of DNA structure and function: Watson and Crick” in Nature Education. Vol.1, Iss. 1, 2008.

Quigg D., (USPTO), Statement, Policy Statement on Patentability of Animals, 1077 Off. Gaz. Pat. Office 24, April 7,1987.

Russo, E. “Special Report: The Birth of Biotechnology” in Nature. Volume 421. Pp.456-457, January 2003.

Schwartz, J. & A. Pollack. (March 29, 2010). "Judge Invalidates Human Gene Patent". *The New York Times*. http://www.nytimes.com/2010/03/30/business/30gene.html. Retrieved 3 December, 2010.

Schneider, K. “Harvard Gets Mouse Patent, A World First” in New York Times. April 13,1988.

Seymour, E. “Cambridge Academics Will Bypass European Stem Cells Ruling” in The Huffington Post. December 1, 2012. http://www.huffingtonpost.co.uk Accessed June 5, 2013.

Smith, A. “‘No’ to ban on stem-cell patents” in Nature. Vol. 472, April 28, 2011.

Stiglitz, J. “How Intellectual Property Reinforces Inequality” in New York Times. July 14, 2013. www.opinionator.blogs.nytimes.com/2013/07/14/how-intellectual-property-reinforces-inequality. Accessed January 3, 2014.

Szczerba, R. Scary Bedtime Stories: Healthcare and the Patent Trolls. www.forbes.com. October 10, 2013. Accessed October 17, 2013

Thomas, S. et al. “Ownership of the Human Genome” in Nature. Vol. 380. Pp.387-388, 1996.

Weiss, R. “How do you Patent a New Elephant” in Washington Post. Sep 20, 1987, at C3.

Van Overwalle, G. et al. ‘Models for Facilitating Access to Patents on Genetic Inventions’ in Nature Reviews Genetics Vol. 7, pp. 143-154, February 2006.

Young, C. “Law is Lagging Genetic Research, Warns Former SCC Judge Binnie,” in The Lawyers Weekly. Vol. 33, No.40, March 7, 2014.

Electronic sources

Bently, L. & M. Kretschmer (eds.) Venetian Statute on Industrial Brevets, Venice (1474), Primary Sources on Copyright (1450-1900). www.copyrighthistory.org Accessed September 29, 2013.

Buckley, T. The Myth of the Anticommons. Biotechnology Industry Organization, May 21, 2007, http://www.bio.org. Accessed February 24, 2012.

“Chiron Grants Nonexclusive HCV License to Prosetta,” PR Newswire. June 22, 2004. http://www.prnewswire.com/news-releases/chiron-grants-nonexclusive-hcv-license-to-prosetta-75096622.html. Accessed November 25, 2014.

Feldman M, A. Colaianni and C. Liu. “Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program” in Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices. (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. 2007. Available online at www.ipHandbook.org. Accessed March 21, 2014.

"Frederick Sanger on Gene Patenting". Cold Spring Harbor Laboratory. http://library.cshl.edu/oralhistory/interview/genome-research/gene-patenting/sanger-gene-patenting Accessed December 9, 2013.

Gellene, D. "Chiron Relaxes Patent Licenses" in Los Angeles Times. June 22, 2004. http://articles.latimes.com/2004/jun/22/business/fi-chiron22. Accessed November 25, 2014.

"Gene by Gene Settles Lawsuit Over BRCA Patents" in Genetic Engineering and Biotechnology News. www.genengnews.com. Accessed February 8, 2014.

Diaceutics.com, (2014). Mystery Solved! What is the cost to develop and launch a Diagnostic? | Diaceutics. [online] Available at: http://www.diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic. Accessed Aug 15, 2014.

Greenpeace, The True Cost of Gene Patents: The Economic and Social Consequences of Patenting Genes and Living Organisms. March 2004. www.greenpeace.de Accessed December 2, 2011.

Human Genome Organisation. HUGO Intellectual Property Statement on Patenting of DNA Sequences. May 1997. http://www.hugo-international.org/img/ip_sequencedata_1997.pdf Accessed November 14, 2013.

Human Genome Organisation. HUGO Intellectual Property Committee Statement on Patenting of DNA Sequences in Particular Response to the European Biotechnology Directive. April 2000. http://www.hugo-international.org/img/ip_dna_2000.pdf. Accessed November 14, 2013.

Human Genome Organisation. HUGO Intellectual Property Committee Statement on the Scope of Gene Patents Research Exemption, and Licensing of Patented Gene Sequences for Diagnostics. December 2003. http://www.hugo-international.org/img/ip_gene_2003.pdf. Accessed November 14, 2013.

John Hopkins Medicine. Use of Human Biological Materials in Research. October 2005. http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/bio_mats.html Accessed July 8, 2013.

Leahy, P. Letter to Dr. Francis Collins. July 12, 2013. http://www.patents4life.com/wp-content/uploads/2013/07/LeahyGeneTesting.pdf Accessed October 2, 2013.

National Institute of Health Genetic Testing Registry. GTR News: Supreme Court Gene Patent Decision Immediately Impacts GTR. June 17, 2013. http://www.ncbi.nlm.nih.gov/projects/gtr/gtr_news.cgi?id=8 Accessed July 18, 2013.

Stoll, K. Correspondence to: The Honourable Daniel E. O'Toole. Re: Consumer Watchdog v. Wisconsin Alumni. January 27, 2014. http://www.laipla.net/wp-content/uploads/2014/01/CW-v-WARF-20140127-Response-to-US-by-WARF-ECF.pdf Accessed May 22, 2014.

Annex I: Business and Legal Stakeholder Questionnaire

Developing Guidelines for Patenting Biotech: A Comparative Interdisciplinary Study in the EU and US

My name is Vivian Mak, and I am a researcher funded by Queen Mary University of London. I am conducting research in the area of patents and biotechnology, which involves important and influential stakeholders. I am writing to you because you are an important authority in this area and my study will benefit from the empiricism you provide. The research conducted here could potentially be used to guide the policy making process. The results will be disseminated to the USPTO and EPO to assist in developing guidelines for biotech patents. This research is educational and not for profit. Interviewers are free to remain anonymous. If you have any concerns about the contents within this questionnaire or with any aspect of the interview, please direct them to my supervisor:

Professor Uma Suthersanen
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Queen Mary, University of London
67-69 Lincoln's Inn Fields
London WC2A 3JB
United Kingdom

Purpose of study

Despite the fact that approximately twenty percent of human genes are patented, the legal standing of gene patents remains controversial. In addition, patents granted for genetically modified organisms like plants and animals have been challenged in courts and continue to face tremendous opposition, particularly from a moral standpoint. There is also the concern that patent claims in this area could impede future research and development in biotechnology and the life sciences. An ideal legal regime would be one that strikes the right balance between promoting incentive for future research and encouraging competition. While patent protection has expanded to include life forms and genetic information, it remains unclear as to whether the current rules can adequately strike this balance. The project intends to inform the debate about the extent and influence of the biotechnology industry and civil society in shaping intellectual property initiatives.

The research questions include:

- Should the existing patent framework be applied to non-traditional kinds of subject matter like: genes, proteins, plants, and animals?
- Is a special set of guidelines required to address the issue adequately?
- If so, what should those guidelines include and/or exclude?

Design

Participants will be asked questions on the following case: ***Association for Molecular Pathology et al v. United States Patent and Trademark Office et al (2011)*** hereafter referred to as "*Myriad*". In addition, participants will have the opportunity to articulate what they believe is appropriate and necessary in protecting biotechnology inventions. At the end of the interviews, I will prepare a three- page briefing to disseminate the results of the interviews to progress knowledge of how different sectors of society respond to this legal issue.

Case: *Association for Molecular Pathology et al v. United States Patent and Trademark Office et al*. (Fed. Cir. 2011)

The US Federal Court of Appeal restored the law to its prior status before the District Court's invalidation of Myriad's patents on BRCA1 and BRCA2 genes in March 2010, in which all isolated DNA was deemed to be patentable subject matter once more. Relying on the standards set out by *Chakrabarty* and *Funk Bros*., the issue was whether the invention had 'markedly' different characteristics from what exists in nature. In regards to cDNA, all three judges held that Myriad's claimed cDNA sequences were patentable as it did not exist in nature and created by man. In regards to isolated DNA, the majority held that isolated DNA sequences were patentable. Judge Lourie, writing for the majority, emphasized that the chemical difference between the isolated DNA and naturally occurring DNA was sufficient to make isolated DNA sequences patentable. "BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it exists in the body, human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a *distinctive chemical identity* from that possessed by native DNA" (para.42). However, the dissent held isolated DNA unpatentable, arguing that there were no "markedly differences" between the isolated DNA and natural DNA found in chromosomes.

Link: <http://www.amp.org/documents/CAFCRulingBRCA_Jul29_2011.pdf>

Introductory questions:

1. Could I ask you to start by briefly explaining the organization and your role in it?

2. To whom is your organization accountable?

3. Have any cases in the past affected your research and development in house?

4. How reliant is your firm on its intellectual property portfolio for attracting investment and funding?

5. Do you think patents should be granted for *all* novel and useful genetic insights?

    a. Yes
    b. No, patents should be granted only for artificially prepared genes that possess new qualities that are different from natural genes and have a new technical application that is not possible with natural genes
    c. No, there should be a blanket exclusion on all gene-related productions
    d. Other

Case study questions:

6. In March 2010, the District Court invalidated Myriad's BRCA1 and BRCA2 patents, declaring the isolated gene sequences to be "products of nature." Do you agree with this?

7. Judge Sweet held that DNA sequences should not be treated the same as other chemicals in regards to patenting because of their "information rich quality." However, Judge Lourie took a different approach, stating: "genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than their functions." Who is right?

8. Dissenting Judge Bryson wrote: "broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine-multiplex tests and whole-genome sequencing." Is your firm or do you know of any firms developing gene technologies encountering any obstacles because of patents?

Technical questions:

9. Do you think isolating and purifying a naturally occurring gene makes the claimed matter 'markedly different' from a naturally occurring form?

10. One of the requirements for patentability is that the invention needs to be useful or industrially applicable. How is a purified version of a gene 'useful?'

11. Is the act of identifying genes and isolated sequences from other DNA and cellular material an 'invention'?

12. At what level of human intervention and difference from naturally occurring sequences should be required to warrant a patent?

Your views on the impact of patents on the biotech industry:

13. Do you think patents will be problematic for the biotech industry in the future?

14. Do you think patenting DNA is a problem?

    a. No, patenting DNA is like patenting any other invention
    b. Problem is with patenting DNA itself
    c. Patenting DNA raises ethical problems
    d. The scope of claims in a DNA patent is the problem
    e. Companies' behaviour in how they assert their patents is problematic
    f. Other

15. Do you think the patent system is the appropriate mechanism to incentivize biotech inventions?

    a. Yes
    b. Yes, but patent pools should be encouraged to reduce transaction costs and increase access to biomedical knowledge and products
    c. No, a prize/reward system would still encourage investment and provide incentive
    d. Other

15. What does the biotech industry need to continue to develop?

Policy and decision-making

17. Judges have a tendency to defer the difficult questions to the legislature to solve, maintaining that it is not their role to make policy decisions. What do you think of this approach?

18. Who should be responsible for solving these issues?

    a. An ethical committee formed by the government
    b. Judges
    c. Patent office
    d. Parliament
    e. Other

Annex II: Civil Society Questionnaire

Developing Guidelines for Patenting Biotech: A Comparative Interdisciplinary Study in the E.U., United States and Canada

My name is Vivian Mak, a researcher funded by Queen Mary University of London and conducting research in the area of patents and biotechnology that involves important and influential stakeholders. I am writing to you because you are an important authority in this area and my study will benefit from the empiricism you provide. The research conducted here could potentially be used to guide the policy making process. The results will be disseminated to the USPTO, U.K., European and Canadian Patent Offices to assist in developing guidelines for biotech patents. This research is educational and not for profit. Interviewers are free to remain anonymous. If you have any concerns about the contents within this questionnaire or with any aspect of the interview, please direct them to my supervisor:

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Purpose of study

Despite the fact that approximately twenty percent of human genes are patented, the legal standing of gene patents remains controversial. In addition, patents granted for genetically modified organisms like plants and animals have been challenged in courts and remain a contentious issue. There is also the concern that patent claims in this area could impede future research and development in biotechnology and the life sciences. An ideal legal regime would be one that strikes the right balance between promoting incentive for future research and encouraging competition. While patent protection has expanded to include life forms and genetic information, it remains unclear as to whether the current rules can adequately strike this balance. The project intends to inform the debate about the extent and influence of the biotechnology industry and civil society in shaping intellectual property initiatives.

The research questions include:

- Should the existing patent framework be applied to non-traditional kinds of subject matter like: genes, proteins, plants, and animals?
- Is a special set of guidelines required to address the issue adequately?
- If so, what should those guidelines include and/or exclude?

Design

Participants will be asked questions on the following case: ***Oliver Brüstle v Greenpeace e.V. (C-34/10) (2011)***. In addition, participants will have the opportunity to articulate what they believe is appropriate and necessary in protecting biotechnology inventions. At the end of the interviews, I will prepare a three- page briefing to disseminate the results of the interviews to progress knowledge of how different sectors of society respond to this legal issue.

Link:
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62010CJ0034:EN:HTML>

Facts:

Greenpeace e.V. "Greenpeace" challenged the validity of Mr. Brüstle's patent concerning neural precursor cells, the process for producing neural precursor cells from embryonic stem cells, and the use of neural precursor cells for therapeutic use. Brüstle argued that the Directive did not explicitly define what an embryo entailed, and that an "embryo" was something that existed only 14 days after fertilisation. Furthermore, he argued that since his embryonic stem cells were obtained from five and six day old embryos, they should not be banned.

Legal basis:

The 1998 *Biotechnology Directive from the European Union (Directive 98/44/EC)* states explicitly that patents cannot be granted if the claimed subject matter and its commercial exploitation would be contrary to 'ordre public' or morality. Specifically, the use of human embryos is banned from patenting in Article 6(2) (c):

> [I]nventions requiring the prior destruction of human embryos or their prior use as base material not patentable even if process descriptions does not refer to use of human embryos.

However, Recital 42 in the preamble to the Directive makes an exception: if human embryos are used for therapeutic or diagnostic purposes, then the patent exclusion no longer applies.

Summary of judgment:

The Court of Justice of the European Union (CJEU) ruled that a process that involved the removal of a stem cell from a human embryo at the blastocyst stage, requiring the destruction of that embryo, cannot be patented. The Court made three main conclusions.

- Wide interpretation of 'embryo,' "any human ovum must, as soon as fertilised, be regarded as a 'human embryo' if that fertilisation is such as to commence the process of development of a human being" (Para. 53(1)).

- Use of human embryos for the purpose of scientific research is excluded from patentability because patents confer commercial rights. However, the use of human embryos for therapeutic or diagnostic purposes that are applied to the human embryo and are useful to it is patentable.

- The process, including the prior destruction of a human embryo or their use as a base material is excluded from patentability.

Introductory questions:

1. Could I ask you to start by briefly explaining the NGO and your role in it?
2. Which are the intellectual property issues that your NGO is active on?
3. To what extent have individual firms and industry associations acted in response to direct dialogue with NGOs?
4. How might the relationship between multilateral institutions and NGOs be enhanced?

Your NGO's stance on patenting stem cells

5. Do you think that the use of stem cells for commercial purposes is justified?
6. What about for therapeutic use?
7. Should there be a blanket ban on their use?
8. The CJEU quoted from the preamble to the Directive in its judgement, emphasizing the importance of treating human biological material with dignity:

[T]he preamble to the Directive states that although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person (Para. 32).

Do you agree with this?

Your NGO's stance on patenting genetic information and genetically modified organisms

9. Should patents be granted for *all* novel genetic insights?
    e. Yes
    f. No, patents should be granted only for artificially prepared genes that possess new qualities that are different from natural genes and have a new technical application that is not possible with natural genes
    g. No, patents should be granted only where the claimed value derives from information-encoding capacity of DNA
    h. No, there should be a blanket exclusion on all gene-related productions

10. Do you agree or disagree that patenting DNA is a problem?

    a. No, patenting DNA is like patenting any other invention
    b. Problem is with patenting DNA itself
    c. Patenting DNA raises ethical problems
    d. The scope of claims in a DNA patent is the problem
    e. Companies' behaviour in how they assert their patents is problematic
    f. Other

11. Some religious figures have suggested that DNA or genes are sacred, and that humans should not tamper with them. What is your response to that?
12. What about genetically modified organisms like plants and animals?

Policy and decision-making

13. Judges have a tendency to defer the difficult questions to the legislature to solve, maintaining that it is not their role to make policy decisions. What do you think of this approach?

14. Who should be responsible for solving these issues?

    a. An ethical committee formed by the government
    b. Judges
    c. Patent office
    d. Parliament
    e. Other

15. Are patents appropriate for incentivizing biotech inventions?

16. Do you think society will benefit from patents in the end? What are the alternatives?

Annex III: Stakeholder Consent Form

Guidelines for Patenting Human Genetic Materials: A Comparative Study in the EU and US

About this research

- Inform the debate about the extent and influence of the biotechnology industry and civil society in shaping intellectual property initiatives.
- Find out whether any previous judicial decisions or legislation has affected research and development in the biotechnology industry.
- Whether the existing patent framework should be applied to non-traditional kinds of subject matter like: genes, proteins, plants, and animals.
- Whether a special set of guidelines is required to address the issue adequately.
- If so, what should those guidelines include and/or exclude?

What you are asked to do

- Provide basic information about yourself (e.g. your role in the workplace).
- Allow me to interview you and to tape-record the interview.
- Allow me to keep this information on an electronic database and analyse it for research purposes.
- Allow me to quote from your interview (anonymously, if you prefer) in reports on my study.

If you have any queries, please telephone my supervisor Uma Suthersanen at +44 (0)20 7882 8100.

If you agree, please sign here:

Name in capitals: _____

Signed:_____

Date:_____

Annex IV: Ethics Approval

Queen Mary, University of London
Room E16
Queen's Building
Mile End Road
London
E1 4NS

Queen Mary Research Ethics Committee
Hazel Covill
Research Ethics Committee Administrator
Tel: +44 (0) 20 7882 2207
Email: h.covill@qmul.ac.uk

c/o Professor Uma Suthersanen
Room 2.4 – Centre for Commercial Law Studies
Queen Mary University of London
67-69 Lincolns Inn Fields
London WC2A 3JB

20th October 2011

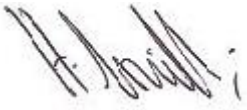
To Whom It May Concern:

Re: QMREC 0640 – Developing Guidelines for Biotech Patents.

I can confirm that Ms Vivian Mak has completed a Research Ethics Questionnaire with regard to the above research.

The result of which was the conclusion that her proposed work does not present any ethical concerns; is extremely low risk; and thus does not require the scrutiny of the full Research Ethics Committee.

Yours faithfully



Ms Hazel Covill
Research Ethics Committee Administrator

Annex V: Table of Interviewed Stakeholders

Sector of Society	Institution	Name of Representative
Legal	Foley & Lardner LLP	Rick Henschel
	McDonnell Boehnen Hulbert & Berghoff	Anonymous
	-	Lord Hoffman
	Kilburn & Strode LLP	Nick Bassil
	IP Asset LLP	Anonymous
	Dehn's, Patents and Trademarks Attorneys	Julian Cockbain
	The Chartered Institute of Patent Agents	Tim Roberts
	University of Edinburgh	Shawn Harmon
	Bird & Bird	Trevor Cook
	World Intellectual Property Organization	Anonymous
	World Intellectual Property Organization	Anonymous
	World Intellectual Property Organization	Anonymous
	DePaul University College of Law	Joshua Sarnoff
	World Trade Organization	Anonymous
	European Patent Office	Anonymous
	Schellenberg Wittmer	Ducor Phillipe
	Leeds University	Graham Dutfield
	Three New Square	Justin Turner
	Hogarth Chambers	Anonymous
	Delft University of Technology	Anonymous
Biotechnology	Wellcome Trust Sanger Institute	John Sulston
	Plasticell Therapeutics	Anonymous
	Kings College London	Anonymous
	GlaxoSmithKline	Anonymous
	University College London Institute of Ophthalmology	Pete Coffey
	Wellcome Trust Sanger Institute	Tim Hubbard
	Oxford University Nuffield Department of Clinical Medicine	Anonymous
Civil Society	Berne Declaration	Anonymous
	Evangelist Church of Germany	Gudrun Kordecki
	Greenpeace	Christoph Then
	University of Sheffield	Margaret Llewellyn
	University of Manchester	Soren Holm
	Edinethics Ltd.	Donald Bruce
	King's College	Roger Brownsword
	Nuffield Council of Bioethics	Anonymous
	University College London	Jo Wolff