The Quagmire of DNA Patents: Are DNA Sequences More Than Chemical Compositions of Matter?

By Brian Gargano

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* Photo courtesy of U.S. Department of Energy Genome Programs Primer, *available at* http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer2001/primer11.pdf.

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Abstract/Executive Summary

This paper discusses and analyzes the current treatment of DNA sequences as mere chemical compositions of matter by the United States Patent Office. Focusing on the ethical, moral, and legal issues DNA sequence patents raise, it becomes apparent that U.S. policy in general concerning DNA sequences is problematic and is harming innovation and denying health care to its citizens as a result of limited access to research and medical diagnostics. Several solutions are proposed and it is argued that the best proposed solution is to expand the patent research-exemption. Finally, it is argued that an expanded patent research-exemption is the most feasible and realistic solution to cure some of the pressing problems that DNA sequence patents present while still fostering innovation and commercialization of DNA sequences.

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I. Introduction

A. Overview of DNA, Gene Sequences and the Human Genome

Deoxyribonucleic acid (DNA) is a molecule composed of numerous coalesced smaller molecules that form an extensive chain.[1] DNA sequences are arrangements of DNA molecules that encode all information necessary for building and maintaining organic life.[2] DNA molecules consist of two strands that wrap around each other to resemble a twisted ladder whose sides, made of sugar and phosphate molecules, are connected by rungs of nitrogen-containing chemicals called bases. [3] More specifically, DNA molecules are composed of a sequence of chemicals called nucleotides.[4] The main component of a DNA molecule consists of four bases.[5] These bases are identified by the chemicals adenine (A), thymine (T), guanine (G) and cytosine (C).[6] The primary function of these bases is to bond in pairs, A with T, and C with G, to form the well known double-helix structure of DNA molecules.[7] Moreover, the specific order and sequence of these bonded pairs are what underlie all of life s diversity. [8]

A gene is a particular segment of a DNA molecule that contains information for constructing proteins.[9] Moreover, it is the production of specific proteins that provide the structural components of all cells and tissues, as well as enzymes for crucial biochemical

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[1] LORI B. ANDREWS, MAXWELL J. MEHLMAN & MARK A. ROTHSTEIN, GENETICS: ETHICS, LAW & POLICY 17-18 (West Group 2002).
[2] DENISE CASEY, U.S. DEP T OF ENERGY, GENOME PROGRAMS, GENOMICS AND ITS IMPACT ON SCIENCE AND SOCIETY: THE HUMAN GENOME PROJECT AND BEYOND 1 (Mar. 2003), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer2001/primer11.pdf.
[3] *Id.*
[4] ANDREWS ET AL., *supra* note 1, at 17. Nucleotides are composed of a sugar, a phosphate, and a base.
[5] *Id.*
[6] *Id.*
[7] *Id.*; NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 4 (July 2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf [hereinafter NUFFIELD COUNCIL].
[8] *The Human Genome Project: Hearing Before the Subcomm. on Energy and Env t of the House Comm. on Sci.*, 106th Cong. (2000), *available at* http://www.house.gov/science/ee_charter_040600.htm (last visited May 3, 2005); *see also* NUFFIELD COUNCIL, *supra* note 7, at 4.
[9] CASEY, *supra* note 2, at 1.

reactions.[10] Furthermore, genes are the fundamental unit of heredity because they contain the traits, diseases, and conditions that offspring inherit from their parents during reproduction.[11]

A gene sequence is the "[t]he ordered arrangement of nucleotides into codons along the stretch of DNA to be transcribed."[12] More specifically, "[i]t is this sequence that carries the genetic information essential for the synthesis of a [ribonucleic acid ("RNA")] molecule that may subsequently direct the synthesis of a protein molecule or . . . be [functionally active in a] cell."[13] The sequencing of a gene is the procedure of figuring out the order of all bases in a DNA section comprising a gene.[14]

With the advent of recombinant DNA technology and advanced techniques in DNA sequencing, it became possible to identify and isolate individual genes.[15] The Human Genome Project, established in 1990, was an international research effort created for the purpose of analyzing the structure of human DNA and ascertaining the location of all human genes by mapping and sequencing the human genome.[16] A "genome" is the set of all DNA and DNA sequences in an organism, including its genes.[17] In June 2000, as a result of both publicly funded and private commercial efforts, the map of the human genome was competed.[18] As a result of this endeavor, scientists have discovered the following:

- The human genome contains approximately three billion chemical nucleotide bases
- On average, a gene will consist of approximately 3,000 bases. However, genes vary greatly in size. For example, the largest known human gene dystrophin contains 2.4 million bases.
- The total number of genes is much lower than previous estimates of 80,000 to 140,000. The total number of genes in the human genome is estimated to be around 30,000.

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[10] Biotechnology Industry Organization, *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine*, *at* http://www.bio.org/ip/primer/printer.asp?p=yes (last visited May 3, 2005).
[11] *Id.*
[12] NDI Foundation, *Gene Sequence*, *at* http://www.ndif.org/Terms/gene_sequence.html (last visited May 3, 2005).
[13] NUFFIELD COUNCIL, *supra* note 7, at 4.
[14] Genome Atlantic, *About Genomics*, *at* http://www.genomeatlantic.ca/genomics/index.cfm (last visited Dec. 1, 2004).
[15] ANDREWS ET AL., *supra* note 1, at 27.
[16] Human Genome Project Information, *About the Human Genome Project, available at* http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml (last modified Oct. 27, 2004).
[17] *Id.*
[18] ANDREWS ET AL., *supra* note 1, at 32.

- All human beings contain 99.9% of the exact same nucleotide bases.
- There is still much more to discover as the functions for over 50% of the discovered genes remain unknown.[19]

The challenge now becomes for us to derive meaningful knowledge from the DNA sequences such as finding genes associated with disease resulting, for example, in development of effective new therapies and diagnostics.

B. Overview of Patents

A patent provides an exclusive right to an inventor who creates an invention which is new, useful, non-obvious and adequately described.[20] Article I of the United State Constitution grants Congress the power [t]o 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. [21] In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* the Supreme Court stated the Patent Clause reflects a balance between the need to encourage innovation and the need to limit and avoid monopoly.[22] The patent system spurs technological innovation by offering a financial incentive of allowing anyone to become a monopolist with regard to his or her invention, albeit for a limited time.[23] This exclusive right enables one to commercially exploit an invention in many ways. For example, a patentee can sell developed products or services that utilize the patented invention, or engage in licensing yielding royalty payments.[24] As a result, these financial incentives attract commercial enterprises to undertake research and development

[19] Human Genome Project Information, *The Science Behind the Human Genome Project, at* http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml (last modified Oct. 27, 2004).
[20] 35 U.S.C. §§ 101-103, 112 (2000).
[21] U.S. CONST. art. I, § 8, cl. 8.
[22] 489 U.S. 141, 146 (1989).
[23] *See* James C. De Vellis, Article, *Patenting Industry Standards: Balancing the Rights of Patent Holders With the Need for Industry-Wide Standards*, 31 AIPLA Q. J. 301, 310-11 (2003). *See also* Jon E. Wright, Comment, *Willful Patent Infringement and Enhanced Damages: Evolution and Analysis*, 10 GEO. MASON L. REV. 97, 99 (2001).
[24] *See id.*; David C. Drews, *Patent License Evaluation*, 786 PLI/Pat 319 (June 2004).

of new technologies.[25] Accordingly, the patent system, as envisioned by the founders, was created for the primary goal of promoting the advancement of technology for the public good by the lure of the opportunity for anyone to handsomely profit from creative innovation.[26]

C. The Patenting of Gene Sequences

The patent system has been instrumental in the technological advancements in the field of DNAs.[27] In 1980, the U.S. Supreme Court opened the door for the patentability of genetically modified organisms when it held that an oil-eating bacterium was patentable subject matter.[28] The Supreme Court stated that patentable subject matter encompassed anything under the sun that is made by man. [29] This includes gene sequences.[30] This holding, coupled with the discoveries resulting from the Human Genome Project, spurred a patent gold rush as world-wide patent offices began to grant patents on genome sequences.[31] According to statistics, as of 2000, there have been over one million sequences published in patent applications, and approximately 25,000 DNA-based patents granted.[32] These patents include purified and cloned gene fragments and full-length genes, regulatory sequences, as well as sequencing and diagnostic methods.[33]

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[25] Frederic M. Scherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1353 (2002).
[26] *Id*. at 1349; Wright, *supra* note 23, at 99.
[27] *See generally* John J. Doll, *The Patenting of DNA*, SCI. MAG., May 1, 1998, at 689; Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 80 (1986); *Gene Patents and Other Genomic Inventions, Hearing Before Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 106th Cong. 52 (2000) (testimony of Randal Scott, President, Incyte Genomics); Robert Kneller, EUBIOS ETHICS INSTITUTE, *Bioethics and the Impact of Human Genome Research in the 21st Century,* (2001) *available at* http://www.biol.tsukuba.ac.jp/~macer/bhgp.htm (last visited May 3, 2005).
[28] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
[29] *Id.*
[30] *See generally* Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004); Noelle v. Lederman, 355 F.3d 1343 (Fed. Cir. 2004); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003); *Barton v. Adang*, 162 F.3d 1140 (Fed. Cir. 1998).
[31] *See generally* Antonio Regalado, *The Great Gene Grab*, TECH. REV., Sept/Oct. 2000, at 48; Giles Stokes, *Patent applications of genetic sequences on the up*, THOMSON SCIENTIFIC, *at* http://thomsonscientific.com/ipmatters/patlife/8205003/ (April 2000).
[32] *See id.*; DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 138 (2004).
[33] NUFFIELD COUNCIL, *supra* note 7, at 32.

As a result of the potential lucrative profits from the commercialization of DNA sequences, there has been a huge growth in the number of biotechnology firms that specialize in genomics.[34] This has contributed to economic growth and further innovation in the field of genomics. Nonetheless, there are important concerns ethically, morally, and economically regarding the effects of patenting DNA sequences. These concerns have resulted in the question of whether patenting DNA sequences should be allowed. As the Nuffield Council on Bioethics has found, [t]he question of whether DNA sequences are eligible for patenting is distinct from the question of whether they meet the[] legal criteria for patenting.[35] This note seeks to analyze the debate about patenting DNA sequences, and proposes a possible solution to address the concerns expressed by the opponents of DNA sequence patents. More specifically, this note analyzes whether the treatment of genetic sequences as mere chemical compositions by the U.S. Patent Office (USPTO) is ethical and truly maximizes the research and commercialization of products from the human genome.

II. The patentability of genetic sequences

A. The USPTO Allows Human Genome Sequences to be Patented by Treating Them Like Chemical Compositions of Matter

Currently, the USPTO does not treat patent applications on human genome sequences any differently than it treats patent applications claiming chemical compositions of matter.[36] For example, the claims in a patent on human polynucleotides encoding proteins are essentially

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[34] Lauren Kramer, *The growth of biotechnology law*, BOSTON BUS. J., Mar. 20, 1998, *available at* http://boston.bizjournals.com/boston/stories/1998/03/23/focus1.html.
[35] NUFFIELD COUNCIL, *supra* note 7, at 27.
[36] American Association of Medical Colleges, *Academic Medicine: Special Issues on Genetic Patents* (statement of Dr. David Korn, AAMA Senior Vice President for Biomedical and Health Sciences Research), *available at:* http://www.aamc.org/research/sloan/start.htm (last visited May 4, 2005); Maurice Cassier, *Private Property, Collective Property, and Public Property in the Age of Genomics*, 54 INT L SOC. SCI. J. 83, 88 (2002).

analogous to claims for a pulmonary delivery for bioconjugation.[37] Both are described in terms of their structure and chemical properties. Human polynucleotides are described in the claims by the structure and property of a nucleotide sequence SEQ ID NO: 3, while the pulmonary delivery for bioconjugation is described in the claims by the structure and property of chemicals such as 2-[2-[4-[(4-chlorophenyl)phenylmethyl[-1-piperazinyl]ethoxy]-maleimido-ethylacetamide.[38] As a result, a human genome sequence is patentable if it satisfies the statutory requirements in 35 U.S.C. §§ 101-103 and 112, which reference the requirements of patentable subject matter, utility, novelty, non-obviousness, and the written description/enablement requirement the same way an invention claiming a chemical composition would.[39]

To satisfy the patentable subject matter requirement under § 101, the Supreme Court has held that an invention can not merely claim a natural substance or phenomena.[40] Instead, to be considered patentable subject matter, there must be a certain degree of human ingenuity in order to qualify as anything under the sun that is made by man. [41] One example of a sufficient level of human ingenuity is the isolation or purification of a naturally occurring substance, because such a substance does not exist naturally.[42] Because natural chemical compositions such as purified adrenalin are patentable, it logically follows that isolated or purified DNA sequences, which are essentially naturally occurring chemical compositions, are patentable as well.[43] Moreover, under the holding of *Diamond v. Chakrabarty*, if the subject matter of a patent is considered an organism that can replicate, it will not be treated any differently than an isolated,

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[37] *Compare* U.S. Patent No. 6,743,907 (issued July 1, 2004), *with* U.S. Patent No. 6,706,892 (issued Mar. 16, 2004)
[38] *Id.*
[39] *See* 35 U.S.C. §§ 101-103 & 112.
[40] *Id*. § 101; *Chakrabarty*, 447 U.S. at 309.
[41] *Id*.
[42] *See, e.g.*, *In re* Kratz, 592 F.2d 1169, 1175 (C.C.P.A. 1979); *In re* Bergstrom, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970); Parke-Davis Co. v. H.K. Mulford Co., 189 F. 95 (2d Cir. 1911).
[43] Jorge A. Goldstein & Elina Golod, *Human Gene Patents*, 77 ACAD. MED. 1315, 1316 (2002)

naturally-occurring chemical, as long as the organism was altered by human intervention.[44] Based on this rule, an invention claiming a human genome sequence is patentable subject matter only if the sequence is isolated or purified.[45] Therefore, a human genome sequence, like a naturally occurring chemical compound, is considered patentable subject matter as long as it is not identical to any naturally occurring chemical compound or structure of DNA.[46]

In satisfying the utility requirement under § 101, a human genome sequence must be useful for some purpose, either explicitly or implicitly.[47] For a human genome sequence to violate the utility requirement it must be totally incapable of achieving a useful result. [48] If the genome sequence is at least partially useful, it passes muster under § 101.[49] In response to concerns that USPTO-granted DNA sequence patents only had proposed utility, the USPTO revised its Utility Examination Guidelines, and established a three-part test to determine whether an invention such as a human genome sequence is useful.[50] A human genome sequence is deemed useful if it is credible, specific, and substantial. [51] One way this is proven in the chemical arts is if the patentee produces evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility.[52] This evidence creates an inference that is supportive of an assertion of therapeutic utility for the new compound.[53] Like pharmacological chemical compounds, a human genome sequence is considered useful by the

[44] *Chakrabarty*, 447 U.S. at 309. One such example is adrenalin.
[45] Goldstein & Golod, *supra* note 43, at 1316.
[46] *Id.*
[47] 35 U.S.C. § 101.
[48] Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571 (Fed. Cir. 1992).
[49] *See* MANUAL OF PATENT EXAMINING PROCEDURE §2107(b) (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/index.htm.
[50] Goldstein & Golod, *supra* note 43, at 1317-18.
[51] *Id.*
[52] *See In re* Jolles, 628 F.2d 1322, 1326-27 (C.C.P.A. 1980).
[53] *Id.*

USPTO if it is proven to be structurally similar to a DNA sequence that has a therapeutic or functional utility.[54]

In satisfying the novelty requirement under § 102, chemical compositions of the isolated or purified human genome sequence cannot have been previously isolated or purified, and details of its isolation or purification can not have been available in the public domain.[55] Moreover, Federal Circuit Judge Lourie Newman points out that like with patentable chemical compounds in any patentable biological organism there will necessarily be many products that are inherent, but which might not be discovered until a much later date. [56] Accordingly, a previously unknown product does not become [anticipated under § 102] simply because it existed before it was discovered. [57] To be anticipated, all of the elements of the claimed isolated or purified sequence must be disclosed in a single prior art reference.[58] Thus, the USPTO treats an isolated or purified human genome sequence no differently than an isolated or purified naturally occurring chemical or organism.[59]

To satisfy the non-obvious requirement under § 103, the differences between the human genome sequence being sought for patenting and the prior must be such that the sequence as a whole would not be obvious at the time of the sequence s isolation or purification to a person having ordinary skill in the art to which said subject matter pertains.[60] More specifically, in

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[54] *See, e.g.,* U.S. Patent No. 6,800,475 (issued Oct. 5, 2004). This is a patent of an isolated human retrovirus. The USPTO found this patent to be non-obvious because the test for non-obvious does not take into consideration the inventiveness of the claimed invention. Rather the USPTO focuses on whether the differences between the sequence or chemical compound sought to be patented and the prior art are such that the sequence as a whole would have not have been obvious at the time the sequence was isolated or purified to a person having ordinary skill in the art to which said subject matter pertains. *See* NUFFIELD COUNCIL, *supra* note 7, at 29-31.
[55] Goldstein & Golod, *supra* note 43, at 1318-19 .
[56] Schering Corp. v. Geneva Pharms., Inc., 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting).
[57] *Id.*
[58] Alissa K. Lipton, *Biopharmaceuticals*: *The Patent System and Incentives for Innovation, at* http://leda.law.harvard.edu/leda/data/641/Lipton.html (Apr. 6, 2004).
[59] *Compare* U.S. Patent No. 6,743,907 (issued June 1, 2004), *with* U.S. Patent No. 6,706,892 (issued Apr. 6, 2004). There is no single prior art reference listed on the patents that claim all of the elements of the claimed invention.
[60] 35 U.S.C. § 103; WMS Gaming, Inc. v. Int l Game Tech., 184 F.3d 1339, 1355 (Fed. Cir. 1999).

regards to chemical compounds, the discovery of an unpredictable and unexpected pharmaceutical activity will make a chemical composition non-obvious despite its structural similarity to prior art chemicals.[61] Similarly, until claimed DNA molecules are actually isolated and purified, it would be highly unlikely for one of ordinary skill in the art to contemplate what was ultimately obtained, despite the sequence s structural similarity to prior art sequences.[62] Finally, the PTO has held that the existence of obvious methods to find genes will not render a sequence obvious because it is similar to method for deriving chemical compounds with unknown properties.[63]

In satisfying the written description and enablement requirement under § 112, it is required that the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the claimed DNA sequence.[64] Also, it must be shown that the DNA sequence in the specification is whatever is now claimed and that the disclosure enables one skilled in the pertinent art to make and use the claimed invention.[65] Thus, according to the USPTO guidelines, this is a question of undue experimentation. [66] The Federal Circuit has stated that the adequate description of claimed DNA requires a precise definition of the DNA sequence itself not merely a recitation of its function or a reference to a potential method for disclosing it. [67] Moreover, the USPTO guidelines state that

> possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was ready for patenting

[61] Goldstein & Golod, *supra* note 43, at 1325.
[62] Amir A. Naini, *Convergent Technologies Divergent Patent Validity Doctrines: Obviousness and Disclosure Analyses in Software and Biotechnology*, 86 J. PAT. & TRADEMARK OFF. SOC Y 541, 548-49 (2004) (citing *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995)).
[63] Goldstein & Golod, *supra* note 43, at 1325.
[64] Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).
[65] *See id.*
[66] *See* MANUAL OF PATENT EXAMINING PROCEDURE § 2164.01(a). Undue experimentation in the 112 context is whether the claimed invention would require undue experimentation to obtain and practice the claimed invention.
[67] *Amgen, Inc.*, 314 F.3d at 1332 (citing The Regents of the Univ. of Cal. v. Eli Lilly, 119 F.3d 1559 (Fed. Cir. 1997)).

> such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.[68]

Thus, like a chemical composition, a human DNA sequence will satisfy the written description requirement by the drawing or written description of its structure, its chemical components, or its purification process.[69]

Therefore, a patent application on a DNA sequence will be treated no differently than a patent application on a chemical component, and if a DNA sequence patent survives the aforementioned patentability requirements, the USPTO will issue a patent on the claimed sequence. However, there is some debate as to whether or not, and under what circumstances, a human genome sequence will survive the patentability requirements [70]

B. The Argument that DNA Sequences do not Meet the Legal Criteria for Patenting

There is growing dissention, particular among the international community, concerning the patentability of DNA sequences.[71] First, scholars have argued that DNA sequences are not patentable subject matter under § 101, and call into question the broad holding of *Chakrabarty*.[72] To begin with, it is argued that DNA sequences are discovered, and not invented.[73] Moreover, DNA sequences should not be treated like chemical compositions of matter by the USPTO and by the courts, because they are inherently different.[74] For example, DNA sequences differ from chemical inventions in that chemical inventions have a certain quality of ingenuity because they

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[68] *See* MANUAL OF PATENT EXAMINING PROCEDURE § 2163.02.
[69] *Amgen Inc.* 314 F.3d at 1331-33.
[70] Goldstein & Golod, *supra* note 43, at 1318-19.
[71] NUFFIELD COUNCIL, *supra* note 7, at 27, 34-35.
[72] Wayne Hall, *Patents on Human DNA Sequences: Patently Right or Wrong?* 3, *at* http://www.uq.edu.au/oppe/PDFS/IP_and_DNA.pdf (last visited May 4, 2005).
[73] *Id.* at 4.
[74] *Id.* at 5.

are designed or modeled on a paper or computer screen and then eventually synthesized.[75] On the other hand, DNA sequences are not designed or necessarily modeled; they are merely found and purified.[76] In addition, it is asserted that DNA sequences are an extension of nature and not of human ingenuity due to the fact that genes are essentially genetic information created by nature.[77] DNA sequences also substantially differ from chemical compounds in that DNA sequences are self-replicating, while chemical compounds are not.[78] Patenting life is essentially patenting natural phenomena, and is quite different from patenting chemical compounds.[79] *Chakrabarty s* premise that living organisms which encompass DNA sequences are analogous and should be treated similarly to chemical compositions is flawed. DNA sequences should be deemed natural phenomena, which the drafters of the 1952 Patent Act explicitly stated were not patentable subject matter.[80] Consequently, DNA sequences do not meet the criteria of patentable subject matter under § 101.

Another argument that DNA patents do not meet the criteria for patenting is that they fail to assert a specific utility under § 101.[81] It is asserted that a DNA sequence only carries with it a theoretical possibility of some future utility, because it is merely information an instruction set needed to synthesize proteins.[82] Put another way, knowing the structure of a gene does not yield comprehension of the structure or the ability to apply an encoded protein for a specific use.[83] Under the recent USPTO Guidelines, most DNA sequence patent applications, as a result of

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[75] Goldstein & Golod, *supra* note 43, at 1324-25.
[76] *Id.*
[77] NUFFIELD COUNCIL, *supra* note 7, at 21.
[78] Goldstein & Golod, *supra* note 43 at 1324-25.
[79] NUFFIELD COUNCIL, *supra* note 7, at 28.
[80] *Chakrabarty*, 447, U.S. at 309.
[81] Goldstein & Golod, *supra* note 43, at 1318-19; John H. Barton, *Patents, Genomics, Research, and Diagnostics*, 77 ACAD. MED. 1339, 1342 (2002).
[82] Hall, *supra* note 72, at 5. The patentability requirements of §§ 101 and 112 go hand in hand. One cannot claim a utility if one has not described it.
[83] Kneller, *supra* note 27.

claiming the structure of a gene by its sequence, cannot possibly have a credible, specific, and substantial utility because the structure of a DNA sequence can not possibly reveal the utility of the sequence.[84] As a result, the argument follows that the utility of a DNA sequence is essentially speculative prospecting at best, and not intuitive development of useful technology.[85]

III. The Arguments Against Patenting Human DNA sequences.

A. Human Genetic Sequences Should Not Be Claimed for Private Commercial Gain Because They Belong to the Public.

Many opponents of the patenting of human DNA sequences argue that human genomics sequences are public property because they are the common property of humanity. It is argued that like the navigational waterways, shorelines, minerals and public parks, human DNA sequences, in which human beings share over 99.9 percent of their genetic code, are a part of our common heritage.[86] This view of human DNA sequences has gained international support. For example, in 1997, the members of the United Nations (U.N.) declared that the human genome is the property of Humanity and in its natural state can not give rise to any financial gains. [87] The U.N. s position seems to be derived from Article 27 of the United Nations Declaration of Human Rights, which recognizes that rights relating to science and culture should be considered universally vested in each person by virtue of their common humanity.[88] Since the

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[84] Hall, *supra* note 72, at 1.
[85] *Id.* at 5.
[86] NUFFIELD COUNCIL, *supra* note 7, at 21-22.
[87] Emilie Bouliong & Sandrine de Montgolfier, *Patentability and the Human Genome: Issues, Debates and Controversies, available at:* http://infodoc.inserm.fr/ethique/etheng.nsf/7adab9aba4615f8dc12569c9005670ca/9c2efd02ef7d19b580256b0b005f7731?OpenDocument (last visited May 4, 2005).
[88] Audrey R. Chapman, World Intellectual Property Organization, *A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science, available at* http://www.wipo.org/tk/en/activities/1998/humanrights/papers/word/chapman.doc (last visited November 1, 2004). The UN s Declaration of Human Rights, Article 27 states that (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. (2) Everyone

U.N. s declaration, the position that the human genome is a public trust has been strongly adopted by many European countries as well as the U.S. National Research Council and the American Society of Human Genetics.[89] For example, the European Parliament s Human Genome Analysis program has affirmatively limited a private right of ownership in DNA sequences and stated that there shall be no right to exploit on an exclusive basis any property rights in respect of human DNA. [90]

Proponents of this argument find further support in a joint statement issued by President Bill Clinton and British Prime Minister Tony Blair on March 14, 2000, which declared that information provided by the human genome is public property.[91] The joint statement acknowledged that [t]o realize the full promise of this research, raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere and that [u]nencumbered access to this information will promote discoveries that will reduce the burden of disease, improve health discoveries around the world and enhance the quality of life for all humankind. [92] Thus, in order to ensure freedom of access, human DNA sequences must be designated as public property because they are a part of our common heritage.

B. DNA Patents Degrade Moral Values and Human Dignity

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has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. The Universal Declaration of Human Rights, G.A. Res. 217A, U.N. GAOR, 3d Sess., 67th plen. Mtg., U.N. Doc. A/810 (1948).

[89] Darryl R. J. Macer, EUBIOS ETHICS INSTITUTE, *Ethical Challenges as We Approach the End of the Human Genome Project*, *available at* http://www.biol.tsukuba.ac.jp/~macer/chgp/chgp107.html (last visited May 4, 2005).

[90] *Id.*

[91] U.K. Prime Minister Tony Blair & U.S. President Bill Clinton, *Joint statement to ensure that discoveries from the human genome are used to advance human health*, Mar. 14, 2000, *available at* http://www.patent.gov.uk/about/ippd/notices/genome.htm.

[92] *Id.*

Another argument made by opponents of patenting human DNA sequences is that due to the unique nature of human DNA, private ownership over human DNA degrades moral and ethical values, as well as human dignity. There has been much debate and scholarship written about the challenges posed by science and technology to human rights and human dignity. One scholar, Jacques Ellul, explains that there is an increasing potential for technology to diminish human dignity and to erode moral and religious values.[93] One of the inherent concerns with a technological society is that modern technology, such as cloning and artificial intelligence, encourages us to treat an expanding range of human relationships as commodities whose utility we measure and consume.[94] Another scholar, Ian Barbour, states that people should be concerned with the inherent danger of extending technological attitudes to all biological life until human beings and other creatures are treated as objects to be exploited.[95] He further points out that technologies create inequitable distribution of costs and benefits, in which technology is used as a product and an instrument of social power.[96] Consequently, technological advances further the concentration of wealth and political power in existing social structures, and lead to affirmation of a class or caste system.[97]

The consideration of the morality of technology and its advancements is nothing new. The European Commission considered the morality of DNA patenting when it determined that the European Patent Convention might refuse to patent any invention that infringes on the rights of a person or violates human dignity.[98] Under the European Commission s patent laws, a patent will not be issued for inventions that are contrary to public morality, unlike patent laws in the

[93] *See generally*, JACQUES ELLUL, THE TECHNOLOGICAL SOCIETY (J. Wikinson trans., 1964).
[94] *See generally id.*
[95] *See generally* IAN BARBOUR, ETHICS IN AN AGE OF TECHNOLOGY (1993).
[96] *See generally id.*
[97] *Id.*
[98] RESNIK, supra note 32, at 62, 128.

United States.[99] According to the European Commission s view, the seminal case of *Diamond v. Chakrabarty* should have been decided differently, because it failed to take the morality of patenting the subject matter into consideration.

Thus, it appears that countries like the United States, who do not completely consider morality when issuing patents, should nonetheless make these patents unenforceable because they violate the public interest. There appears to be support in American law for this proposition when confronted with issues of private property, morality seems to play an important role. For example, courts have refused to enforce private rights when the public interest of promoting the welfare and morals of society has outweighed the utility and right of private ownership.[100] The U.S. Constitution has been interpreted to allow the government to either quash or not enforce a private right of interest in property in cases where the principles of justice require, where the importance of a public interest exists, where there is an important social need present, or where there is a highly important public utility present.[101] One such example is the statutory immunity granted to physicians in patent infringement suits who perform patented medical procedures.[102] Congress decided not to enforce these patents due to the potential effects on health.[103]

The commercialization of human body parts is another example. Currently, there exists no private right of property in human body parts because it is deemed immoral and illegal to sell one s organs or purchase another person s organs, and could also be deemed a violation of the 13th Amendment if it is determined that the private right effectively allows ownership of another

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[99] *Id.*
[100] *See, e.g.,* Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990).
[101] *See id.*
[102] *See* Steven L. Nichols, Comment, *Hippocrates, The Patent-Holder: The Unenforceability of Medical Procedure Patents*, 5 GEO. MASON L. REV. 227 (1997).
[103] *Id.*

human being.[104] The seminal case of *Moore v. California Regents* best illustrates this point.[105] In *Moore*, the California Supreme Court held that human body parts cannot be commercialized because the sale or license of a body part, such as a kidney, is immoral and unethical.[106] An analogy may be made that because human body parts cannot be considered private property, DNA sequences cannot be private property. However, proponents for private property rights of DNA sequences assert that the analogy to human body parts is misplaced, and the better analogy compares DNA sequences to human cells and tissues, which are permissibly commercialized.[107] Unfortunately, the U.S. Supreme Court has not addressed the issue of whether recognizing a property interest in human cells and human DNA sequences is the same as recognizing a property interest in human body parts.

The ideal of human dignity is intrinsic in the concept of human rights. Human rights are a set of individual and collective rights that are inalienable for all people.[108] One of the most important human rights that we all have is the right to self-ownership.[109] This is evidenced by the U.S. Constitution in the 13th Amendment, which holds that people may not be owned as slaves.[110] The right of self-ownership encompasses the right to ownership of one s body, including one s genes. DNA patents commodify human nature by treating people . . . as a market commodity. [111] Yet, one must consider on a daily basis that the worth of our lives is constantly being assessed: insurance policies, salaries, compensatory lawsuits, etcetera.[112] The

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[104] *Moore*, 793 P.2d at 479-496.
[105] *Id.*
[106] *Moore*, 793 P.2d at 479-496.
[107] *See* Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research,* 292 JAMA 2500 (2004).
[108] Dr. Sarah Pritchard, Australasian Legal Information Institute, *Introduction to the International Law of Human Rights, available at* http://www.austlii.edu.au/au/other/HRLRes/2001/2/ (last visited May 4, 2005).
[109] *Id.*
[110] *See* U.S. CONST amend. XIII.
[111] Hall, *supra* note 72, at 1.
[112] RESNIK, supra note 32, at 112-129.

capitalist way of life sends the message that anything is for sale. However, our society should not readily accept this thinking when it concerns the commoditization of human DNA. This philosophy is backed by Imanual Kant, who "condemned all marketing of the human body . . . because all marketing of one's body treats one's own person as a mere means."[113] For example, different international texts such as the European Council Convention of Human Rights and Biomedicine, state that "the human body and its parts must not, in themselves, be sources of profit."[114]

The imposition of a private right, such as ownership, over unique sequences of people's DNA essentially violates that population's human right to self-determination[115] on two levels; individual and population. This is especially problematic with DNA sequences from indigenous populations, because entities in highly developed nations such as the United States or England will exploit these populations without allowing them to benefit from the knowledge of their respective DNA sequences.[116] The argument follows that the law should only allow indigenous populations to have control over their genetic material and no one else's material.[117] If research companies can legally harvest DNA sequences from certain populations, researchers have the potential of labeling a gene or sequence (good or bad) as native to that specific population. In doing so, science appears to segregate and discriminate that population of people in the name of progress. For that reason, Native American tribes who are indigenous populations have a legal right to determine what research, if any, can proceed on their community and therefore they have

[113] RESNIK, supra note 32, at 112-129.
[114] *See* Bouliong & de Montgolfier, *supra* note 87.
[115] Victoria Tauli-Corpuz, Third World Net, *Biotechnology and Indigenous Peoples*, *available a*t http://www.twnside.org.sg/title/tokar.htm (last visited May 4, 2005).
[116] *Id.*
[117] *Id.*

shared control over ownership of that research.[118] To further this argument, science can appear to segregate and discriminate on the individual level as well, by finding a difference in an individual s genetic code (demarcating people by genetic determinism) and disassociating them from their people.

Proponents for DNA patents argue that the legal and moral justifications are not equivalent.[119] A decision can be considered legal because it follows procedure and precedent, yet still be deemed immoral.[120] This is why there is a growing legal consensus concerning human gene patents, and significant fears about their morality persist. Experts in patent law believe an immoral stigma could be lifted from the patenting of human DNA sequences provided the confusion over basic legal and scientific facts is clarified.[121] In fact, the main controversial issues in human gene patents are merely misunderstandings with what is being patented; legally patentable genes with naturally occurring genes, and thereby confusing patenting genes with owning them. Patents do not bestow legal ownership. One does not have to own the entity being patented because the only legal right conferred by a patent is the right to prevent others from using or possessing one s invention. [122] Therefore, the two key aspects of ownership, possession and use, are not bestowed within patent rights, which removes one of the main arguments concerning moral justification.

C. Patent Ownership of Human Genes Undermines Our Religious Values

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[118] Vida Foubister, *Research reservations: As researchers increasingly look to DNA of Native American tribes and other groups for clinical answers, is an ethical imperative to seek community consent emerging?*, (Jan. 31, 2000), *at* http://www.ama-assn.org/amednews/2000/01/31/prsa0131.htm

[119] Annabelle Lever, *Ethics and the Patenting of Human Genes*, 1 J. PHIL., SCI., & L. 1 (Nov. 2001) *at* www.psljournal.com/archives/papers/ethics_lever.cfm.

[120] *Id.*

[121] *Id.*

[122] *Id.*

Another argument made by opponents of patenting of human DNA sequences is that they undermine and degrade religion and religious values. These theologically based objections are primarily premised on the idea that genes belong to God, and not to humanity.[123] Thus, religious leaders maintain that patents on human DNA sequences violate divine law. For example, Richard Land of the Southern Baptist Federation states, for human beings to claim ownership of [genetic material], to reduce it to the legal equivalent of a mineral right like uranium or gold that can be mined out of the earth, is to us grotesque and horrendous. [124] Land further stated that, marketing human life is a form of genetic slavery. Instead of whole persons being marched in shackles to the market block, human cell lines and gene sequences are labeled, patented and sold to the highest bidders. [125] Land added a judgment against playing God in the laboratory: We see altering life forms, creating new life forms, as a revolt against the sovereignty of God and an attempt to be God. [126]

Such religious backlash to technological innovation is not surprising given the dogma of many religions. The argument that God is the author of life and that only He has the power to make things alive is analogous to the position of many religious leaders in public policy debates ranging from abortion to human embryo experimentation.[127] Many religious leaders feel that to claim a patent over a living organism amounts to some kind of blasphemy or occupying a place properly reserved for God.[128] In 1995, religious leaders representing more than 80 different groups signed a statement opposing patenting of human DNA at a Washington Press Conference,

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[123] *See* Ted Peters, *Genetics and Gene Ethics: Are We Playing God?* CENTER FOR THEOLOGY AND THE NATURAL SCIENCES (1997), *available at* http://www.counterbalance.org/genetics1.html.
[124] *See* Peters, *supra* note 123; Lever, *supra* note 119.
[125] *See id.*
[126] *See* Lever, *supra* note 119, at 4.
[127] *See id.*
[128] *See id.*

called the Joint Appeal against Human and Animal Patenting.[129] Numerous Roman Catholic bishops, along with Jewish, Protestant, Islamic, Hindu, and Buddhist leaders, signed the following statement:

> We, the undersigned religious leaders, oppose the patenting of human and animal life forms. We are disturbed by the U.S. Patent Office s recent decision to patent human body parts and several genetically engineered animals. We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions.[130]

D. Patents of Human Genes Impede Access to Research and Medical Diagnostics as well as Stifle Innovation

Opponents of patenting human DNA sequences also argue that the patenting of human DNA impedes rather than advances innovation. Thus, the commercialization of genetic science clearly has discouraged data sharing among scientists and thus hinders research. The argument for this proposition is as follows:

> A research group, academic or commercial, identifies the DNA sequence for a particular gene. The research group applies for a patent on this sequence, the patent is issued by the [USPTO], and once . . . issued, and the research group requires that anyone who applies knowledge of that sequence for any use -- medical, commercial, or whatever -- must pay royalties to the patent-holder.[131]

Moreover, one specialist in biotechnology patenting has described the situation as being that:

[there is] no longer . . . a clearly bounded territory of open noncommercial science . . . It s like a lottery of sorts, and no one wants to discover they ve just parted with a winning lottery ticket. The result . . . is that the world of genomics is becoming a place where people are much more reluctant to share.[132]

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[129] *See id.*
[130] *Id.*
[131] Nigel Williams, *On Gene Patents*, 12 CURRENT BIOLOGY 577 (2002), *available at* http://scienceweek.com/2003/sc030905.htm.
[132] Chapman, *supra* note 88, at 1.

The most problematic area of concern regarding the sharing of human DNA sequences is when sequences are used for diagnostic purposes in human genetic tests. This concern prompted the Human Genome Organization (HUGO) to issue a statement opposing the patenting of cDNAs because of the high risk of the patents creating an impediment to the free flow of scientific information.[133] The statement reads:

> HUGO is worried that the patenting of partial and uncharacterized cDNA sequences will reward those who make routine discoveries, but penalize those who determine biological function or application. Such an outcome would impede the development of diagnostics and therapeutics, which is clearly not in the public interest. HUGO is also dedicated to the early release of genome information, thus accelerating widespread investigation of functional aspects of genes.[134]

The International Covenant on Economic, Social and Cultural Rights (ICESCR) also voices this concern because human rights are violated by the monopoly created as a result of private ownership over human genes.[135] The covenant explains that this monopoly severely affects access to and delivery of health services. Such an impediment is considered a violation of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and the obligations of states to ensure [t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness. [136]

The most frequently cited example is the case of Myriad Genetics. Myriad Genetics holds nine U.S. patents on the breast/ovarian cancer genes BRCA1 and BRCA2.[137] These patents essentially give Myriad a monopoly over the genes and any information, related to or derived from them, as well as control over the genetic test it has developed for hereditary breast

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[133] Peters, *supra* note 123, at 1.
[134] Peters, *supra* note 123, at 1.
[135] E. Richard Gold & Timothy A. Caulfield, *Human Genetic Inventions, Patenting and Human Rights,* HEALTH LAW INSTITUTE (2003), *at* http://www.cipp.mcgill.ca/db/published/00000003.pdf.
[136] *Id.* at 35, n.137.
[137] Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 123 (2002); Hall, *supra* note 72, at 1.

and ovarian cancer.[138] Myriad has used this monopoly to generate revenue by licensing its patents for monopoly type fees and has threatened to enforce its patents against numerous public laboratories that perform these tests unless they pay Myriad royalties.[139] As a result, the cost of the test is prohibitive because many health insurers and governments are unwilling to pay these high fees.[140] Therefore, access is severely limited and many people are denied this potential life saving benefit.

The argument that patents on DNA sequences stifled innovation is based on the tragedy of the commons principle to explain why people overuse shared resources.[141] However, there exists another related argument regarding biomedical research, called the anticommons problem which states people under-use scarce resources because too many owners can block each other s use.[142] Thus, it is argued that the privatization of biomedical research impedes upstream research and downstream product development.[143] As a result, this leads to less development of products and services in exchange for improving human health. The problem of a patent thicket regarding DNA sequences where each patent holder has a potential veto right over the innovations of others occurs when the too many different patent holders possess patents on different gene fragments.[144] This results in the balkanization of patents on DNA sequences.

To obtain use of one patented DNA sequence, a researcher will have to deal and license with many different patent holders in order to get use of the entire sequence.[145] This results in higher transaction costs and a burdensome inconvenience to the researcher.[146] One solution that

[138] Williams-Jones, *supra* note 137, at 132.
[139] *Id.* at 131.
[140] Williams-Jones, *supra* note 137, at 133.
[141] *See* Lipton, *supra* note 58, at 1.
[142] *See id.*
[143] *See id.*
[144] *See id.*
[145] *See id.*
[146] *See id.*

seeks to combat this problem is the creation of patent pools, where multiple patent holders agree to make all pooled patents available to each member of the pool.[147] The major problem with patent pools is that they tend to bring about antitrust concerns, thus consequently, most shy away from this practice.[148]

In sum, opponents of patents on human DNA sequences assert that public ownership of DNA sequences helps to assure that the knowledge resulting from DNA sequences is accessible to all while respecting the rights of others, and that this knowledge promotes the common welfare of all humanity.

IV. Are Genetic Sequences More Than Just Chemical Compositions of Matter?

A. Genetic Sequences are More then Just Chemical Compositions of Matter

It appears from the arguments presented above that the nature and character of DNA sequences do, in fact, make DNA sequences more than just chemical compositions of matter.[149] The mere fact that DNA encodes genetic information the information that is essential to the creation and functioning of organic life validates the argument that DNA is no ordinary chemical compound and is therefore deserving of special treatment. Furthermore, the idea that all naturally occurring human DNA sequences are part of our common heritage is also accurate, because like the ocean, minerals, and shorelines, sequences are naturally created by Mother Nature.[150] However, it is inaccurate to say that non-naturally occurring human DNA sequences are a part of our common heritage, because unlike the ocean, minerals, and shorelines, these are

[147] *See id.*
[148] *See id.*
[149] *See supra* Section III.
[150] *See supra* Section III.A.

not naturally created by Mother Nature, but are instead created with human ingenuity. This is precisely why *Diamond v. Chakrabarty* was correctly decided. This argument also undercuts the theological view that only God creates human DNA sequences.[151]

The argument that the allowance of patenting human DNA sequences is the equivalent of treating human beings as market commodities is not accurate.[152] A human being is made up of millions of organic cells; the cells are made up of millions of strands of DNA.[153] Patenting DNA does not necessarily result in patenting the person. For example, patenting a new human-engineered polymer is not necessarily the same as patenting a rubber chair that is composed of the new polymer. The question becomes whether the scope of the claims support the assertion that the chair is protected under the polymer patent. Furthermore, the commodity argument is hypocritical. People are frequently treated as commodities, albeit not as a complete commodity.[154] For example, a life insurance policy places a market value on a person s life or limb.[155] Another example is the cost-benefit analyses conducted by agencies such as the FDA, which balance the lives saved or lost verses the economic costs of improving safety in food and medicines.[156]

In consideration of the theological argument, a primary flaw in its line of reasoning is that not all people accept the Joint Appeal against Human and Animal Patenting theological view.[157] This world contains varying religious views, and to accept one as authoritative is to undermine all the others. In addition, our Founding Fathers, in creating the First Amendment,

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[151] *See supra* Section III.C.
[152] *See supra* Section III.B.
[153] Biotech.com, *Human Cloning: Science Fiction or Reality?*, *at* http://www.bioteach.ubc.ca/Biomedicine/HumanCloning/.
[154] RESNIK, *supra* note 32 at 112-129.
[155] *Id.*
[156] *Id.*
[157] *See supra* Section III.C; *id.*

made a strict delineation between church and state.[158] For our legislators and our courts to accept this theological argument over scientific and economic ones is to violate this demarcated dividing line.

Despite all the ethical and theological objections to patenting DNA sequences, we should accept and embrace the notion of patenting DNA.[159] If we do not allow patenting on human DNA, we do more harm than good. For example, there could be a lack of economic incentive for private research and development in area of genomics. Moreover, without private investment in research and development, there could be a great reliance on public research and development.[160] Unfortunately, government funded institutions lack the economic resources to adequately fund potential advancements.[161] As a result, research and development in the field of genomics would essentially come to a halt.[162] However, the current U.S. policy regarding the patenting of DNA has been problematic.

Current U.S. policy does not adequately address some important concerns raised in Section III. To begin with, although the patenting of human DNA does not violate human dignity, patenting human DNA does threaten to violate human dignity.[163] Although there appears to be a minimal risk in light of the Thirteenth Amendment and *Moore* that human beings and human body parts may be sold and treated as market commodities, the possibility that patents on DNA sequences will lead down that path exists nonetheless. For example, a patentee who held patents on a substantial quantity of human DNA sequences could hold a patent on a material or tissue that could be used to generate a human embryo, which then could develop into

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[158] U.S. CONST. amend I.
[159] *See supra* Section III.
[160] RESNIK, supra note 32 at 80-81, 136-39; *see* Bayh-Dole Act, 35 U.S.C. § 202(c)(4) (2000)).
[161] RESNIK, supra note 32 at 80-81, 136-39.
[162] *Id.*
[163] *See supra* Section III.B.

a human being.[164] Theoretically that human being could owe royalties to the patentee for just merely being alive. Moreover, the concern that the granting of DNA patents has led to a balkanization effect resulting in reduced access to research and medical diagnostics appears well founded.[165] The Myriad Genetics scenario is a perfect illustration of how DNA patents can result in reduced access in the form of a threat of a patent infringement claim or in the form of cost prohibitive royalty payments.[166] In addressing these problems, we must conduct a cost-benefit analysis in deciding the best way to approach these problems so that we take measures to ensure that our policy towards the issue of patenting human DNA is the right one.

B. Proposed Solutions to Fixing the Problem with DNA Sequence Patents

1. Do not allow patents on DNA sequences

One advocated argument is that we should only allow copyright protection on DNA sequences because there is a strong fair use exception which can solve the problem of access and balkanization.[167] Under 17 U.S.C. § 101, a person or an entity may obtain copyright protection on original works of authorship fixed in a tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated. [168] Thus, when a scientist creates a new sequence of nucleotides to form a DNA strand, [that scientist] creates an original work of authorship. [169] Moreover, the creation of a new DNA sequence will qualify as an original work of authorship because the specific order or sequence of the base pairs in DNA can be fixed in a tangible medium of expression such as on a sheet of

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[164] RESNIK, *supra* note 32 at 112-129.
[165] *See supra* Section III.D.
[166] *See id.*
[167] James G. Silva, *Copyright Protection of Biotechnology Works: Into the Dustbin Of History?* 2000 B.C. INTELL. PROP. & TECH. F. 012801 (Jan. 28, 2000), *at* http://www.bc.edu/bc_org/avp/law/st_org/iptf/articles/content/2000012801.html.
[168] 17 U.S.C. § 102.
[169] Silva, *supra* note 167.

paper or in a MP3 computer file.[170] In addition, DNA sequences are analogous to computer programs which are already copyrightable because genetic sequences are simply organized strings of symbols of the nucleotides of DNA.[171] Hence, like a computer program which instructs a computer to carry out a specified task, DNA sequences function as a set of instructions in order for cells to carry out specified tasks such as production of proteins.[172]

However, there seems to be several problems with copyrighting DNA sequences. First, DNA sequences are obtained from nature and are probably not original.[173] Under *Fiest*, there appears to be no independent creation present because a researcher who constructs a DNA sequence does so based on a sequence he or she knows of in nature that is not based on his or her own imagination.[174] Second, under the *Baker* test, the doctrine of merger seems to remove DNA sequences from the scope of copyright protection.[175] For example, the idea of combining promoters, plasmids, genes and bacteria can only be expressed in limited ways, and therefore is not protectable.[176] Furthermore, this principle seems to differentiate sequences from computer programs in that there is only one way to express a genetic program.[177] In essence, there is only one program language to express the method of producing proteins in cells.[178] Computer programs, on the other hand, can have a single instruction expressed in numerous ways via different program languages.[179] Finally, under 17 U.S.C. § 101, one cannot get copyright protection on an expression that only has a utilitarian function, or an expression whose

[170] *Id.*
[171] Silva, *supra* note 167.
[172] *Id.*
[173] *Id.*
[174] *Id.*
[175] *Id.*
[176] *Id.*
[177] *Id.*
[178] *Id.*
[179] *Id.*

originality is inseparable from its utilitarian function.[180] For example, DNA sequences code for proteins and therefore the DNA sequence must be specific to produce a protein. [181] Moreover, the DNA sequence cannot be physically removed from the DNA strand and as a result, the originality of the new sequence is blurred with the utilitarian features and inherently inseparable.[182]

Another argument proposes that we should allow trade secret protection on DNA sequences because this protection still provides the incentive necessary to further innovation. As a result, a ban on DNA sequence patents should have very little effect on the progress and advancement in the field of biotechnology. Moreover, an important advantage of trade secret protection is that the only real costs of this form of protection are in guarding the secret.[183] A trade secret, if kept secret, theoretically lasts forever, unless someone else invents the same object and either patents or publishes it.[184]

There are problems with trade secret protection. One problem with trade secret protection is that it fails to provide accurate and reliable information on the quality and quantity of technology. [185] As a result, it is more difficult to commercialize the technology.[186] For example, a trade secret licensee cannot fully monitor the complete disclosure of the secret by the licensor.[187] Another problem trade secrets have is that they lack a predetermined term of protection and their enforcement can be problematic.[188] A final problem with trade secret protection is that it prevents the dissemination of information essential to cutting edge

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[180] *Id.*
[181] *Id.*
[182] *Id.*
[183] Nuno Pires de Carvalho, *The Problem of Gene Patents,* 3 WASH. U. GLOBAL STUD. L. REV. 701, 738 (2004).
[184] *Id.* at 740.
[185] *Id.* at 739.
[186] *See id.* at 703-707.
[187] *See Id.*
[188] *See id.*

biotechnology research.[189] The sharing of information is highly important because there is more input, more cooperation, and more brainpower to create and scrutinize new ideas and methods.[190] Thus, trade secrets stifle technological innovation due to the fact that the information needed for further research has to be reinvented. [191]

2. Allow only process claims on DNA sequences

A patent application has several components; among the most important are the specification, drawings, and claims.[192] The most important part, the claims, serve both to distinguish the invention from the prior art and to define the scope of protection the patent will afford. [193] There are three primary types of claims that can be drafted: a product claim, a process claim, and a product-by-process claim.[194] Of the types of claims a patentee may draft, a product claim is the broadest in scope, while a process claim is the narrowest claim in scope.[195] The great utility of a product claim is that it gives the patentee the right to prevent others from making, using or selling the product. [196] Not surprisingly, many patentees who seek patent protection on DNA sequences draft product claims.[197] On the other hand, a process claim gives a patentee the right to only prevent others from using or selling rights to employ a specific claimed process. [198]

Thus, one way to prevent balkanization and allay some ethical concerns would be to allow only process claims to be granted on DNA sequences. This would allow protection on

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[189] *See* RESNIK, *supra* note 32, at 135-40.
[190] *See id.*
[191] *See id.*
[192] *See* CHISUM ON PATENTS § 8.0-8.5 (2004).
[193] Brian S. Tomko, Comment, *Scripps or Atlantic: The Federal Circuit Squares Off Over the Scope of Product-By-Process Claims*, 60 BROOK. L. REV. 1693, 1701 (Winter 1995).
[194] *Id.* at 1695-96.
[195] *Id.* at 1706.
[196] *Id.* at 1701.
[197] *Id.* at 1695-99.
[198] *Id.* at 1701.

only specified methods of using the DNA sequence, and would not allow protection on the sequence itself. Thus, researchers would essentially be able to use DNA sequences as research tools while being restricted to novel and unobvious uses of a particular DNA sequence.[199]

3. The granting of patents on DNA sequences should be the exception and not the rule

In June 2000, the Nuffield Council of Bioethics convened a group of experts to set up a Round Table Group to consider the ethical and legal issues raised by the patenting of DNA sequences.[200] The Nuffield Council report stated that many patents are being granted, and many are of doubtful validity because the criteria set out for deciding if they are patentable or not are not being strictly adhered to.[201] As a result, the Council was concerned with the scope of patent protection DNA sequences were receiving because they found that the majority of these patents were overbroad, resulting in stifled innovation and research.[202] More specifically, the Council was concerned that many commercial entities were patenting DNA sequences for research purposes, rather than specific therapeutic use.[203] This resulted in the further stifling of research and technological advances in the field of genomics and DNA medicine.[204]

The Council took issue with some of the patentability requirements of the USPTO. The Council pointed out that the European Patent Offices rules and guidelines concerning biotech inventions were better in weeding out overbroad and harmful patents.[205] For example, the USPTO s standard on non-obvious does not consider the inventiveness of an invention, and as a result, the USPTO has issued unnecessary patents. Take the example of the patenting of isolated DNA sequences. As a result of the advancement in the field of genomics, *in sillico* techniques

[199] *Id.*
[200] NUFFIELD COUNCIL, *supra* note 7, at v.
[201] *Id.* at xi.
[202] *Id.* at 33, 74.
[203] *Id.* at 33.
[204] *Id.* at 70.
[205] *See generally* NUFFIELD COUNCIL, *supra* note 7, at 23-30.

were developed.[206] The use of *in sillico* techniques have enabled a machine to take an unknown human DNA sequence from a database and match the sequence with a similar DNA sequence in an animal genome where the function may be already known.[207] A researcher then seeks a patent on the unknown human sequence, based on the asserted similarly of function to the animal DNA sequence, and the USPTO subsequently finds that this is non-obvious.

The Council recommended that the USPTO follow the procedures of the European Patent Office, which does consider the inventiveness of an invention.[208] Moreover, the Council recommended that the USPTO should follow its own utility and written description guidelines and allow only a limited scope of protection on specifically defined uses.[209] For example, the Council urged the USPTO to interpret product claims on asserted uses of DNA patents narrowly.[210] The Council also recommended that the USPTO should discourage and no grant patents and claims for DNA sequences claiming use as a research tool.[211] The Council concluded that if these recommendations are followed, the current problems of access to research and medical diagnostics will be alleviated because the granting of patents on DNA sequences would be the exception rather than the rule.[212]

4. Treat the enforcement of DNA sequences patents similarly to patents on medical treatments and procedures

Another proposed solution is for Congress to expand the Physician Exemption Statute to

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[206] *See, e.g.*, Lukasz Huminiecki and Roy Bicknell, *In Silico Cloning of Novel Endothelial-Specific Genes*, *at* http://www.genome.org/cgi/content/full/10/11/1796.
[207] *See* D. E. Moody, *Genomics techniques: An overview of methods for the study of gene expression*, 79 J. ANIM. SCI. E128-E135 (2001).
[208] NUFFIELD COUNCIL, *supra* note 7, at 69.
[209] *Id.* at 70.
[210] *Id.* at 73.
[211] *Id.* at 71.
[212] *Id.* at 70-73.

include human DNA sequences.[213] The Physician Exemption Statute, 35 U.S.C. § 287, exempts medical practitioners and their health care entities from patent infringement liability when performing a medical or surgical procedure that is patented.[214] As a result, the patent is unenforceable and rendered virtually worthless. [215] The intent of Congress in promulgating this statute was to deny medical or surgical procedure patents the right of enforcement because limiting the use of these techniques conflicts with the greater good.[216] Congress found that that these types of patents will potentially cause improper influence on a practicing physician s judgment as well as affect the availability of medical treatments for patients.[217] Furthermore, Congress was deeply concerned that the holder of a medical procedure patent possessed the legal power to prevent anyone from using [a] patented procedure during the term of the patent. [218] More specifically, Congress was concerned that:

> (a) a patent-holder may refuse to allow a doctor to use a patented procedure needed by patients; (b) a patent-holder may make it expensive or otherwise difficult to obtain a license, thereby inflating the cost of health care; (c) a doctor who has a license to perform a patented procedure may unwisely advocate the procedure to make use of the license; and (d) an unlicensed doctor may hesitate to perform a patented procedure for fear of infringing the patent.[219]

Similarly there is an analogous concern that DNA sequence patents limit the ability of doctors to diagnose and research genetic-based diseases. [220] As a result, DNA sequence patents should be unenforceable because they also conflict with the greater good. The Medical

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[213] *See* Steven L. Nichols, Comment, *Hippocrates, The Patent Holder: The Unenforceability of Medical Procedure Patents*, 5 GEO. MASON L. REV. 227 (Winter 1997).
[214] *Id.* at 237.
[215] *Id.*
[216] *Id.*
[217] *Id.* at 238.
[218] *Id.*
[219] *Id.* at 238.
[220] Gregory P. Lekovic, *Genetic Diagnoses and Intellectual Property Rights: A Proposal to Amend The Physician Immunity Statute,* 4 YALE J. HEALTH POL'Y, L. & ETHICS 275, 284 (Summer 2004).

Procedure Patent Coalition argues that the patent incentive is unnecessary in medical practice, as the development of new medical procedures [and diagnostics] often occurs during the normal course of medical practice and generally does not require significant capital investment. [221] Thus, the Medical Procedure Patent Coalition makes the argument that researchers derive motivation from non-monetary incentives, such as a desire to improve their professional stature or reputation.[222]

This argument is flawed because most of the research and development on DNA sequences has come from the private biotech sector, and not from medical research doctors.[223] DNA patents protect companies investments, and therefore have the net effect of increasing research and development, resulting in more diagnostic tests, drugs, and novel therapies.[224] Without enforceability, there would be few, if any, patents. Without patents, there would only exist trade secret protection, which as previously discussed, inhibits the sharing of information, and consequently, inhibits innovation and research.[225]

V. Conclusion

The best approach to making a decision on how to address the problems that DNA patents present is to conduct an old fashioned balancing test. The benefits from DNA patents must be weighed against the harms that DNA patents inflict. The greatest benefit DNA patents bring is the promise and potential of curing, treating, diagnosing, and eliminating medical conditions that afflict all living organisms. This benefit seems to outweigh the concerns and harms that DNA patents bring. However, these benefits cannot be realized without future

[221] *Id*. at 301.
[222] *Id.*
[223] *See* RESNIK, *supra* note 32, at 168-75.
[224] *See id.* at 131-53*;* Lipton, *supra* note 58, at 1.
[225] *See supra* Section III.D.

research and innovation. The way to create innovation and entice further research is the lure of huge profits from the commercialization of products and services from the human genome. The best way to maximize innovation that leads to future advancements in biotechnology is to allow patents on DNA sequences. However, the mere allowance of DNA patents is not enough to achieve maximization of research and innovation. It is important for us to achieve this goal ethically, because if we do not, the wonderful promise of DNA technology will not be realized by all. Therefore, in consideration of the important goal to ethically maximize research and innovation in the area of DNA technology, it is imperative that Congress or the courts give real teeth to the patent research exemption.

In *Madey v. Duke University*, the Federal Circuit held that university research was ineligible for the experimental-use exemption because it unmistakably further[s] the institution s legitimate business objectives, including educating and enlightening students and faculty participating in these projects. [226] The Federal Circuit struggled in applying this common law doctrine to distinguish commercial use of a patented technology from a noncommercial use, and ultimately chose to apply an expansive definition of commercial use.[227] Consequently, the Federal Circuit s expansive interpretation of commercial use now only allows very few activities to be deemed unrelated to an alleged infringer's legitimate business. [228] The time has come for either the United States Supreme Court or for Congress to expand the experimental-use exemption to specifically include public sector research and genetic medical diagnostic tests.[229]

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[226] *See* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002).
[227] *Id*. at 1351.
[228] *See* Katherine J. Strandburg, Note, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 84 (2004).
[229] David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools By Implementing A Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1037 (2004).

One may argue that the application of an expanded experimental-use exemption will deprive patentees of control over the uses of their research and DNA medical diagnostic-based inventions, and will thus preclude the receipt of any royalties stemming from their inventions.[230] This, in turn, would diminish the incentive to invest resources in the development of initial as well as future inventions on these exempted subjects.[231] However, to address this concern as an expanded experimental-use exemption could permit exempted use only of any DNA based research tool and medical diagnostic for which an equivalent substitute is not readily available.[232] This would allow a DNA patent to further achieve one of the most important purposes of a patent an efficient way of effectuating the patent disclosure so that it advances the state of the art of the patented invention.[233] The patent system, with respect to a patented product or process, actually encourages the act of designing and inventing around patents (but stops short of reverse engineering) because it tyically leads to new inventions and publications.[234] Thus, as one commentator has stated [k]eeping track of a competitor s products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made. [235] Accordingly, an expanded research exemption for the patent system would be the most feasible and realistic solution to cure some of the pressing problems that DNA sequence patents present, while still fostering innovation and commercialization of DNA sequences.

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[230] *See* Strandburg *supra* note 228, at 87-88.
[231] *See id.*
[232] *See* Hoffman *supra* note 229, at 1036-39.
[233] *See id.*
[234] *See id.*
[235] *See* Strandburg, *supra* note 228, at 102.