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THE ETHICS OF GENETIC PATENTING AND THE SUBSEQUENT IMPLICATIONS ON THE FUTURE OF HEALTH CARE

Suzanne Ratcliffe^{*}

I. INTRODUCTION

Over the past two decades, significant scientific and technological advancements have resulted in researchers and corporations procuring patent rights to human genomic material. However, patenting genetic sequences poses quite the controversial ethical dilemma for biotechnology scientists and patent holders. Patent holders are granted exclusive rights—through patent protection—to make, use, and sell their invention to the exclusion of others in exchange for disseminating the information in the public domain. It appears at first blush that patenting genetic sequences benefits society by providing innovative information to the benefit of the public's welfare. However, careful analysis suggests such gene patenting might not be as beneficial as originally assumed, since researchers are unable to further research and develop such information.

Patenting genetic sequences offers substantial opportunities for scientific advancements and subsequent medical breakthroughs. Discovering and understanding genetic sequences ultimately results in new diagnostic testing and treatment of diseases that have traditionally bewildered physicians and scientists alike. An essential element of the biotechnology community's success lies in the patent system; such success, however, might serve to frustrate future research. Patent claims to genetic sequences continue to be critically important to motivating costly research and development. Alternatively, further research is stymied when researchers and scientists are unable to access the newly patented information. Gene patents are the subject

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of a controversial debate between biotechnology corporations and researchers regarding the implications of such patents on ethics and morality, health care, and future global genetic research. This Comment sets forth a framework for the ethical debate surrounding human gene patenting and suggests proposals for potential future reforms to the current patent process as well as policy alternatives. Part II provides an overview of United States patent law and the various statutory requirements. Part III provides discussion and analysis of the ethical implications of gene patenting as well as considering the subsequent effects on health care. Part IV provides an international perspective on the ethics of gene patenting. Finally, Part V suggests possible reforms and policy alternatives to the current patent process.

II. U.S. PATENT LAW FRAMEWORK

Article I of the Federal Constitution first recognized the need to reward and promote technological advancements by granting Congress the power “[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”¹ The basic structure of current patent law, the United States Patent Act, 35 U.S.C.A. §§ 1-376, was enacted by Congress under its constitutional grant of authority to secure, for limited times to inventors, the exclusive right to their discoveries.² Patent law is federally regulated, with key decisions from the United States Patent and Trademark Office (“USPTO”).³ Under current patent law, anyone who “invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent.”⁴

An important distinction is made between “a *discovery* of something that exists in nature, which is not patentable, and a true *invention*, which requires that human beings contribute something of significance.”⁵ However, the debate continues regarding whether genetic sequences are discoveries or inventions and whether this genetic material is patentable subject matter as opposed to a product of na-

¹ U.S. CONST. art. I § 8, cl. 8.

² 35 U.S.C.A. §§ 1-376 (West 2009).

³ USPTO is the Executive branch’s federal agency that grants patents.

⁴ 35 U.S.C.A. §101.

⁵ Ruth Macklin, *The Ethics of Gene Patenting*, in GENETIC INFORMATION: ACQUISITION, ACCESS, AND CONTROL 129, 130 (Alison K. Thompson & Ruth F. Chadwick eds., 1999).

ture.⁶ The Supreme Court interpreted 35 U.S.C.A. § 101 broadly in *Diamond v. Chakrabarty*,⁷ holding that microorganisms produced by genetic engineering are entitled to patent protection.⁸ More importantly, the Supreme Court recognized the patentability of “non-naturally occurring” living matter.⁹ This standard provided the necessary precedent for the Federal Circuit Court to find any gene sequence in a non-natural state patentable.¹⁰ However, critics argue that since genes are naturally occurring in the human body and part of our common human heritage, genes are a product of nature and should not be patentable.¹¹ Defenders of gene patenting suggest that ownership of altered genes is no different from other biotechnology patents relating to human beings.¹²

Once it is established that the genetic sequence is patentable subject matter, the applicant must demonstrate that the invention is novel, useful, and non-obvious.¹³ However, there is much debate surrounding each of these requirements when considering patents on genetic information.¹⁴ An invention is novel if it has not been “known or used by others.”¹⁵ The Patent Act specifically requires that “an applicant . . . be the ‘first inventor to confer the benefit of the

⁶ See 35 U.S.C.A. § 101 (identifying inventions that are patentable as new, different, or useful improvements of existing machines, processes, “composition of matter,” or manufactures).

⁷ 447 U.S. 303 (1980).

⁸ Patent applicant, a microbiologist, filed a claim for patenting human-made, genetically engineered bacterium. *Id.* at 305. The application was originally denied since the bacterium was living material; however, the Supreme Court reversed the decision by interpreting composition of matter broadly to include “nonnaturally” occurring matter invented through human intervention. *Id.* at 309, 317-18.

⁹ *Id.* at 309.

¹⁰ *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991). United States Patent and Trademark Office had previously granted patent for the method of purifying Erythropoietin (EPO). *Id.* at 1203. The Federal Circuit Court found the subsequent application for the genetic sequence of EPO did not infringe the previous patent and found the genetic sequence patentable. *Id.* at 1214.

¹¹ See Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Mankind*, 13 AM. U. INT'L. L. REV. 219, 249-50 (1997).

¹² Macklin, *supra* note 5, at 132.

¹³ See 35 U.S.C.A. §§ 102-103.

¹⁴ See generally Lisa A. Karczewski, *Biotechnological Gene Patent Applications: The Implications of the USPTO Written Description Requirement Guidelines on the Biotechnology Industry*, 31 MCGEORGE L. REV. 1043 (2000).

¹⁵ 35 U.S.C.A. § 102(a).

invention on the public.’ ”¹⁶ Critics argue that it is impossible for gene sequences to meet such a requirement since genes occur naturally and are the very core of rudimentary human function.¹⁷ Others argue that although the Patent and Trademark Office requires that genetic material be altered from its natural state to meet the statutory patent requirements, this manipulated genetic material remains identical to the original genetic sequence and thus fails to meet the required modified status.¹⁸ This argument hinges on the notion that genetic material—whether naturally occurring or in its isolated and purified state—is merely “information expressing a pre-existing scientific principle” that should not be considered novel and consequently is non-patentable.¹⁹ However, this argument fails since the genetic sequences must be altered in such a way to create something dramatically different from those occurring naturally.²⁰

The utility requirement has also posed some difficulty for patenting gene sequences. Although it is well established that non-naturally occurring full DNA sequences with a known function are patentable, the answer is not so certain in terms of partial genetic sequences, also known as Expressed Sequence Tags.²¹ In order to provide further insight and guidance for patent examiners, the Patent and Trademark Office published the Utility Examination Guidelines.²² According to the Guidelines, in order to satisfy the utility requirement, the patent application must disclose a “specific, substantial, and credible utility for the claimed isolated and purified gene.”²³ The Revised Utility Examination Guidelines returned to the heightened utility standard established by the Supreme Court in *Brenner v. Manson*,²⁴ requiring a showing of “substantial” utility.²⁵ Under this

¹⁶ Karczewski, *supra* note 14, at 1055 (citing Andrew T. Knight, *Pregnant with Ambiguity: Credibility and the PTO Utility Guidelines in Light of Brenner*, 73 IND. L.J. 997, 1008 (1998)).

¹⁷ *See id.* at 1055.

¹⁸ Debra Greenfield, *Intangible or Embodied Information: The Non-Statutory Nature of Human Genetic Material*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 467, 473 (2009).

¹⁹ *Id.* at 474.

²⁰ *See id.*

²¹ Donald L. Zuhn, Jr., *DNA Patentability: Shutting the Door to the Utility Requirement*, 34 J. MARSHALL L. REV. 973, 977-79 (2001).

²² Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

²³ *Id.* at 1093.

²⁴ 383 U.S. 519 (1966). Patent applicant filed an application for the “novel process of making certain known steroids[,]” which was denied. *Id.* at 520-21. The Court reasoned the

heightened utility standard, it is unlikely that full or partial DNA sequences with no known function will be awarded a patent. However, in practice, the utility requirement has had little or no effect on the ability to obtain a patent, since any proposed use has generally been sufficient.²⁶ Thus, any and all proposed usages—as indicated in the application—are accepted, and patents are subsequently granted even if the use is ultimately unknown.

Similarly, the language of the non-obvious requirement has posed substantial problems for gene patents. According to the Patent Act, an invention is non-obvious if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”²⁷ This language does not specify whether such a requirement can be satisfied “by the method of acquiring the sequence or” whether the sequence itself must be obvious.²⁸ Accordingly, a heightened, more stringent standard for the non-obvious requirement—as applied to gene-related patents—could provide potential advantages to the public such as “maintain[ing] uniformity with other biotechnolog[y]” patents, “reduc[ing] irresponsible gene patenting behavior,” and regaining the public’s power to bargain in contracts.²⁹ In order for the applicant to meet and satisfy this heightened non-obvious requirement, “[t]he applicant must sequence a complete gene, or at least enough of a gene necessary to determine its function and preliminary diagnostic applications.”³⁰

The Federal Circuit decision of *In re Deuel*³¹ specifically ad-

utility requirement had not been met since the framers of the Constitution and Congress intended to grant exclusive rights only when the public “benefits from an invention with substantial utility.” *Id.* at 534-35. The applicant had not developed the process to the point where a specific benefit existed in an available form; therefore, there was no justification for granting the application. *Id.*

²⁵ *Id.*

²⁶ Council on Ethical & Judicial Affairs Report 2, Am. Med. Ass’n, Patenting the Human Genome (1997), <http://www.ama-asn.org/ama1/pub/upload/mm/code-medical-ethics/2105a.pdf> [hereinafter CEJA Report].

²⁷ 35 U.S.C.A. § 103(a).

²⁸ Karczewski, *supra* note 14, at 1057.

²⁹ Sara Dastgheib-Vinarov, *A Higher Nonobviousness Standard for Gene Patents: Protecting Biomedical Research from the Big Chill*, 4 MARQ. INTELL. PROP. L. REV. 143, 144 (2000).

³⁰ *Id.*

³¹ 51 F.3d 1552 (Fed. Cir. 1995).

dressed the non-obvious requirement within the realm of genetic sequencing.³² The court held that although the method employed might have been obvious, the end result was not; therefore, “what cannot be contemplated or conceived cannot be obvious.”³³ In contrast, the recent Federal Court decision of *In re Kubin*³⁴ held the claim obvious since “appellants used conventional techniques [previously patented] . . . to isolate a gene sequence”³⁵ This decision could potentially have a profound effect on the future of gene patentability as well as the validity of patents previously granted.

The future of human genomic patenting remains uncertain based on recent Federal Circuit Court decisions and Patent and Trademark Office Guidelines.³⁶ The current trend seems to be leaning toward implementing either more stringent or completely different standards for biotechnology patents. It is true that patent rights provide the necessary protection for inventors to continue on the quest of discovering new technologies; however, regulation is required to ensure the rights concerning living material are not abused.

III. GENE PATENTING: THE ETHICAL DEBATE AND THE FUTURE OF HEALTH CARE

Patenting human genetic material is highly controversial and fuels substantial ethical debate within the research and biotechnology communities since some rights are granted to the exclusion of others. Patent law has long provided the means to reward an inventor for toiling in research through economic gain and acknowledgment within the scientific community.³⁷ However, granting exclusive rights within this area of biotechnology could prove to limit research and

³² *Id.* at 1553-54. Patent applicant purified a protein thought to be useful in repairing and replacing damaged tissue. *Id.* at 1554. The applicant first determined the amino acid sequence of the protein, synthesized the fragments representing all the possible sequences, and then used those sequences to isolate the full sequence. *Id.* at 1555.

³³ *Id.* at 1558.

³⁴ 561 F.3d 1351 (Fed. Cir. 2009).

³⁵ *Id.* at 1356. Claimant applied for a patent for genetic sequences that encoded the Natural Killer Cell Activation Inducing Ligand (“NAIL”) protein, a cell-surface protein implicated in the activation of natural killer cells, which is a type of human immune system cells. *Id.* at 1352. The NAIL protein had been previously discovered and disclosed in a prior patent, but the sequence of the protein had not been disclosed. *Id.* at 1354, 1361.

³⁶ See, e.g., *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008); see also *In re Kubin*, 561 F.3d 1351.

³⁷ Sturges, *supra* note 11, at 233.

hinder future innovations.

Based on the nature of genetic material, there are various ethical arguments that must be addressed. There are at least five non-consequentialist or deontological³⁸ arguments that human gene patenting can harm human dignity: (1) it modifies our genetic integrity; (2) it is equivalent to ownership of humans; (3) it commercializes body parts, which should not be turned into commodities; (4) human genes should be treated as common property since they are part of a common human heritage; and (5) distributive justice, i.e., the proper distribution of benefits and burdens in society requires that no group be deprived of the benefits of genomic research.³⁹

The drastic alteration of genes could eventually prove harmful to common genetic heritage and genetic integrity, thereby resulting in harm or loss of human dignity.⁴⁰ Although current biotechnology efforts concentrate on beneficial medical discoveries and advancements in disease prevention and treatment, the potential for eugenic abuse exists through the “enhancement and improvement of the human race.”⁴¹ Critics argue that altering human genetic material to create new and improved humans interferes with nature and natural processes and it substantially affects biodiversity.⁴² Eventually, genetic integrity may be compromised by this inappropriate modification of our genetic material.

Another nonconsequentialist argument is that patenting human genes confers property rights, which eventually leads to the ownership of human beings.⁴³ According to Kantian theorists, individuals are autonomous beings and must not be used as a means to an end.⁴⁴ The Kantian argument that patenting human genomic material is ethically wrong proceeds as follows: Patenting genes treats people as property since rights to the genetic sequences of various individuals are owned and ultimately controlled by the patent holder; “it is

³⁸ *Deontological Ethics*, ENCYCLOPEDIA BRITANNICA, <http://www.britannica.com/EBchecked/topic/158162/deontological-ethics> (last visited Mar. 12, 2011) (defining the term “deontological ethics” as the approach to ethics that judges the morality of an action based on the action's adherence to a rule or rules).

³⁹ Macklin, *supra* note 5, at 132-34.

⁴⁰ *Id.* at 132.

⁴¹ Sturges, *supra* note 11, at 227.

⁴² *Id.*

⁴³ Macklin, *supra* note 5, at 132.

⁴⁴ *See id.*

morally wrong to treat persons as property; [therefore,] the practice of patenting human genes is morally wrong.”⁴⁵

Critics argue that patents should not be issued for genes because the human genome sequence is the very essence of what it means to be human; therefore, no individual or corporation should retain ownership or control over any genetic material.⁴⁶ However, since patents confer intellectual property rights as opposed to ownership rights over the patented material, many argue that the result is not human ownership, but a right to an invention.⁴⁷ Supporters suggest that gene patents merely confer intellectual property rights; therefore, the patent does not confer legal ownership over the human body.⁴⁸ It is argued that “the only thing [the gene] patent-holder ‘owns’ is the right to petition a court to stop [another from] unauthorised [sic] use” and manipulation of the patented invention.⁴⁹ However, even if a patent holder merely retains intellectual property rights over the genetic sequence, these property rights could be construed as ownership of the sequence. The ability of an individual to exclude any other person from using, making, or researching the patented genetic sequence can be equated to ownership.

Another nonconsequentialist argument suggests that patenting of human genetic material commercializes human genetic material, which is a part of nature and, consequently, should not be “commodified.”⁵⁰ Human gene patenting can be considered dehumanizing since it alters the traditional notion of humans from beings possessing “dignity and respect into objects that can be bought, sold, or modified.”⁵¹ Patents have traditionally served an economic function, which “presuppose[s] an ability to determine the economic value of

⁴⁵ *Id.*

⁴⁶ See Sturges, *supra* note 11, at 249-50.

⁴⁷ See Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 TEX. INTELL. PROP. L.J. 221, 233 (2003).

⁴⁸ See Annabelle Lever, *Ethics and the Patenting of Human Genes*, J. PHIL. SCI. & L. (2001), available at http://www6.miami.edu/ethics/jpsl/archives/papers/ethics_lever.html.

⁴⁹ See R. Stephen Crespi, *Ethico-Legal Issues in Biomedicine Patenting: A Patent Professional Viewpoint*, 11 SCI. & ENGINEERING ETHICS 117, 121 (2005).

⁵⁰ See Macklin, *supra* note 5, at 133-34; see also *Commodify*, MERRIAM WEBSTER ONLINE, <http://www.merriam-webster.com/dictionary/commodify> (last visited Mar. 12, 2011) (defining the term “commodify” as the transformation of goods and services or things that may not typically be regarded as goods or services into a commodity).

⁵¹ Macklin, *supra* note 5, at 133.

the patentable entity.”⁵² Using economic theory in discussing human genetic material implies that human beings and their “parts” are salable and can be reduced to commodities. In effect, this conception of humans as salable parts for economic gain extinguishes the essence of what it means to be human.

Yet others argue that since human genetic material is shared among all humans, it should be considered common property—belonging to all humans—as opposed to one individual or corporation retaining exclusive rights to the patent.⁵³ Moreover, unlike the development of drugs, which has traditionally been privately funded, genetic research and development in the United States has been largely undertaken by public organizations, such as the National Human Genome Research Institute and the National Institutes of Health.⁵⁴ This fact leads to the argument that since the research is publicly funded, no private individual or company should retain any type of right to the discovered information, especially to the exclusion of all others. Human genomic material is common to all individuals and should be available in the public domain for research and development as opposed to being under the exclusive control of only one entity.

The final nonconsequentialist argument suggests that, in the interest of justice, no individual or group of people should be deprived of the benefits associated with genomic research.⁵⁵ Critics argue that genomic research will largely benefit wealthier countries and wealthy individuals in those countries.⁵⁶ However, within the concept of justice lies the notion of fairness. Researchers and investors are entitled to economic reward for the time and money they invested in genomic research.⁵⁷ The limited monopoly provided for is in exchange for the disclosure of patent information. Accordingly, the public benefits from the patented information and the inventor is allowed to recoup his investment and reap the financial reward, which in turn encourages others to disclose their inventions in a similar

⁵² CEJA Report, *supra* note 26, at 4.

⁵³ See Macklin, *supra* note 5, at 133.

⁵⁴ See, e.g., *World Survey of Genomics Research*, STANFORD-IN-WASHINGTON PROGRAM, <http://www.stanford.edu/class/siw198q/websites/genomics/entry.htm> (last visited Mar. 6, 2011).

⁵⁵ Macklin, *supra* note 5, at 134.

⁵⁶ *Id.*

⁵⁷ *Id.*

manner.⁵⁸

Similarly, there are at least four consequentialist arguments pertaining to the issue of patenting human genetic material that generally concern the future of health care: (1) the delay in disseminating information; (2) the effect of submarine patents;⁵⁹ (3) the development of new diagnostic tests and medications; and (4) the impact on patient autonomy and confidentiality in the doctor-patient relationship.⁶⁰ According to many utilitarians, genetic sequence patenting is ethical since it is “likely to lead to medical innovations that promote the greatest happiness for the greatest number.”⁶¹

Critics of gene patenting argue that researchers waiting for patent approval are less likely to share information until the patent is granted.⁶² Scientists are unlikely to share material or information to ensure they would be entitled to the patent rights as well as gain the financial rewards.⁶³ According to the Journal of the American Medical Association, one in every five medical scientists delays publishing research results for at least half a year to protect their financial interest and patent rights.⁶⁴ Not only do scientists delay publishing their genetic research, but collaborative research has been similarly inhibited. A 2002 study noted that forty-seven percent of geneticists surveyed had been denied requests from colleagues for information, data, or materials regarding published research.⁶⁵

Alternatively, the right to patent genes is defended “in terms

⁵⁸ Hill, *supra* note 47, at 236.

⁵⁹ Steve Blount, *The Use of Delay Tactics to Obtain Submarine Patents and Amend Around a Patent that a Competitor has Designed Around*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 11, 13 (1999) (explaining that “submarine patent” is a term designated for a patent in which an inventor files an original patent application with wide-ranging claims, but then later files a series of subsequent applications, which “keep[s] the patent submerged in the patent office”).

⁶⁰ See Macklin, *supra* note 5, at 134-35.

⁶¹ Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1659 (2001).

⁶² Macklin, *supra* note 5, at 134.

⁶³ Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 79 (2002).

⁶⁴ David Blumenthal et al., *Withholding Research Results in Academic Life Sciences*, 277 J. AM. MED. ASS'N 1224, 1224 (1997).

⁶⁵ David Blumenthal et al., *Data Withholding in Academic Genetics*, 287 J. AM. MED. ASS'N 473, 477 (2002).

of invention, disclosure, and innovation.”⁶⁶ Supporters view gene patents as the catalyst for future research since they provide the requisite incentive to develop and research new inventions.⁶⁷ It has also been suggested that patents on genetic material create an incentive for researchers to disseminate information since patent rights protect their discoveries.⁶⁸ Accordingly, it is presumed that gene patenting fulfills the constitutional purpose of promoting the progress of science by encouraging innovation through the exclusive right to discovery.⁶⁹ However, even though information might be delayed, it is ultimately disseminated to the public. Without patent protection, the specific details regarding these genetic sequence inventions would most likely be kept as trade secrets by many corporations and individuals, resulting in thwarted research and delayed innovative diagnostic and treatment methods.

Additionally, complications can arise during the pendency of patent applications. Since the patent application can take years or even decades to be processed and ultimately decided, a common occurrence during the pendency of the patent is another researcher discovering the same genetic sequence.⁷⁰ While the original patent application is pending, the researcher continues to research the sequence and ultimately develops an innovative treatment.⁷¹ However, when the original patent application is eventually approved, known as a submarine patent, the owner may prohibit the second researcher from making the test or treatment available and can require a substantial licensing fee from the subsequent researcher.⁷² Unfortunately, for fear of liability to the original patent owner, these innovative medical treatments and tests are not made available to the public. Nondisclosure of this innovative medicine adversely affects society by preventing public access to advancements in medical care.

Similarly, it is argued that the patent process hinders research and development of new diagnostic tests and medications.⁷³ Given that the patent holder possesses the exclusive right to prevent any

⁶⁶ Hill, *supra* note 47, at 240.

⁶⁷ *Id.* at 237.

⁶⁸ Macklin, *supra* note 5, at 134.

⁶⁹ Hill, *supra* note 47, at 238.

⁷⁰ Andrews, *supra* note 63, at 86.

⁷¹ *Id.*

⁷² Blount, *supra* note 59, at 13.

⁷³ Macklin, *supra* note 5, at 135.

other individual or corporation from testing for a particular gene, many are concerned about the quality, access, and cost of such testing and treatment.⁷⁴ Corporations hold the monopoly on certain genetic sequences and prohibit any laboratory or doctor from performing the necessary research and diagnostic testing for the newly patented genetic sequences, which results in increased medical costs.⁷⁵ Unfortunately, if an individual is unable to afford the testing, there are no other alternatives available. Similarly, there is no guarantee that the individuals who donated the genetic material will receive any benefit or even be able to afford the test that was created using their genetic material and information.⁷⁶

Currently, Myriad Genetics holds the patents on the BRCA 1 and BRCA 2 genes and the mutations.⁷⁷ These genetic sequences “have been linked to hereditary . . . breast and ovarian cancer.”⁷⁸ Myriad Genetics offers the only screening test for the disease at the exorbitant cost of \$3,200.⁷⁹ On May 12, 2009, the American Civil Liberties Union and the Public Patent Foundation (“PUBPAT”), a non-profit organization affiliated with the Benjamin N. Cardozo School of Law, filed a lawsuit in the United States District Court, Southern District of New York, against Myriad Genetics and the Patent and Trademark Office, claiming that “the patents increase patient cost, eliminate the possibility of second opinions,” and hinder research on the genes.⁸⁰ Similarly, a company with exclusive rights to a gene sequence related to Alzheimer’s disease prohibits any laboratory other than its own from performing the necessary diagnostic test.⁸¹ Consequently, many individuals will forego the necessary testing based on cost and availability. More importantly, these patents make discovering the mutations linked to these diseases almost impossible, which ultimately prevents people from being properly diagnosed.⁸² Sadly, with the high costs of diagnostic testing, access to

⁷⁴ Andrews, *supra* note 63, at 89.

⁷⁵ *Id.*

⁷⁶ *Id.* at 91.

⁷⁷ Brendan L. Smith, *Wrangling Genes: As the Law Changes and New Medical Frontiers Open, the Dispute over Genetic Patents Intensifies*, 95 A.B.A. J. 56, 57 (2009).

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* The lawsuit is currently pending as of the date of this publication.

⁸¹ Andrews, *supra* note 63, at 89.

⁸² *Id.*

health care is effectively limited to only those individuals who can afford the tests. As a result, gene patenting discriminates against the poor and widens the disparity between the classes in our society.

However, biotechnology giants argue that gene patents are necessary when considering the vast amount of resources invested for research and development.⁸³ According to the biotechnology industry, gene patents promote efficiency by providing greater numbers of safer, cheaper, and more effective drugs reaching the public.⁸⁴ Additionally, those in the biotechnology industry suggest that gene patents provide a method of “test[ing] drugs for toxicity and effectiveness against known classes of genes, thereby eliminating many costly drug failures late in . . . development.”⁸⁵ The contention posited is that without patent protection, competitors would be free to develop products without incurring the high costs of the requisite research, resulting in an extremely high profit margin for the competitor at the expense of the corporation researching the product.⁸⁶ Large corporations are driven by the ability to turn a profit and without patent protection, many fear the incentive to engage in such research and development would be lost.⁸⁷ Although gene patents provide the necessary incentive for companies to make substantial financial contributions to genetic research, the resulting inability for members of society to access the innovative procedures must not be overlooked.

Further, it is argued that patent protection “promotes efficiency, reducing duplicative research and wasteful funding” that would not otherwise occur within the context of independent research.⁸⁸ Accordingly, patenting allows for added research and more rapid implementation since the information is disseminated into the public domain.⁸⁹ Alternatively, it is possible that some genetic research will be unprofitable—and ultimately abandoned—resulting in the loss of

⁸³ Hill, *supra* note 47, at 236-37.

⁸⁴ See *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Prop. of the H. Comm. on the Judiciary*, 106th Cong. 53 (2000) (statement of Dr. Randall W. Scott, President & Chief Scientific Officer, Incyte Genomics).

⁸⁵ Hill, *supra* note 47, at 240.

⁸⁶ Allen C. Nunnally, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 324 (2002).

⁸⁷ *Id.* at 323.

⁸⁸ Macklin, *supra* note 5, at 135.

⁸⁹ *Id.*

benefits to those affected by the disease.⁹⁰ Upon realizing the research has not turned a profit, many companies “quash entirely” the test related to the condition, leaving those afflicted with the rare diseases searching for alternatives.⁹¹ Although patents might provide research incentives and promote efficiency, many scientists are prevented from further developing the patented genetic information, which results in delays of possible future innovations in health care.

Finally, patient autonomy and confidentiality must be considered in the context of gene patenting. Due to the ability to patent genetic material, physicians and researchers realize that patients are potential “treasure troves” for researching “lucrative genes.”⁹² Physicians and genetic researchers rely on patients and their families to supply tissue, blood, and bone marrow samples in search of genes.⁹³ Patients chance genetic harvesting without first consenting to the procedure or to the research; there is no federal law mandating patient consent to genetic testing.⁹⁴ There are, however, state based initiatives mandating patient consent to genetic harvesting, such as Section 79-1 (2)(a) of the New York State Civil Rights Law, which provides that “no person shall perform a genetic test on a biological sample taken from an individual without the prior written informed consent of such individual.”⁹⁵ Without federal regulation requiring mandatory patient consent to testing, patients’ autonomy and genetic integrity may be harmed, their bodies exploited, and their genetic information could become a commodity used by doctors for their own pecuniary and professional gain.⁹⁶ Consequently, such individuals who inadvertently donate genetic material reap no benefit from the subsequent patent. Nevertheless, courts are hesitant to place limitations on genetic patents for fear that progressive research will be

⁹⁰ *Id.*

⁹¹ Andrews, *supra* note 63, at 91.

⁹² *Id.* at 92.

⁹³ *Id.* at 97.

⁹⁴ See, e.g., Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990). Plaintiff brought an action alleging conversion and breach of physician's disclosure obligations against physician, university researcher, university regents, and licensees of rights to patented cell line from plaintiff's T-lymphocytes and its products after the plaintiff underwent treatment for hairy-cell leukemia. *Id.* at 480-81. The court found that the plaintiff had no property rights to the cells used, but the researcher did have an obligation to reveal his financial interest in the harvested genetic material. *Id.* at 485-86, 488-89.

⁹⁵ N.Y. CIV. RIGHTS LAW § 79-1 (McKinney 2009).

⁹⁶ See Andrews, *supra* note 63, at 93.

stalled.

Accordingly, the American Medical Association (“AMA”) has taken a stance on human genetic material patents. The AMA calls for “ ‘equitable access to licenses . . . of gene patents for diagnostic genetic tests to any Clinical Laboratory Improvement Act [(“CLIA”)]—certified laboratory at a reasonable royalty, . . . development of special guidelines for . . . promoting research and other benefits,’ and careful monitoring of the ‘impact of gene patenting and licensing agreements on access to relevant medical care.’ ”⁹⁷ Physicians and medical organizations are entrusted with the duty to prevent the infliction of harm on patients. Many in the medical community are concerned that patents on genetic material will prevent patients’ access to healthcare and detrimentally affect patient health. The AMA’s Code of Ethics also mandates that patients give consent before doctors commercialize products developed from their genetic material.⁹⁸ Overall, the medical community appreciates the need for genetic research—to achieve improved medical treatments and technologies—but strongly believes patent protection should not hinder this ultimate goal nor impair patient autonomy.⁹⁹ The medical community continues to struggle with balancing the need for patent protection to encourage the necessary research for advancements in medical technology, while maintaining patient integrity. In one respect, the medical community understands and appreciates the necessity of genetic research for future medical breakthroughs, but at the same time, doctors realize the potentially negative impact on patients and the possibility of patient exploitation.¹⁰⁰

Under the theory of beneficence, advocates of human genetic material patenting indicate that the future of medicine is contingent on genetic discoveries and invention.¹⁰¹ Not only would innovative testing and medication be possible, but also personalized medications

⁹⁷ Nunnally, *supra* note 86, at 325 (quoting Report 9 of the Council on Scientific Affairs, Am. Med. Ass’n, Patenting of Genes and Their Mutations (2000), <http://www.ama-assn.org/ama/no-index/about-ama/13570.shtml>).

⁹⁸ Council on Ethical & Judicial Affairs, Frank A. Riddick, Jr., Am. Med. Ass’n, The Use of DNA Databanks in Genomic Research: The Imperative of Informed Consent (2000), <http://www.ama-assn.org/ama1/pub/upload/mm/code-medical-ethics/2079a.pdf>.

⁹⁹ Nunnally, *supra* note 86, at 325.

¹⁰⁰ *Id.*

¹⁰¹ See Smith, *supra* note 77, at 58.

tailored to each individual could potentially become a reality.¹⁰² Personalized medications are possible by using specific “information about a patient’s . . . makeup to tailor individualized medical care.”¹⁰³ Since future discovery and advancements in medicine and healthcare are so closely related to genetic discovery, it is possible that stringent limitations on gene patents will stifle progress.

Although there are strong arguments in support of and in opposition to patenting human genetic material, it is unlikely that any opposition will be successful enough to completely eliminate gene patenting. This position garners more support in Europe, where there is a heightened value placed on the ideal of morality.¹⁰⁴ There are numerous ethical concerns regarding the issue of patenting human genetic information, which fuel passionate debate throughout the biotechnology community. Although scientists’ motivation in seeking patent protection for their inventions holds some merit, the resulting patent must not jeopardize human dignity and integrity.

IV. INTERNATIONAL PATENT LAW COMPARISON

Internationally, as in the United States, patenting human genomic material is subject to academic and professional debate, but the ethical objections to human gene patents are more vigorous in Europe.¹⁰⁵ Accordingly, European countries share the belief that moral and ethical principles must not be compromised by an individual’s, or a corporation’s, desire to turn a profit on inventions.¹⁰⁶ Unlike the United States Patent Act, the European Patent Convention of 1973 (“EPC”), article 53(a) “expressly mandates that morality be considered when determining patent eligibility.”¹⁰⁷ The EPC states that:

European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality, provided that the exploitation shall not be deemed to be

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Gitter, *supra* note 61, at 1654.

¹⁰⁵ *See id.*

¹⁰⁶ *Id.*

¹⁰⁷ Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising From Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247, 256 (2000).

so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.¹⁰⁸

Similarly, the Trade-Related Intellectual Property Rights (“TRIPS”) agreement of the World Trade Organization, promulgated in 1995, and the Biotechnology Directive of 1998 augment the EPC.¹⁰⁹ However, the Biotechnology Directive “provide[s] a supplemental framework [extending] beyond the EPC.”¹¹⁰ The TRIPS Agreement merely “mandates that all countries adher[ing] to [the] requirements provide patent protection”; however, the countries may choose “to exclude [certain] subject matter[s] on the basis of [EPC] article 53(a)-type concerns.”¹¹¹

The Biotechnology Directive is based on EPC article 53(a), but further develops the concepts by establishing specific categories of inventions that contravene morality and the “ordre public.”¹¹² The Directive specifically states that the following four categories are in violation of the EPC and thus 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; [and] (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.¹¹³

The preamble indicates that this list is not exhaustive, but merely an illustration of what is to be considered a violation of morality and “ordre public.”¹¹⁴ Subdivision 38 of the Directive’s preamble states:

Whereas the operative part of this Directive should al-

¹⁰⁸ European Patent Convention, Art. 53(a) (1973), available at <http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ar53.html>.

¹⁰⁹ See Ho, *supra* note 107, at 274.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Council Directive 98/44 on Legal Protection of Biotechnological Inventions, 1998 O.J. (36), available at <http://eur-lex.europa.eu/lexuriserv/lexuriserv.do?uri=OJ:L:1998:213:0013:0021:EN:PDF>.

¹¹³ *Id.* art. 6(2).

¹¹⁴ *Id.* pmbl. (38).

so include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to *ordre public* and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability.¹¹⁵

However, a potential problem arises by creating such categorical exceptions. Each of the above categories is considered unpatentable regardless of whether they continue to violate morality or not.¹¹⁶ Fluctuations in societal perspectives of morality will require the proposal of a subsequent Directive, which could take years to enact. Ultimately, such exclusions could potentially frustrate discovery in biotechnology since certain subject areas have conclusively been deemed unpatentable. This Directive has yet to be employed; therefore, the implications of the language have yet to be seen. Comparison of United States patent law with analogous European directives results in European countries manifesting far more concern with ethical implications. However, even with these morality provisions, European biotechnology companies are in direct competition with United States biotechnology advancements and therefore are likely to follow precedent set by the United States patent law trends, meaning patents for genetic sequences will be granted regardless of the ethical exclusions.

Specific categorical exclusions based on morality such as those discussed earlier would likely beget similar issues in the United States. Enacting a similar framework of patentability including a morality provision could potentially prove detrimental since new legislation would need to be proposed and enacted to reflect the public's change in perspective regarding ethical issues.¹¹⁷ Moreover, patent examiners would be entrusted with deciding what is ethical or moral and what is not.¹¹⁸

¹¹⁵ *Id.*

¹¹⁶ Ho, *supra* note 107, at 281.

¹¹⁷ *Id.* at 282-83.

¹¹⁸ *See id.* at 283.

Unfortunately, the current framework of the United States patent system is not conducive to the integration of a morality component since United States patent law focuses primarily on the objective scientific nature of the invention.¹¹⁹ Patent examiners are employed to objectively review the facts as indicated in the application—not assess what is ethically right and wrong.¹²⁰ Although the addition of a morality component would attempt to create global uniformity in gene patenting, the results of subjective opinion most likely would be highly controversial. It is difficult to believe that patent examiners would be capable of making an objective determination free from their own ethical inclinations.

Perhaps the greatest apprehension regarding genetic patenting lies in the populations of underdeveloped countries.¹²¹ Generally, developed countries advocate on behalf of patenting since individual rights are highly valued. In contrast, underdeveloped countries are hesitant to patent genetic material to the exclusion of all others since they place great emphasis on the notion of community and believe information such as this should be available in the public domain.¹²² Further, it became apparent that developed countries were harvesting the genetic material of underdeveloped, remote populations after discovering immunities to many diseases afflicting others around the world.¹²³ Underdeveloped countries are even more concerned than developed countries about the possibility of exploiting individuals and believe patenting human genetic material is unnecessarily interfering with nature.¹²⁴

With the advent of the International Human Genome Project in 1990, countries around the world aspired to identify all the “20,000–25,000 human genes and make them accessible for further biological study.”¹²⁵ The Human Genome Project was originally established to promote international collaboration, thereby promoting

¹¹⁹ *Id.* at 280.

¹²⁰ *Id.*

¹²¹ See Sturges, *supra* note 11, at 244.

¹²² *Id.*

¹²³ *Id.* at 245.

¹²⁴ See *id.* (noting that “Third World empathizers claim that these actions are evidence of ‘genetic colonialism’ ”).

¹²⁵ *History of the Human Genome Project*, HUMAN GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/project/hgp.shtml (last visited Mar. 9, 2011).

discovery of what is considered commonly human.¹²⁶ “Although the Human Genome Project is an international effort” composed of twenty-six countries including France, the United Kingdom, Japan and Germany, the United States has contributed substantially more than the rest of the member countries.¹²⁷ The United States Department of Energy Human Genome Program and the National Institutes of Health sponsor the United States Human Genome project collaboratively.¹²⁸ Scientists originally believed that the Human Genome Project would provide a method of discovering and treating genetic disorders.¹²⁹ However, it was soon realized that with the potential advancements in medical technology, came significant ethical concerns.¹³⁰ The two departments reported devoting approximately three to five percent of their annual budgets toward the Ethical, Legal, and Social Implications (“ELSI”) program to study the many ethical issues surrounding availability of genetic information.¹³¹ The ELSI program of the Human Genome Project studies not only issues directly affecting the project, but also issues affecting individuals.¹³² Based on the findings, the ELSI program suggests policies that ensure discoveries made by the project are used for the benefit of society.¹³³

The international community has continuously stressed the importance of dissemination of inventive information and collaborative research as opposed to secretive withholding.¹³⁴ As compared to the United States, European Union nations as well as other countries appear to appreciate the importance of collaborative thinking for the future of genetic research.¹³⁵ Additionally, countries around the globe value the importance of human sanctity and are concerned that patenting genetic sequences could lead to the exploitation of both developed and underdeveloped populations.

¹²⁶ Sturges, *supra* note 11, at 235.

¹²⁷ *Id.* at 229-31.

¹²⁸ *Id.* at 230.

¹²⁹ *Id.* at 224.

¹³⁰ *See id.* at 230.

¹³¹ *Ethical, Legal and Social Issues*, HUMAN GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml (last visited Mar. 17, 2011).

¹³² Sturges, *supra* note 11, at 230.

¹³³ *Id.*

¹³⁴ *Id.* at 231-32.

¹³⁵ *Id.* at 230-32.

V. GENE PATENTING REFORM AND POLICY ALTERNATIVES

Although the Patent and Trademark Office Guidelines imposed a heightened standard for the utility requirement, there is still need for further reform. As indicated previously, patent law is subject to three governing bodies in the United States: the Patent and Trademark Office, the Federal Circuit, and Congress.¹³⁶ Since the Patent and Trademark Office is under significant pressure to approve gene patents and the Federal Circuit is unable to implement any change without the filing of costly lawsuits, it appears the most efficient vehicle for change is legislation enacted by Congress.¹³⁷ It is unlikely that any substantial changes will be proposed and enacted in the U.S. because of the insurmountable pressure placed on the Patent and Trademark Office to adopt a liberal perspective regarding gene patents in an effort to attract domestic and foreign investment in biotechnology.¹³⁸

One possible solution is Congressional enactment of compulsory-licensing legislation.¹³⁹ Under compulsory licensing, the government would require the owner of gene sequence patents to license the sequence to physicians and scientists pursuing research related to the sequence for a reasonable royalty fee to be paid to the patent holder.¹⁴⁰ In order for this fee to be fairly assessed, it would be determined by the commercial value of the product developed resulting from the research, as opposed to a fee established by the patent holder.¹⁴¹ Although it is possible that such licensing could come about absent government involvement, it is unlikely that patent holders would voluntarily license their invention for a nominal fee. There are various reasons scientists and researchers would not want to license their inventions: they want to create extensive patent portfolios or patent collections to remain competitive in the scientific community; monetary incentives; to prevent other researchers and scientists from inventing around the patent; and to gain acknowledgement in their respective field.¹⁴² Accordingly, Congressional initiative is necessary

¹³⁶ Andrews, *supra* note 63, at 96.

¹³⁷ *See id.*

¹³⁸ *See id.*

¹³⁹ Gitter, *supra* note 61, at 1679.

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *See id.* at 1681.

to facilitate this proposed solution.

A second potential solution is “Congressional [c]odification of an [e]xperimental-use [e]xemption for [n]oncommercial research . . . on gene sequences.”¹⁴³ Although an experimental use exception currently exists, the exception is limited to research strictly for philosophical inquiry, curiosity or amusement with no commercial use.¹⁴⁴ Legislation regarding the experimental-use exemption could expand the limitations to include public sector and nonprofit researchers.¹⁴⁵ This option would allow researchers “to pursue research on patented [genetic material] for noncommercial purposes” free of any licensing fee, and alleviate fear of liability in an infringement action.¹⁴⁶ Inventors could potentially transform their understanding of a sequence through subsequent research that would not be possible under the current patent system.¹⁴⁷ Under the current patent system, the patent holder retains exclusive rights to use and manipulate the newly invented genetic sequence; both rights prevent other researchers and scientists from augmenting the material and making further discoveries.¹⁴⁸ An experimental-use exemption would provide a method for researchers to continue the valuable research necessary for future medical advancements, absent the fear of legal action being commenced against them.

Statutory codification of an experimental-use exemption has already been realized in the TRIPS Agreement; specifically, TRIPS Article 30 provides that “[m]embers may provide limited exceptions to the exclusive rights conferred by [] patent[s as long as it does] . . . not unreasonably conflict with” the interest of the patent holder.¹⁴⁹

¹⁴³ *Id.* at 1684.

¹⁴⁴ Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1018-19 (1989).

¹⁴⁵ Gitter, *supra* note 61, at 1684.

¹⁴⁶ *Id.* at 1684-85. See also 35 U.S.C.A. § 271. Patent infringement is the unauthorized “mak[ing], us[ing], offer[ing for] s[ale] or sell[ing] any patented invention, within the United States or United States Territories or import[ing] into the United States [of] any patented invention during the term of the patent.” *Id.* § 271(a). A patent holder may bring a patent infringement action in the Federal Circuit against the party, which commercially manufactures, imports, uses, sells, or offers for sale patented technology during the term of the patent resulting in the payment of damages if found liable. *Id.* § 271(e)(4)(c).

¹⁴⁷ See Gitter, *supra* note 61, at 1684-85.

¹⁴⁸ See Eisenberg, *supra* note 144, at 1021.

¹⁴⁹ THE AMERICAN SOCIETY OF INTERNATIONAL LAW, *General Agreement on Tariffs and Trade-Multilateral Trade Negotiations: Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, in INTERNATIONAL LEGAL

The meaning of the provision is unclear, but based on comparative law and legislative history it is likely that this article is intended to allow exceptions for private, noncommercial purposes, research, experimentation for testing or improvement, and educational purposes.¹⁵⁰ An experimental-use exception mirroring TRIPS Article 30 would enable researchers in the United States to continue developing newly patented information without fear of legal action being taken against them.

Another possible solution to the current gene patent controversy is “patent pools.” In December 2000, the Patent and Trademark Office published an article suggesting patent pools as the answer to the looming problem of access to biotechnology patents. The article notes: “[N]o single company or organization . . . has the resources to develop . . . the genetic information If proprietary information is not freely available or licensed in an affordable manner, researchers will be precluded from using these protected [gene sequences] to develop new therapeutics and diagnostics.”¹⁵¹ A “patent pool” may be defined as either an agreement between two or more patent owners to license one or more of their patents to each other or a third party, or “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool.”¹⁵² Patent pools provide the means necessary to disseminate information quickly to facilitate further research while eliminating licensing costs.¹⁵³ They also provide an incentive to large biotechnology corporations by affording a type of financial insurance in that they can increase the likelihood that the company will recover the research and development costs.¹⁵⁴

MATERIALS 95 (1994).

¹⁵⁰ CARLOS M. CORREA, PATENT RIGHTS, INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 189, 208 (2008).

¹⁵¹ JEANNE CLARK ET AL., U.S. PATENT & TRADEMARK OFFICE, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? 3 (2000), *available at* <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>.

¹⁵² Joel I. Klein, Acting Assistant Attorney Gen., Antitrust Div., U.S. Dep’t of Justice, Cross-Licensing and Antitrust Law, Address Before the American Intellectual Property Law Association, n.3 (May 2, 1997), *available at* <http://www.justice.gov/atr/public/speeches/1118.htm>.

¹⁵³ CLARK et al., *supra* note 151, at 8.

¹⁵⁴ Steven C. Carlson, Note, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. on REG.

Additionally, modifications to patent requirements may be necessary due to the special nature of genetic material. Currently, as long as the genetic sequence is considered non-natural living material and meets the novel, useful, and non-obvious criterion, the patent will be approved. The abundance of genetic patents will require lawmakers to reconsider the process by which patents for living material are granted. Although adding a morality provision, like the European Union, might create more problems than solutions, alternate requirements should be imposed in terms of genetic material. European Union nations have a very different perspective on issues of morality and ethics in terms of patents on genetic material.¹⁵⁵ Frameworks have been implemented with provisions specifically addressing the issue of morality and subject matter patentability. The effect of such provisions are yet unclear; however, due to the nature of genetic material, United States patent law may need to implement specific requirements for patents relating to biotechnology and genetic sequences.

More importantly, genetic patenting requires the harvesting of human genetic material, which is, in effect, human experimentation. Researchers and scientists should be mandated to comply with the regulatory and ethical guidelines governing such experimentation in order to maintain patient autonomy and protection. According to the National Institutes of Health, there are various guidelines in place to protect the autonomy of individuals participating in human experimentation. These guidelines include: Title 45 of the Code of Federal Regulations governing the protection of human subjects; The Belmont Report promulgating the Ethical Principles and Guidelines for the Protection of Human Subjects of Research; the Nuremberg Code providing Directives for Human Experimentation; the World Medical Association Declaration of Helsinki; and the National Institutes of Health's own Guidelines for the Conduct of Research Involving Human Subjects.¹⁵⁶ Each provides specific guidelines, which must be respected when conducting experiments on human subjects. Obtaining the genetic material required for researching and developing the sequences should be considered within the purview of human expe-

359, 381-82 (1999).

¹⁵⁵ Gitter, *supra* note 61, at 1658.

¹⁵⁶ See *Regulations and Ethical Guidelines*, OFF. HUMAN SUBJECTS RES., <http://ohsr.od.nih.gov/guidelines/index.html> (last visited Mar. 8, 2011).

rimentation; therefore, these guidelines—or others specifically tailored to genetic material harvesting—must be employed to maintain patient autonomy, dignity, and protection.

VI. CONCLUSION

The continuous debate on the ethical issues of gene patenting, and the subsequent effect on the future of health care, reveals the need for change. Although inventors are entitled to patent protection, genetic sequencing information must be made available to researchers and scientists in order to ensure further advancement in healthcare and medicine. Research in this field is imperative to foster beneficial medical discoveries and advancements in disease prevention and treatment, but such advancements must not come at the cost of jeopardizing human integrity and dignity.

Significantly, the international perspective regarding patents on human genetic material deviates drastically from that of the United States. Various European directives have squarely addressed the question of morality and ethics. Although the impact of legislative effects remains to be determined, the mere existence of morality provisions indicates European commitment to considering the ethical implications of genetic patents. Additionally, countries throughout the world seem to appreciate and understand the need for international collaboration when dealing with human genetic material. The international community recognizes that the future success of researchers and scientists depends on the ability to access newly patented genetic information. United States patent law should follow the precedent set by the international community and encourage scientific collaboration for the greater good of society.

Under the current framework of United States patent law, any subject matter is patentable if the subject of the invention is not naturally occurring in nature and meets the statutory requirements. Generally, genetic sequences that have been manipulated in such a way to be considered non-natural with a known function are considered patentable. However, the patent system focuses on the objective scientific nature of inventions without ever considering whether the patent implicates any ethical or moral issues. Although adding a statutory morality requirement, as written in the EPC or Biotechnology Directive, is unlikely based on the current trends in genetic patents, modifications to the current system are necessary for biotechnology pa-

tents since the subject matter is specific to humans.

Even if statutory reforms to patent law requirements are not implemented, Congressionally enacted compulsory-licensing and experimental-use exemption legislation could provide a means for sharing patented innovative discoveries in the scientific community, while providing patent protection to inventors. Patent pools are also a viable option for disseminating newly patented genetic sequence information without incurring costly licensing fees. Lastly, since genetic patenting requires the harvesting of human genetic material, guidelines regulating human experimentation, or others specifically tailored to genetic patenting, should be applied to ensure patient autonomy and protection.

Critical analysis of the current ethical issues involved in patenting genetic material evidences that modifications to the current patent laws are required to ensure that human integrity and the interests of biotechnology researchers are both protected. Although none of these issues are easily resolved, a balance must be sought in order to foster new inventive thought for the benefit of society, while remaining cognizant of the resulting implications on human beings.