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WHO DEFINES “HEALTHY”? ETHICAL DILEMMAS ACROSS COMPETING INTEREST GROUPS ON GENETIC MANIPULATION AND GENE PATENTS

*Haley Guion**

I. INTRODUCTION

Genetic manipulation has led to significant advancements in the field of medicine and continues to hold a great deal of potential. The term “genome” refers to the total array of genes in a particular individual. The human genome contains approximately 25,000 genes within its 3,000,000,000 base pairs of DNA, which form the 46 chromosomes found in a human cell.¹ Genomic medicine is an emerging area of medicine that involves the use of genomic information about an individual as a part of their clinical care.² Scientists employ gene therapy techniques to treat diseases in an individual patient by administering genetic material (DNA) rather than a drug.³ This kind of genetic manipulation is developing at a remarkable pace, due largely to the efforts of the Human Genome Project. The Human Genome Project, formed in October 1990,⁴ is proof that the use of genetic manipulation to develop medicine is growing. The Human Genome Project sets out to sequence the human genome and “map” all of the human genes to the twenty-three pairs of chromosomes that exist in each cell, excluding sperm and egg cells.⁵ The organizations responsible for the efforts and administration of the Human Genome Project’s activities in the U.S. include the National Human Genome Research Institute of the National Institute of Health and the United States Department of En-

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¹ Genome Definition, MERRIAM-WEBSTER DICTIONARY (2014), available at <http://www.merriam-webster.com/dictionary/genome>.

² NHGRI Definition of “Genomic Medicine,” National Human Genome Research Institute (2012) at http://www.genome.gov/pages/About/NACHGR/Sept2012AgendaDocuments/Genomic_Medicine_Definition_080112_RChisolm.pdf.

³ Nathan A. Adams, IV, *Creating Clones, Kids & Chimera: Liberal Democratic Compromise at the Crossroads*, 17 NOTRE DAME J.L. ETHICS & PUB POL’Y 71, 71 (2003).

⁴ About NHGRI: A Brief History and Timeline (2014), available at <http://www.genome.gov/10001763#1988>.

⁵ CARL H. COLEMAN, ET. AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS, 697 (2005).

ergy. In addition, the Human Genome Project has also benefited from research conducted in Britain, France, Germany, Japan, China, and Canada.⁶ It has nine research branches,⁷ each comprised of investigators who study the functions within the human genome. For example, the Cancer Genetics and Comparative Genomics Branch seeks to identify genes that contribute to cancer susceptibility and progression.⁸ By 2020, it has been predicted that the Human Genome Project will release new gene-based “designer drugs” for diabetes, hypertension, and mental illness into the market.⁹ The manipulation of the human genome for the purpose of developing medicine to treat disease holds a great deal of promise for adults and children living with certain illnesses. As these efforts advance, there is a growing need for a regulatory regime over genetic manipulation that acknowledges its ties to ethical issues.

With the potential that gene therapy research and development holds in the field of medicine comes significant ethical dilemmas about the definition of “illness.” An illness to one person may be, to another, the cause of an engaging personality trait or rare talent; the qualities of a healthy baby to one parent could be the same qualities that trigger another mother’s decision to receive an abortion. According to Merriam-Webster, illness is “a condition of being unhealthy in your body or mind” and “a specific condition that prevents your body or mind from working normally; sickness or disease.”¹⁰ How unhealthy do these “conditions” have to be to warrant a cure? What does it mean to have a body or mind that is not working “normally”? To compare, Merriam-Webster defines healthy as “enjoying health and vigor of body, mind, or spirit.”¹¹ Again, one individual’s source of enjoyment could be the same source of another’s pain.

In order to consider the ethical dilemmas that arise from genetic manipulation, one must understand the groups who are interested in its regulation. To begin, Part II identifies the varying opinions of government agencies, states, the Supreme Court, patent attorneys, bioethicists and scholars about its regulation. Part III then outlines concerns about how the role of genetic manipulation could change the nature and norms of prenatal

⁶ National Human Genome Research Institute, at <http://www.genome.gov/25019925>.

⁷ NHGRI Research Branches (2014), available at <http://www.genome.gov/10000010>.

⁸ NHGRI Cancer Genetics and Comparative Genomics Branch, National Human Genome Research Institute (2014), available at <http://www.genome.gov/10000012>.

⁹ Francis S. Collins, Victor A. McKusick, & Krin Jeganian, *Implications of the Genome Project for Medical Science*, JAMA (Feb. 7 2001), available at <http://jama.jamanetwork.com/article.aspx?articleid=193524>.

¹⁰ Illness Definition, MERRIAM-WEBSTER DICTIONARY (2014), available at <http://www.merriam-webster.com/dictionary/illness>.

¹¹ Healthy Definition, MERRIAM-WEBSTER DICTIONARY (2014), available at <http://www.merriam-webster.com/dictionary/healthy>.

testing and mental illness. It describes the Supreme Court’s recent decision regarding the patent eligibility of non-naturally occurring material in *Association of Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013), also referred to as “Myriad V”. Part IV introduces two different societies and how each could regulate genetic manipulation and suggests a regime rooted in a traditional society. Lastly, Part V predicts the ethical dilemmas that will arise with respect to genetic manipulation in mental illness and prenatal diagnosis and calls for attention to how to resolve these dilemmas.

II. GENETIC MANIPULATION AND GENE PATENTS

A. Interest Groups

The viewpoints on the regulation of genetic manipulation and the patent eligibility of human genetic processes fall on a spectrum. In *Myriad V*, the Court ruled that subject matter that is itself an abstract idea, natural phenomenon or law of nature is not patent eligible.¹² Thus, at present, the law forbids patenting a human genetic process that is naturally occurring. In this case, *Myriad*’s patents on *BRCA1* and *BRCA2*, genetic processes associated with detecting breast cancer and colon cancer¹³ were invalid as “products of nature.”¹⁴ The Court denied *Myriad*’s request for patents on the processes involving these genes, holding that the genetic material is patent ineligible because it is naturally occurring.¹⁵ The invention at issue in *Myriad V* is an isolated gene. *Myriad Genetics, Inc.* and, in part, the University of Utah Research Foundation, patented the genetic processes, and the primary issue in the case was whether or not the processes are patent eligible, given that they use a naturally occurring segment of DNA. In *Myriad V*, the U.S. Supreme Court granted *Association for Molecular Pathology*’s petition for *certiorari* exclusively on the question, “Are human genes patentable?”¹⁶ In a 9-0 decision, the Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, and, conversely, that cDNA is patent eligible because it is not naturally occurring.¹⁷ Justice Thomas writ-

¹² *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

¹³ *Id.* at 2109

¹⁴ *Id.*

¹⁵ *Id.* at 2111

¹⁶ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 133 S. Ct. 2107 (U.S. 2012) (*Myriad V*).

¹⁷ *Supra* note 12 at 2120.

ing for the majority explained that “genes and the information they encode are not patent eligible under §101 of the U.S. Patent Act simply because they have been isolated from surrounding genetic material.”¹⁸ The Court labeled the notion that Myriad did not “create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes” an “undisputed fact.”¹⁹ Justice Thomas reasoned:

“The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.”²⁰

Medical researchers believe the decision to make naturally occurring genes patent ineligible will inhibit medical research.²¹ Dr. Michael Crichton disagrees. In the introduction to his 2006 novel *Next*, he writes, “Stop patenting genes.”²² Patent lawyers argue that the Court has gotten “off track” in its patent eligibility jurisprudence; that the naturally occurring exception is “inconsistent with both the statute and constitutional plan for the U.S. patent system.”²³ From the perspective of patent law attorneys, Myriad V marked “yet another [instance] in a series of recent decisions by the Supreme Court that identifies the dividing line between patent-eligible and patent ineligible subject matter.”²⁴ The decision places subject matter that is fundamental to scientific and technological work outside the domain of patent protection.²⁵

Others believe the Court’s approach to genetic patents places an unnecessary limit to genetic research and does not contribute meaningfully

¹⁸ *Supra* note 12 at 2120.

¹⁹ *Id.* at 2116.

²⁰ *Id.*

²¹ See Robert D. Truog, *Will ethical requirements bring critical care research to a halt?* 31 INTENSIVE CARE MED. 338, Issue 3 (March 2005), who believes that if current trends continue, within several years it could become nearly impossible to conduct research in critical care medicine. See generally Robert Cook-Deegan, “Gene Patents,” in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley 69-72 (2008).

²² MICHAEL CRICHTON, *NEXT*, (Harper Collins 2006). See also, Michael Crichton, *Patenting Life*, N.Y. TIMES, February 13, 2007, available at http://www.nytimes.com/2007/02/13/opinion/13crichton.html?_r=0

²³ Garth Janke, *An Appeal to Reason Post-Myriad and Mayo – to Follow the Statute and the Constitutional Plan for the U.S. Patent System When Deciding Questions of Patent Eligibility*, available at <http://about.bloomberglaw.com/practitioner-contributions/an-appeal-to-reason-post-myriad-and-mayo-to-follow-the-statute-and-the-constitutional-plan-for-the-u-s-patent-system-when-deciding-questions-of-patent-eligibility/>

²⁴ Charles R. Macedo, David Goldberg, *U.S. Supreme Court Addresses Patent Eligibility of Isolated DNA and cDNA in Myriad V*, Journal of Intellectual Property Law & Practice, available at <http://www.arelaw.com/publications/view/092913myriadv/>

²⁵ *Id.*

to the protection of human subjects.²⁶ It is unlikely the result of *Myriad V* will delay discovery of genetic techniques that could save lives from terminal illness, such as cancer. The barrier of patent ineligibility to certain genetic manipulation techniques will have little effect on the *discovery* of treatment processes that could cure cancer. In February 2014, the National Institutes of Health announced its progress in the Cancer Genome Atlas, which was implemented in 2005 to “speed up the identification of cancer genes.”²⁷ As the tests and treatments expand the options for treatment of particular illnesses, the patent system will make them increasingly commercialized.

Proof that patent protection maximizes the quantity of favorable products is an empirical question that is very difficult to test.²⁸ It has been put forth that the claim of commercial rights to a gene therapy technique is not the only driving force behind genetic research.

Justice Kennedy explained the Court’s role in addressing this dilemma of placing limits on genetic research for the sake of protection at the expense of medical advancements. He stated, “I’m sure that there are substantial arguments in the amicus brief that this investment [in BRCA1 and BRCA2 patents] is necessary and that makes sense. But I certainly don’t think we can decide the case on that ground.”²⁹ The Court recognized in its decision that “. . . patent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘impeding the flow of information that might . . . spur invention.’”³⁰ Simply put, the opinion reads, “. . . *Myriad* did not create anything. . . it found an important and useful gene, but separating that gene from surrounding genetic material is not an act of invention.”³¹ Failure to create this carve out in the patent system for naturally-occurring material would, in fact, be “at odds with the very point of patents, which exist to

²⁶ David Ozonoff, *Just When You Thought It Was Safe, An Update on the Risks of Recombinant DNA Technology*, 472; See also, Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 547 arguing for the “well-accepted principle” that the principle goal of the American patent system is to stimulate innovation (Feb. 2009).

²⁷ Carl Zimmer, *A Catalog of Cancer Genes That’s Done, or Just A Start*, N.Y. TIMES, (Feb. 6, 2014), available at http://www.nytimes.com/2014/02/07/science/a-catalog-of-cancer-genes-thats-done-or-just-a-start.html?hpw&rrref=science&_r=0.

²⁸ See M.A. Heller & R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, (1998); See also R.S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1031 (1993).

²⁹ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) oral argument ¶15, available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-398-amc7.pdf

³⁰ *Myriad*, 133 S. Ct. at 2116 quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012).

³¹ *Id.* at 2117

promote creation.”³² Justice Scalia did point out that the Supreme Court might not be suited to rule on legal issues about patent eligibility of human genetic material, concurring in part on the basis that he could not affirm his knowledge of the fine details of molecular biology.³³

Some have faith that, although the potential for abuse exists, the value of future medical advancements from genetic manipulation outweighs any risks of abuse. “Genomic medicine holds the ultimate promise of revolutionizing the diagnosis and treatment of many illnesses. Potential misuses of genetic information . . . will need to be dealt with swiftly and effectively.”³⁴ The Executive Branch also carries the same faith. An Executive Order issued on March 9, 2009, by President Barack Obama served to “remove [prior Presidential actions that limited] scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America’s scientists to important new discoveries and new therapies for the benefit of humankind.”³⁵

State statutes on genetic manipulation fall all over the spectrum. Massachusetts’ law prohibits its residents from creating an embryo with the sole intent of donating the embryo for research.³⁶ By contrast, California law gives authority to an advisory committee, comprised of nine members, including at least one representative from the areas of medicine, religion, biotechnology, genetics, law, and from the general public, as well as at least three independent bioethicists that reflect a representative range of religious and ethical perspectives in California regarding the issues of human biotechnology.³⁷ This committee advises the Legislature and the Governor on issues relating to human biotechnology.³⁸

Regulations by federal agencies fall in an area on the spectrum that appreciates a balancing test, but these agencies likely seek policies that give its interests the most weight. A 2003 report by the Federal Trade Commission recommended a proper balance be struck between competition, law, and policy in the patent system. “Competition and patents stand out among the federal policies that influence innovation. Both competition and patent policy can foster innovation, but each requires a proper balance

³² 133 S. Ct. at 2116.

³³ *Id.* at 2120

³⁴ *Supra* note 9.

³⁵ Executive Order 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells* (Mar. 9, 2009), available at http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/.

³⁶ 105 CMR 960.005.

³⁷ Cal. Health & Saf. Code § 24186(a)(1)-(3).

³⁸ Cal. Health & Saf. Code § 24186(a)(1).

with the other to do so.”³⁹ The FTC looks to policies through the lens of how they affect innovation. By comparison, the Food and Drug Administration’s Center for Biologics Evaluation and Research (“CBR”) regulates human gene therapy products and uses the Public Health Service Act and the Federal Food Drug and Cosmetic Act as enabling statutes for oversight.⁴⁰ The role of this agency is to oversee clinical studies to ensure compliance with these Acts and give scientific and regulatory advice to medical researchers and manufacturers in the area of novel product development,⁴¹ a role quite different from that of the FTC. A final example is the Recombinant DNA Advisory Committee of the National Institutes of Health, a panel of up to twenty-one national experts representing various fields of science, medicine, genetics, ethics, and patient perspectives that considers the current state of knowledge and technology regarding gene therapy research.⁴² Again, the role of this federal agency is quite distinct from the other two. The decision-making process of this agency relies on a unique set of expert opinions with diverse viewpoints.

It is evident that opinions differ on how to strike a balance between creation and regulation with respect to human genetic manipulation. Going forward, this divide raises concerns about the ethical treatment of certain illnesses.

III. CONCERNS ABOUT GENETIC MANIPULATION

Because of the differing opinions on how genetic manipulation should function in society, the moral compass that guides decisions by interest groups on ethical issues in this area is inconsistent, if not entirely absent. When the definition of “illness” diverges among these groups, individuals with a certain genetic makeup are vulnerable. Individuals who are particularly vulnerable are those involved in prenatal testing and those who have mental illness. Because of this current lack of ethical consideration for these individuals, certain manipulation and prenatal testing of chromosomal disorders and hereditary diseases should be limited and excluded from the patent system.

³⁹ FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, (2003), available at <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf>.

⁴⁰ *Cellular & Gene Therapy Products* (2013), available at <http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/default.htm>.

⁴¹ *Id.*

⁴² National Institutes of Health, Office of Biotechnology Activities, *Frequently Asked Questions about the NIH Review Process for Human Gene Transfer Trials* (Apr. 2013), available at http://osp.od.nih.gov/sites/default/files/NIH_Review_Process_HGT.pdf.

A. Prenatal Testing and Mental Illness

Today, genetic testing is available for more than 2,000 rare and common conditions in over 500 laboratories.⁴³ The tests include: diagnostic testing, a process used to identify a genetic condition that is making or in the future will make a person ill; predictive and pre-symptomatic genetic testing, which find genetic variations that increase a person's chances of developing specific diseases; pharmogenetic testing, which reveals information about how certain medicines are processed in a person's body . . . and prenatal testing, a test available during pregnancy to identify certain diseases in fetuses.⁴⁴ These genetic tests involve gene therapy, which is the replacement of a defective or malfunctioning gene.⁴⁵

Physicians perform genetic testing of a fetus, also known as prenatal testing, through amniocentesis. The test involves the withdrawal of a small amount of amniotic fluid that surrounds the fetus from the uterus.⁴⁶ The fetal cells are then examined for any hereditary diseases, including Tay-Sachs disease, spina bifida, and Down syndrome.⁴⁷ The process is capable of detecting chromosomal disorders.⁴⁸ The rates of discovery are high. In a 1992 study, among the 760 women and adolescents who chose amniocentesis, 20 cases of fetal Down's syndrome were detected, along with 7 other chromosomal disorders.⁴⁹ Before 1984, prenatal screening for Down's syndrome was restricted to solely asking a pregnant woman her age.⁵⁰ She could have the procedure if she was 35 years or older.⁵¹ The rationale behind this limit was based upon a "well-documented trend of an increasing risk of Down's syndrome in fetuses as maternal age increased."⁵² Then, the accessibility to the screening expanded to include women under 35 when medical trials and subsequent reports discovered a new technique that could improve the detection rate of Down's syndrome in fetuses in women younger than 35.⁵³

⁴³ National Institute of Health, *Genetic Testing: How it is Used for Health Care*, at <http://www.report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=43&key=G>.

⁴⁴ *Id.*

⁴⁵ BONNIE F. FREMGEN, PH.D., *MEDICAL LAW & ETHICS*, 173 (2002).

⁴⁶ *Id.* at 204.

⁴⁷ *Id.*

⁴⁸ James E. Haddow et al., *Prenatal Screening for Down's Syndrome With Use of Maternal Serum Markers*, 327 N. ENG. J. MED. 588 (Aug. 27 1992).

⁴⁹ *Id.* at 590.

⁵⁰ *Id.* at 588.

⁵¹ *Id.*

⁵² *Id.* citing E.B. hook, *Down's syndrome: frequency in human population and factors pertinent to variation in rates*.

⁵³ *Id.* The technique in the reports refers to maternal serum alpha-fetoprotein concentrated at midtrimester.

The concern here is the treatment of those fetuses whose genetic makeup includes one or more of chromosomal disorders. A newly discovered chromosomal disorder is not, to some, a disorder in the non-scientific sense of the word. As gene transfer techniques develop, and should regulations on it fail to materialize, researchers will detect more of these "chromosomal disorders," disorders that may be, to some, better left undiscoverable. To make available to pregnant mothers the ability to learn of a fetus' predisposition for a disorder or hereditary disease opens the door to the robbing of society's complexity. Those who suffer from certain mental illness offer value to society that, if eliminated from prenatal testing, would be devastating.

Mental illness permeates the minds of individuals around the world. In the United States, research shows that approximately one in four adults—61.5 million Americans—experiences mental illness in a given year.⁵⁴ One in seventeen—13.6 million—lives with a serious mental illness, such as schizophrenia, major depression, or bipolar disorder.⁵⁵ It has been estimated that one in seven Americans will experience a major depressive episode in their lifetime.⁵⁶ With the sheer volume of humans affected by mental illness, any medical treatment of it must be handled with care.

In 2010, a medical journal published a report that stated researchers at New York-Presbyterian Hospital were able to reverse depression-like behavior in mice with therapy techniques using human and animal genes. That the therapy technique used human genes means that the application of this gene therapy to reversing depression-like symptoms could be successful in humans.⁵⁷ Research genetic testing helps scientists learn about how genes contribute to health and disease and develop gene-based treatments in response to these findings.⁵⁸ Such testing gives rise to the possibility of what Kay Jamison, Professor of Psychiatry at Johns Hopkins Medical School, who also serves on the National Advisory committee for Human Genome Research, predicted in 1993.⁵⁹ After conducting numerous studies on the connection between creativity and the artistic tempera-

⁵⁴ National Alliance on Mental Illness. *Mental Illness Facts and Numbers* (Mar. 2013), available at http://www.nami.org/factsheets/mentalillness_factsheet.pdf

⁵⁵ *Id.*

⁵⁶ National Healthcare Disparities Report, 2010, Chapter 2: Effectiveness of Mental Health and Substance Abuse, available at <http://www.ahrq.gov/research/findings/nhqdr/nhdr10/Chap2b.html>

⁵⁷ Brian Alexander, et. al., *Reversal of Depressed Behaviors by p11 Gene Therapy in the Nucleus Accumbens*, 2 *Sci. Transl. Med.* 54; see also <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3026098/>

⁵⁸ *Supra* note 29.

⁵⁹ Kay Redfield Jamison, *Touched With Fire: Manic Depression Illness and the Artistic Temperament*, 253 (Free Press 1993). She predicted that prenatal testing for manic-depressive illness and abortion based on a determination that a fetus is at risk for the disease may be available before the end of the century.

ment in writers, artists, and poets,⁶⁰ Jamison concludes that while the decision to abort a fetus with manic-depressive illness a “particularly problematic” decision, she underscores that the disease is treatable, fairly common and the symptoms of the disease vary in severity.⁶¹ Leon R. Kass, M.D., Ph.D, has expressed arguments against abortions on the basis of prenatal test results and is also worth noting. The following excerpt illustrates the difficulty of the debate:

I have failed to provide myself with a satisfactory intellectual and moral justification for the practice of genetic abortion . . . Perhaps the pragmatists can persuade me that we should abandon the search for principled justification, that if we just trust people’s situational decisions or their gut reactions, everything will turn out fine. Maybe they are right. But we should not forget the sage observation of Bertrand Russell: ‘Pragmatism is like a warm bath that heats up so imperceptibly that you don’t know when to scream.’ Before we submerge ourselves irrevocably in amniotic fluid, we should note its connection to our own baths, into which we have started the hot water running.⁶²

B.cDNA Patents

Another issue that accompanies the concern of the availability of prenatal genetic testing is the patent eligibility of such prenatal tests and genetic techniques, specifically in the form of cDNA patents. In 1985, legal scholar John Robertson stated, “Gene manipulation is potentially a very potent and very precise tool. We need to proceed with deliberate care, as we largely have proceeded, until we have a clearer sense of its dangers and benefits.”⁶³ His prediction that gene manipulation could be a “precise tool” has been realized, as private firms and universities continue to strive to obtain rights to human genetic processes in order to patent medical advancements. A 2013 study shows that more than 4,000 genes, 20% of human genes, have been patented in the United States.⁶⁴

⁶⁰ See generally Kay Redfield Jamison, *Touched With Fire: Manic Depression Illness and the Artistic Temperament*, Chapter 3: Could It Be Madness—This?, (Free Press 1993)

⁶¹ *Supra* note 57.

⁶² L.R. Kass, *Toward a More Natural Science: Biology and Human Affairs*, 98 (New York Free Press, 1988).

⁶³ John A. Robertson, *Genetic Alteration of Embryos: The Ethical Issues*, in GENETICS AND THE LAW III 115, 125 (Aubrey Milunsky & George J. Annas eds., 1985).

⁶⁴ Stefan Lovgren, *One-Fifth of Human Genes Have Been Patented, Study Reveals*, NATIONAL GEOGRAPHIC NEWS (Oct. 13, 2005), at http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html.

In order to patent a human gene, researchers are subject to 35 U.S.C. §101. "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."⁶⁵ A patent gives the patent holder the right to exclude others from making, using, selling, or importing an invention for a period of time, usually twenty years.⁶⁶ On June 14, 2014, the Supreme Court clarified how this statute relates to the patent eligibility of human genes and genetic processes.

In *Myriad V*, the Court, in addition to its ruling that naturally-occurring genes are patent ineligible, it also ruled that complementary DNA, or cDNA, from the human genome is patent eligible because such genetic material is not naturally occurring.⁶⁷ The blanket approval of all non-naturally occurring genetic material as patent eligible is worrisome. The Court has approved of the patent eligibility of these processes, and their commercialization, without knowing what they are, what they do, what they eliminate, what they produce, and how they affect the health of humankind. In his noteworthy observation of the function of the legal system, professor and philosopher Terrance McConnell argues that, "in our society, if behavior is not legally prohibited, then presumably people will not be forcibly prevented from engaging in such conduct. To that limited extent, legally permitted behavior has society's stamp of approval."⁶⁸ The Court has given a blind stamp of approval.

Researchers in *Myriad V* modified the genetic makeup of people by replacing a mutated gene that causes disease with a healthy copy of the gene, inactivating an improperly functioning mutated gene, or introducing a new gene into the body to help fight the disease.⁶⁹ The goal of gene transfer research is to cure the disease by modifying the genetic information of the person's cells.⁷⁰ The Court in *Myriad V* reasoned, "the lab technician unquestionably creates something new when cDNA is made" because, "it is distinct from the DNA from which it was derived" and, "is

⁶⁵ 35 U.S.C. §101 (2012).

⁶⁶ Robert Cook-Deegan, *Gene Patents*, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS at 69 (Mary Crowley ed., 2008). [available at http://www.w.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf](http://www.w.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf).

⁶⁷ *Supra* note 12 at 2109.

⁶⁸ TERRANCE MCCONNELL, *INALIENABLE RIGHTS: THE LIMITS OF CONSENT IN MEDICINE AND THE LAW*, 83 (Oxford University Press 2000).

⁶⁹ *Gene Therapy Handbook*, Genetics Home Reference, [at http://ghr.nlm.nih.gov/handbook/therapy?show=all](http://ghr.nlm.nih.gov/handbook/therapy?show=all).

⁷⁰ *Id.*

not a product of nature.”⁷¹ With respect to cDNA patents, the concern is how one decides the incentives that will guide interest groups during the course of their manipulation over non-naturally occurring DNA. What will be the ethical check on commercializing genetic material, despite the fact that it has been isolated? Health law professionals, medical providers, and genetic researchers must carefully consider these issues, challenge each other and answer them, keeping in mind the unique value of every human life.

IV. A CALL FOR A REGULATORY REGIME ROOTED IN A TRADITIONAL SOCIETY MODEL

The desire for immediate results from genetic manipulation has begun to corrode ethical considerations. The Court’s decision in *Myriad V* has provided a long overdue pause in the realm of human genetic manipulation and given all interest groups reason to address its ethical concerns. Moving forward, technology as powerful as genetic manipulation should be regulated with a regime that encourages caution among researchers, promotes active involvement from bioethicists, respects the human genome and acknowledges the potential for irreparable harm to human kind.

Philosopher Stephen Toulmin distinguishes between two kinds of societies, which can serve as a framework for how one may decide to regulate genetic manipulation. When one considers the hopes and expectations around which people have structured their lives in different cultures and societies and at different stages in history, Toulmin argues it is possible to recognize a spectrum of inherited forms of life and standard operating procedures. The societies range from attitudes prevalent in highly traditional societies at one extreme and so deliberately modernizing ones at the other.⁷²

In traditional societies, life is structured around *idées reçues*, or “the conventional wisdom.”⁷³ For those living in these societies, what *ought* to be done about any problem is equated with what *is* done. The traditional society functions based on fixed techniques and procedures.⁷⁴ By contrast, in modernizing societies, people continually ask how the same needs

⁷¹ *Gene Therapy Handbook*, *supra*.

⁷² Stephen Toulmin, *Technological Progress and Social Policy: The Broader Significance of Medical Mishaps*, in Mark Siegler et al., eds., *Medical Innovation and Bad Outcomes: Legal, Social, and Ethical Responses* (Ann Arbor: Health Administration Press, 1987), 24.

⁷³ *Id.*

⁷⁴ *Id.*

might be met "more efficaciously, economically, and elegantly."⁷⁵ The modernizing society is subject to continual refinement.⁷⁶

Based on the history of American medicine, Toulmin argues that current medical practices in the United States is expected to align more closely with the progressive than to the traditional ideal.⁷⁷ The public expects physicians to continually refine and improve their techniques and researchers to develop new and more effective medical treatments. The possibility of "a revolutionary new treatment" is never far from the minds of patients and doctors.⁷⁸ In modernized societies, medical experimentation is accepted as an indispensable activity and provides the best way of improving current techniques in medicine.⁷⁹ Moreover, once experimentation has demonstrated effective and reasonably safe new procedures in any field, there is public support for putting those procedures to general use.⁸⁰ Here, one may ask, "Does society want drugs that are the result of experimentation on the human genome to yield 'reasonably safe' procedures?" Surely not. Society expects a far higher standard. The disparity between the moral compasses of a traditional and a modern society illustrates how the different goals of interest groups would result in widely different regulatory regimes.

Moving forward, genetic manipulation should be regulated under a traditional society model. Interest groups tied to the manipulation and research of human genes should resist Toulmin's theory that the United States is expected to align with a modernizing society. The future of genetic technologies, by their very nature, will challenge the human complexity inherent in a unique and well-balanced society. Regulations that emulate the goals of a traditional society will prevent what Toulmin refers to as "the unavoidable price to be paid for maintaining the socially desired momentum of medical advance."⁸¹

A brief look at how other countries regulate genetic manipulation and gene patents indicates a lean towards a traditional society model. In both Japan and New Zealand, the most acceptable type of genetic manipulation is of plants and the least acceptable is in humans.⁸² New Zealand

⁷⁵ Stephen Toulmin, *supra*.

⁷⁶ *Id.*

⁷⁷ *Supra* note 72.

⁷⁸ *Id.* at 25.

⁷⁹ *Id.*

⁸⁰ *Id.* at 29.

⁸¹ *Id.* at 34.

⁸² Darryl R. J. Macer, *Biotechnology and Bioethics: What is Ethical Biology?* 12 MODERN BIOTECHNOLOGY: LEGAL, ECONOMIC AND SOCIAL DIMENSIONS, 115, TABLE 2: Reasons given for Unac-

recently proposed a bill entitled “GE Free New Zealand,”⁸³ which pushes against patenting the human genome. A German study of university students and professors asked the subjects the major reasons cited for the unacceptability of genetic manipulation. The study placed the reasons in the following five categories: (1) Unnatural, playing God, unethical, feeling; (2) disaster, fear of unknown, ecological and environmental effects; (3) human misuse, insufficient controls, eugenics, cloning, humanity changed; (4) health effects, mutations; (5) not stated.⁸⁴ Interestingly, although 42% of the public considers gene therapy morally wrong, Section 101 of the U.S. Patent Act does not include an ethical limitation on human gene therapy.⁸⁵

V. LAW VERSUS ETHICS AND THE FUTURE OF GENETIC MANIPULATION

Biotechnology raises moral questions that are not “simply difficult in the familiar sense, but are of an altogether different kind.”⁸⁶ Spokespeople for the Human Genome Project have acknowledged the public’s ethical concerns about genetic manipulation. “With every new genetic breakthrough comes great apprehension that the information contained in the human genome and deciphered...will be used for ill. The anticipated problems are legion and include the fear of genetic discrimination. While the phrase ‘genetic discrimination’ has become ubiquitous in both popular and academic presses, the exact definition of the term, and the nature of the anticipated problem, remain unclear.”⁸⁷ Medical researchers, lawmakers, and others, must work together to establish a common impetus, drawn from an ethical theory, on genetic manipulation and use it as a moral compass when ethical dilemmas arise.

Here are two ethical theories that may offer guidance to the interest groups on ways to think about genetic manipulation. Utilitarianism, the most prominent consequence-based theory, accepts one and only one

ceptability of Genetic Manipulation (Weinheim, Germany, 1995) available at <http://www.eubios.info/Papers/VCH.htm> (last accessed February 28, 2014).

⁸³ GE-Free New Zealand, available at <http://www.gefree.org.nz/> (last accessed February 28, 2014).

⁸⁴ Macer, *supra* note 84, at 13.

⁸⁵ *Id.* at 21.

⁸⁶ Donald P. O’Mathúna, *Bioethics and biotechnology*, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2267612/>

⁸⁷ Jennifer Geetter, *Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System*, AM. J. L. & MED., (March 22, 2002) at <http://business.highbeam.com/42/article-1G1-86064879/coding-change-power-human-genome-transform-american>

basic principle of ethics: the principle of utility.⁸⁸ This principle asserts what we ought always to produce the maximal balance of positive value over disvalue (or the least possible disvalue, if only undesirable results can be achieved).⁸⁹ Rule utilitarians believe that an act's conformity to a justified rule (that is, a rule justified by utility) makes the act and that rule is not expendable.⁹⁰ By contrast, act utilitarians argue that observance of a rule (such as truth-telling) does not always maximize the general good.⁹¹ In the context of genetic manipulation, utilitarians would favor a regulatory regime rooted in a traditional society model if the regime maximizes utility. Utility could be a variety of things in this context. It may be the utility brought from the prohibition of a gene therapy drug that, if made available to the public, could wipe out healthy fetuses with treatable illnesses or no "illness" at all. The traditional society model maximizes utility by protecting against the elimination of valuable members of society. The utility maximized by this regulatory regime over genetic manipulation may also be the safeguards it develops against the potential for a eugenic society. Philosophers, doctors, and medical ethicists argue that without drawing the line on the scope of research and manipulation of genetic material, society could be deprived of its diversity.⁹² The fear is "those who have power often are so imbued with their own freedom that they disremember those who are disadvantaged."⁹³ Society that is all the same is certainly not a desirable society.

A second ethical theory is Kantianism, an obligation-based theory.⁹⁴ A Kantian maintains that the moral worth of an individual's action depends on the rule that determines the individual's will, where the rule is understood as a morally valid reason that justifies the action.⁹⁵ A morally valid reason for the rule that genetic manipulation to cure illness is not acceptable in a traditional society could be that society expects human makeup never be capitalized upon or exploited, but rather be respected for its capability to form human life.

⁸⁸ Tom L. Beauchamp & James F. Childress, *PRINCIPLES OF BIOMEDICAL ETHICS* 341 (5th ed. 2001).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² See generally W. French Anderson, M.D., *Human Gene Therapy: Why Draw A Line?* 14 *J. MED. & PHILOSOPHY* 681 (1989); Sarah Chan & John Harris, *The Ethics of Gene Therapy*, 8 *MOLECULAR THERAPEUTICS* 377, 5th Ed. (2006); Claire Deakin, et al. *The Ethics of Gene Therapy: Balancing the Risks*, 12 *MOLECULAR THERAPEUTICS* 578, 5th ed. (2010); Sarah Goering, *Gene Therapies and the Pursuit of a Better Human*, 9 *CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS* 330, 3d Ed. (2000).

⁹³ James E. Bowman, *The Road to Eugenics*, 3 *U. CHI. L. SCH. ROUNDTABLE* 491, 494 (1996).

⁹⁴ *Id.* at 350

⁹⁵ *Id.*

The risk to the individuals involved in prenatal diagnosis and affected by mental illness is becoming victims of a rapid succession of advancements in medicine, at the expense of ethical treatment to these individuals. The components that distinguish a human being as an artist, a writer, a composer, a musician, a director, or a world leader, lay embedded in their DNA. Marc Lappe illustrates the effect that an already existing gene therapy technique could have on society. He writes:

“A case in point could be the recently uncovered loci that seem to flag the presence of genes that predispose carriers to manic depressive illness. Should we use the knowledge of the likely presence of such “deviant” genes to abort affected fetuses? Such a program could conceivably reduce the genetic burden brought about by the presence of these genes in the human population, but it would also potentially deprive us of great poets like Sylvia Plath or politicians like Winston Churchill, each of whom suffered from bipolar manic depression.”⁹⁶

Myriad V keeps the powerful technology of genetic manipulation and subsequent patents on these techniques in check, for now. Yet, scholars believe that in evaluating policy decisions concerning the human DNA, “. . . the well-focused and clearly articulated financial interests of the biotechnology industry will overcome the diffuse and difficult-to-articulate social and moral interests of the world’s majority,” a theory known as the public choice justification.⁹⁷

Seymour Lederberg, Ph. D, reminds researchers and physicians that “the purpose in treating genetic handicaps should be to reduce illness and harm to the individual.”⁹⁸ This is a utilitarian approach, the utility being the maximization of health. If interest groups can agree on what is “healthy,” then these groups can begin to resolve ethical dilemmas on how to define chromosomal disorders in the context of human health and whether or not genetic manipulation should come into play.

VI. CONCLUSION

No single solution can resolve the ethical dilemmas that will arise from the manipulation of the human genome. However, society needs a

⁹⁶ Marc Lappe, *The Limits of Genetic Inquiry*, 17 Hastings Center Report 5 (1987).

⁹⁷ Pilar N. Ossorio, *The Human Genome As Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425, 427 (2007).

⁹⁸ Seymour Lederberg, Ph. D, *Governmental Responsibilities and Genetic Disease*, in GENETICS AND THE LAW III 425, 429 (Aubry Milunski et al. 2012).

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moral compass to guide interest groups on how to handle the human genome. Competing interest groups must come to an agreement on driving force behind genetic manipulation and gene therapy techniques. Pair this with a regulatory regime rooted in traditional societal ideals and a solution becomes clearer. Is the goal of genetic manipulation to eliminate a certain illness? What kind of illness? How does one characterize this illness as “unhealthy”? One must ask the same question when it comes to the goal of gene patents. Does a company seek to patent a gene in order to stimulate innovation? Gain recognition? Catalyze the development of a healthy society? Jones Day, the law firm that represented Myriad Genetics, released a statement saying it was pleased with Myriad V because it reinforces the notion that “intellectual property rights and patents drive innovation.”⁹⁹ Is this true? Certainly patent law firms do not always consider the ethical dilemmas about genetic patents, but society may want to begin to expect this of them in the future. Interest groups can only begin to resolve the challenge of ethical dilemmas once they recognize that society characterizes certain illnesses in different ways. In light of the Myriad V decision, health law professionals, medical researchers, and state legislators will be forced to ask questions about the ethics, regulation, and responsible manipulation of the human genome. With so many interest groups seeking to get their hands on a specific piece of genetic manipulation, it is nearly impossible to centralize its regulation in a common ideal. Now is the time to address and answer the following question: How does society want to define “healthy” in the context of genetic manipulation? Interest groups must keep in mind how far they are willing to go for research and where they are willing to place limits on their powers. Laws are not always moral, nor do they include ethical considerations. In the future, the law and ethics related to genetic manipulation and the patent eligibility of certain genetic processes will undoubtedly collide. Failure to recognize this imminent issue on genetic manipulation could allow for irreversible harm. Moving forward, interests groups should remember the famous words of Confucius: “Too many hands in the cookie jar only leads to crumbs for none.”

⁹⁹ Murray Griffin, *Australian Court Holds Gene Patent Valid, Rejects U.S. Supreme Court Myriad Ruling*, Bloomberg News BioTech Watch (Sept. 8, 2014) at http://news.bna.com.ezproxy.depaul.edu/bwdm/BWDMWB/split_display.adp?fedfid=55877365&vname=btballissues&jd=a0f5r0q8x7&split=0