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ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS, INC. AND ITS IMPACT ON THE PATENTABILTY OF "DESIGNER" GENES

AMANDA H. RUSSO*

With the rapid advances in biotechnology and the widespread availability and popularity of assisted reproductive technologies, biologists may soon have the ability to manipulate human gametes and embryos in order to create children with certain desirable characteristics. Despite the fact that this scientific idea is closer to becoming a reality, the question remains whether such techniques or the altered genetic material itself are eligible for patents. After the Supreme Court's decision in Association for Molecular Pathology v. Myriad Genetics, Inc., — US. —, 133 S. Ct. 2107 (2013), the court held that isolated DNA was not the proper subject matter for patent under 35 U.S.C. § 101, while holding a patent on synthetic DNA, or "cDNA." This article argues for a narrow reading of the holding in Myriad Genetics regarding cDNA, which would limit its application to the medical uses and gene therapy.

* J.D. Candidate, New York University School of Law, 2015; B.A. and B.S., *cum laude*, University of Florida, 2012. The author wishes to express her sincerest appreciation to the editorial board and members of the NYU Journal of Intellectual Property & Entertainment Law for their dedication and hard work throughout the editorial process.

INTRODUCTION

Would you like blue eyes with that? In the near future, prospective parents might be able to select their children's genetic features from a drop-down menu.[1] With a heightened societal focus on perfection, it is not absurd to think parents would want to create the ideal child, nor to think it would be impossible. Advances in the biotechnology industry have increased scientists' understanding of the human genome and enhanced their ability to genetically modify eggs, sperm, and human embryos. These developments have the potential to make "designer" babies a very stark reality.

The Supreme Court's decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*[2] could be interpreted as paving the way for patenting

[1] *See, e.g.*, Dov Fox, *23andme's Designer Baby Patent*, HUFFINGTON POST (Oct. 4, 2013), http://www.huffingtonpost.com/dov-fox/23andmes-designer-baby-pa_b_4042165.html.

[2] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., — U.S. —, 133 S. Ct. 2107, 2118–19 (2013) [hereinafter *Myriad Genetics*].

genetically altered genome or gamete cells. Every gene in the human body is encoded as deoxyribonucleic acid ("DNA"), and *Myriad Genetics* confronted the issue of whether a naturally occurring segment of DNA was eligible for patent.[3] The Court held that, while isolated, naturally occurring DNA was outside the realm of patent, complimentary DNA ("cDNA"), or a synthesized DNA copy, was patent-eligible.[4] However, the Court specifically concluded its opinion by noting that the "scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of [patent eligibility] to such endeavors."[5]

If biotech scientists have the ability to manipulate the genes of an embryo or gamete cell for non-therapeutic purposes, it could be argued that these genetically modified cells are in fact patentable "inventions," given that the material was not, in that particular sequence, naturally occurring. The country has already seen movement in this area. In September 2013, the United States Patent and Trademark Office awarded a patent to 23andMe for its gamete donor selection techniques, including genetic and computer technologies.[6] These technologies allow prospective parents to select a gamete donor who would increase the likelihood that a child would be born with or without certain hereditary characteristics. With the technology, parents can choose from a variety of traits which go beyond medical conditions, enabling them to specify certain physical and psychological characteristics. It is true that the company was not attempting to patent actual sperm or egg cells, but merely facilitate a "preview" of unborn children. Most of the current technologies that closely resemble actual genetic selection focus on testing the embryo or fetus to screen for several undesirable physiological genetic characteristics. For example, pre-implantation genetic diagnosis ("PGD") has grown to be a common service at fertility clinics, allowing couples undergoing *in vitro* fertilization to test multiple embryos for genetic disorders before deciding which one to implant.[7]

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[3] *Id.* at 2111.

[4] *Id.*

[5] *Id.* at 2119–20.

[6] Fox, *supra* note 1; Terry Baynes, *Genetic-Testing Patent Raises Concerns About 'Designer Babies'*, COUNCIL FOR RESPONSIBLE GENETICS (Oct. 9, 2013), http://www.councilforresponsiblegenetics.org/blog/post/Genetic-testing-patent-raises-concerns-about-e28098designer-babiese28099.aspx.

[7] *Id.*

Recognizing this trend, Congress passed section 33 of the America Invents Act ("AIA")[8] in 2011, resulting in, among other things, a prohibition on patents for inventions "directed to or encompassing a human organisms."[9] Unfortunately, the AIA never expressly defines any of the terms in this provision, so it is not entirely clear what specific subject matter would fall under the prohibition. Moreover, in *Myriad Genetics*, the Supreme Court found that an identical provision was inapplicable in a discussion on real and synthetic human genes, noting that the "Act does not even mention genes, much less isolated DNA."[10] While one can consequently interpret *Myriad* in a way that limits the scope of the Act, it leaves open the question of the patentability of modified human gametes and embryos and the altered or synthetic gene sequencing which could potentially be encompassed within those gametes and embryos.

Patentability of inventions is governed by 35 U.S.C. § 101, which has several requirements. First, it must be of patentable subject matter — "process, machine, manufacture, or composition of matter . . . or improvement thereof."[11] Second, it must be "new" or "novel."[12] And, third, it must be "useful."[13] While no express clause excludes inventions that contravene morality from patent-eligibility, courts historically imposed a "socially beneficial" standard under the third prong of utility; in effect, this standard served as a morality condition rendering inventions with a use deemed "injurious to the well-being, good policy, or good morals of society"[14] ineligible for patent protection. Now, though, the PTO and federal courts rarely enforce this morality standard.[15] In fact, in the context of genetic material, the PTO expressly rejected the morality-based argument that "patents

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[8] Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (codified as amended in scattered sections of Title 35 of the U.S. Code).

[9] *Id.* § 33(a), 125 Stat. at 340.

[10] *Myriad Genetics*, 133 S. Ct. at 2118–19. Prior to the America Invents Act, Congress had banned the patenting of human embryos and organisms through annual budget appropriation acts since 2004. The Court was addressing the language found in Consolidated Appropriations Act of 2004, which is nearly identical to that in the America Invents Act. *See* Consolidated Appropriations Act of 2004, Pub. L. No. 108–199, § 634, 118 Stat. 101 (codified as amended in scattered sections of Title 35 of the U.S. Code) ("None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism.")

[11] 35 U.S.C. § 101 (2012).

[12] *Id.*

[13] *Id.*

[14] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568).

[15] Laura A. Keay, *Morality's Move Within U.S. Patent Law: From Moral Utility to Subject Matter*, 40 AIPLA Q.J. 409, 429 (2012).

should not issue for [human] genes [simply] because the sequence of the human genome is at the core of what it means to be human."[16] In *Myriad Genetics*, the Supreme Court did not even consider morality-based arguments.[17] But despite the move away from a requirement of socially beneficial utility, courts have generally been reluctant to step on the toes of legislatures when they have specifically excluded a subject matter from the realm of patentability for ethical or moral concerns.[18]

With the diminished strength of the morality safeguard and huge advance in the biotech industry, *Myriad Genetics* could arguably be read in support of patents on manipulated or synthetic genes or genome sequences for use in human embryos and gametes. This Note will argue that *Myriad Genetics* should not be interpreted in such a way. Instead, *Myriad Genetics* should be read narrowly, limiting patent-eligibility of cDNA to only its uses in medical research and testing and gene therapy. Part I will explore the history of genetically altered human genes and feasibility of manipulating human embryos within the biotech industry. Part II will analyze the *Myriad Genetics* decision and its current impact on the patent-eligibility of biotech "inventions." Part III will examine court precedent within the area of gene patenting and will argue for narrow application of *Myriad Genetics* to genetically altered human gametes and embryos, specifically in light of Section 33(a) of the AIA.

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[16] Dep't of Comm., U.S. Pat. & Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093–94 (Jan. 5, 2001), *available at* http://www.uspto.gov/web/offices/com/sol/og/2001/week05/patutil.htm.

[17] Fox, *supra* note 1.

[18] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) ("[B]alancing of competing values and interests, which in our democratic system is the business of elected representatives … should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts."); Juicy Whip, Inc., v. Orange Bang, Inc., 185 F.3d 1364,1366-68 (Fed. Cir. 1999) (upholding patent on deceptive product, but noting that it would defer to Congress if it were to make the patenting of such devices illegal).

I
THE HISTORY OF ASSISTED REPRODUCTIVE TECHNOLOGIES

A. Understanding Genetics & the Future of Biotechnology

1. Basic Genetic Concepts

"We're on the cusp of having much more information, and the appearance of having much greater discretion, in choosing the traits of our children," said Thomas H. Murray, Senior Research Scholar and President Emeritus at The Hastings Center, a nonpartisan bioethics research institution.[19] Murray asked, "What use will they make of it, and should there be limits?"[20]

Before one can understand the implications of patenting genetically altered or synthetic gametes or embryos, it is useful to understand basic genetic concepts. The cells contained within an early embryo are of two types: germ cells and somatic cells.[21] The germ cells contain hereditary information and become the gametes (i.e. eggs and sperm) of a developing organism, which transmit such information.[22] Every other cell in the body is a somatic cell.[23] All of these cells contain genes, but only those in the germ cells are passed on to offspring.[24] Chromosomes are contained in the nucleus of all cells.[25] Each chromosome is made up of DNA molecules that are held together by chemically-joined nucleotides, creating a system of cross-bars[26] that support the DNA's double-helix structure.[27] The sequencing of these nucleotides within the DNA molecule creates

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[19] Tia Ghose, *Children to Order: The Ethics of "Designer Babies"*, LIVE SCIENCE (Mar. 13, 2014, 2:00 PM), http://www.livescience.com/44087-designer-babies-ethics.html.

[20] *Id.*

[21] *See* COUNCIL FOR RESPONSIBLE GENETICS, POSITION PAPER ON HUMAN GERMLINE MANIPULATION (updated Fall 2000), http://www.councilforresponsiblegenetics.org/Viewpage.aspx?pageid=101 [hereinafter POSITION PAPER].

[22] SUSANNAH BARUCH ET AL., GENETICS & PUB. POL'Y CTR, HUMAN GERMLINE GENETIC MODIFICATION: ISSUES AND OPTIONS FOR POLICYMAKERS 11 (2005), available at http://www.dnapolicy.org/images/reportpdfs/HumanGermlineGeneticMod.pdf.

[23] *Id.*

[24] POSITION PAPER, *supra* note 21.

[25] National Institutes of Health, *What is a Chromosome?*, GENETICS HOME REFERENCE (Nov. 24, 2013), http://ghr.nlm.nih.gov/handbook/basics/chromosome.

[26] *Myriad Genetics*, 133 S. Ct. at 2111.

[27] National Institutes of Health, *What is DNA?*, GENETICS HOME REFERENCE (Nov. 24, 2013), http://ghr.nlm.nih.gov/handbook/basics/dna.

the human genome[28], and determines the information available for building and maintaining an organism, serving a similar function to letters that are strung together to create words and sentences.[29] These sequences of nucleotides enable the creation of amino acids, which form the proteins in the body.[30] The nucleotides that code for amino acids are called "exons," and those that do not are called "introns."[31] For purposes of this article, it is also important to note that scientists can extract and isolate DNA molecules from cells in order to study specific sequences.[32] In addition, they can create composite DNA ("cDNA") from these molecules, which are exon-only strands of nucleotides.[33]

2. Current Reproductive Biotechnologies

A number of current reproductive technologies seem to be bringing the reality of designer children closer and closer. The successes and failures of these technologies undoubtedly provide biologists with a deeper understanding of human genetic makeup and the human body's interaction and response to scientifically manipulated genes. What follows is an introduction to some current biotechnologies that are undoubtedly accelerating scientists' ability to genetically enhance the children of tomorrow.

i. In Vitro Fertilization and Pre-Implantation Genetic Diagnosis

The increasing availability of *in vitro* fertilization unquestionably increases the potential for the specific selection of genetic characteristics to be passed on to offspring. *In vitro* fertilization ("IVF") is a method of producing an embryo *ex utero* — outside of the uterus — and the subsequent implantation of that embryo

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[28] The human genome consists of a complete collection of DNA. For more information, *see* Human Genome Project, *Human Genome: Introduction*, HUMANGENES.ORG (2014), http://humangenes.org/human-genome-introduction [hereinafter NIH, *What is DNA?*].

[29] *Id*.

[30] National Institutes of Health, *Intron Definition*, GENETICS HOME REFERENCE (Nov. 24, 2013), http://ghr.nlm.nih.gov/glossary=intron [hereinafter NIH, *Intron Definition*]; National Institutes of Health, *Exon Definition*, GENETICS HOME REFERENCE (Nov. 24, 2013), http://ghr.nlm.nih.gov/glossary=exon [hereinafter NIH, *Exon Definition*].

[31] NIH, *Intron Definition*, *supra* note 30; NIH, *Exon Definition*, *supra* note 30.

[32] *Myriad Genetics*, 133 S. Ct. at 2112.

[33] For more information on cDNA, *see* Human Genome Project, *cDNA (Complementary DNA)*, HUMANGENES.ORG (2014), http://humangenes.org/cdna-complementary-dna (last visited Dec. 1, 2014).

inside a woman's uterus.[34] At the beginning of this process, sperm and ovum are cultured and researchers calculate the optimal time for fertilization.[35] After an embryo is successfully created, the embryo is transferred into the uterus of the mother in hopes of implantation. Prior to this transfer, clinicians typically wait two to five days[36], during which time they evaluate the shape and appearance of the embryo.[37]

Another currently available technology, which complements IVF, is known as pre-implantation genetic diagnosis ("PGD").[38] This method allows scientists to test an embryo prior to implantation, in order to determine whether it carries a particular genetic disease[39], similar to a process known as gene therapy[40]. The embryos that are determined to be disease-free are those that are then implanted in the mother.[41] According to the Wall Street Journal, some United States clinics have even been using PGD to allow customers to choose the gender of their child.[42] The same method could be used with relative ease to select particular physical traits of unborn children like eye or hair color.[43] Other characteristics like intelligence or athleticism would be harder to select for using PGD, given that they are made up of several genetic factors, but seemingly not impossible[44]

Advocates claim that the use of PGD to screen embryos has the potential to eliminate complete lines of hereditary diseases, even those that have run in families

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[34] PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 26, 30 (Mar. 2004), *available at* http://hdl.handle.net/10822/559381 [hereinafter REPRODUCTION AND RESPONSIBILITY].

[35] *Id.* at 26.

[36] Some clinicians wait until five days after fertilization (also known as the blastocyst stage) in order to maximize the probability of implantation. *Id.* at 30.

[37] *Id.*

[38] Gautam Naik, *'Designer Babies:' Patented Process Could Lead to Selection of Genes for Specific Traits*, WALL STREET J. (Oct. 3, 2013), http://online.wsj.com/articles/SB10001424052702303492504579113293429460678.

[39] *Id.*

[40] Gene therapy is a process discussed infra that is primarily focused on curing or reducing human diseases and conditions. See Kathi E. Hanna, Genetic Enhancement, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (last reviewed April 2006), http://www.genome.gov/10004767.

[41] Naik, supra note 38.

[42] *Id.*

[43] *Id.*

[44] *Id.*

for generations.[45] While proponents reject the idea that PGD will lead to the possibility of designer children[46], the ability to select for or against certain genetic conditions raises the question of why that same procedure could not also be used to select for physical or psychological characteristics.

ii. Cloning

The ability of scientists to genetically clone animals and humans is another technique that significantly adds to the possibility for designer babies. Cloning is a term that refers to a number of techniques that enable the production of genetically identical organisms, and comes in three types, gene cloning, reproductive cloning, and therapeutic cloning — all of which remain controversial.[47] Gene cloning involves the isolation and copying of genes from within an organism's cells, while therapeutic and reproductive cloning entails the creation of a cloned embryo, containing genes identical to the original organism, albeit for different purposes[48]. Scientists can now use such processes to successfully clone a variety of genes and organisms, including mammal embryos.[49] In one method of cloning, scientists can take and isolate a single gene and then create a complimentary sequence of DNA, or cDNA.[50] The cDNA can then be used for study or use in a pharmaceutical setting, or, alternatively, the cloned genes could be inserted into other organisms.[51] In utilizing each of these techniques, the existing genetic code of the clone cell or organism is effectively altered to contain a genetic sequence that was not naturally occurring. Thus, such methods could theoretically be used in the genetic enhancement of human embryos.

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[45] Designer Babies: Controversy Over Embryo Selection, TELEGRAPH (Jan. 9, 2009, 9:59 AM), http://www.telegraph.co.uk/health/healthnews/4206623/Designer-babies-Controversy-over-embryo-selection.html.

[46] Id.

[47] Natonal Institutes of Health, *Cloning*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (last reviewed April 28, 2014), http://www.genome.gov/25020028 (hereinafter NIH, Cloning).

[48] *Id.*

[49] NEIL A. CAMPBELL & JANE B. REECE, BIOLOGY 375 (6th ed. 2002). *See, e.g.*, I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810 (1997) (discussing the cloning of genes in sheep); REPRODUCTION AND RESPONSIBILITY, *supra* note 34, at 126 (discussing the successful cloning of human embryos for embryonic stem cell lines).

[50] CAMPBELL & REECE, *supra* note 49, at 380–81.

[51] *Id.* at 377. cDNA is distinct from isolated DNA segments, in that the introns, as discussed above, are completely removed from the cDNA sequence and are not naturally occurring. *Id.* at 380–81.

Several examples serve to demonstrate the success of advances in cloning technologies in recent years. For instance, through the use of cDNA, genes from foreign organisms can be inserted into the cells of other organisms, regardless of whether it is of the same or different species.[52] In fact, it has become quite common for biologists to genetically engineer non-human organisms, including mammals, by inserting and removing genes from their genomes to create an entirely novel organism.[53] Moreover, even as far back as a decade ago, scientists had cloned hybrid human-animal embryos through the fusion of human cells with enucleated eggs from rabbits and enucleated oocytes from cows, resulting in nonhuman organisms.[54] Most significantly, South Korean researchers claimed to be the first to verify the successful cloning of human embryos in 2004.[55] They claimed to have produced 30 cloned human embryos and continued to cultivate them to the blastocyst stage.[56] The experiment allegedly resulted in the growth of the embryos to an age in which researchers could derive a pluripotent[57] embryonic human stem cell line.[58] However, in January of 2006, Science Magazine retracted the study papers produced by the South Korean researchers, after an independent investigating committee found misconduct and data fabrication.[59] Nonetheless, these obvious scientific progress in the ability to genetically alter human embryos through cloning techniques make genetic enhancement of humans all the more likely.

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[52] *Id*. at 376.

[53] JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 262 (5th ed. 2004).

[54] REPRODUCTION AND RESPONSIBILITY, *supra* note 34, at 125 (citations omitted).

[55] Woo S. Hwang et al., *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Human Blastocyst*, SCIENCEXPRESS (Feb. 12, 2004), *available at* http://www.bedfordresearch.org/newsandlibrary/files/HuESSCNT.pdf.

[56] Reproduction and Responsibility, *supra* note 34, at 126.

[57] "Pluripotent" stem cells are those cells that have the ability to develop into nearly all cells in the body, and, so, when isolated from the embryo, these cells have the potential to produce almost all human cells. *See* Ian Murnaghan, *Pluripotent Stem Cells*, Explore Stem Cells (updated June 18, 2014), http://www.explorestemcells.co.uk/pluripotentstemcells.html.

[58] Reproduction and Responsibility, *supra* note 34, at 126 (citing Woo S. Hwang et al., *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Human Blastocyst*, Sciencexpress (Feb. 12, 2004), *available at* http://www.bedfordresearch.org /newsandlibrary/files/HuESSCNT.pdf).

[59] Donald Kennedy, Editorial Retraction, Science Mag. (Jan. 20, 2006), http://www.sciencemag.org/content/311/5759/335.2.short.

iii. Somatic and Germ-line Gene Modification

In addition to the abovementioned, biotechnological advances have made it possible to modify the chromosomes of both human and animal cells through the insertion of new DNA segments into the existing chromosome.[60] Such techniques are referred to as somatic or germ-line genetic modifications. If changes are performed on specialized or differentiated body tissue — cells like liver, muscle, or blood cells — it is referred to as somatic cell gene modification, which affects only the individual whose DNA is modified.[61] On the other hand, if the insertion is performed on eggs or sperm cells prior to fertilization or in an embryo in its early stages where its cells are undifferentiated, it is called germ-line genetic modification.[62] With germ-line modification, the effects of the altered genes go beyond the individual organism on which the insertion was originally performed.[63] Given that DNA is incorporated into the embryo's germ cells, those genes will be passed on to future generations.[64]

Scientists have performed genetic modification of both somatic and germ-line cells in animals in order to examine the resulting impact of this alteration. Somatic gene modifications have in fact been performed on humans dating back to 1990, which have targeted cells in attempts to correct an existing disease or condition in that individual.[65] But experiments with genetic modification on laboratory animals like mice indicate that germ-line modification might be technically easier than somatic.[66] This might be because early embryonic cells are more accepting of foreign DNA and more readily synthesize corresponding proteins than most somatic cells.[67] In one experiment successfully utilizing the germ-line technique, researchers inserted into fertilized mouse eggs a gene that promoted the synthesis of growth hormone.[68] As a result, the developing mice produced unusually high levels of the growth hormone and, ultimately, grew to two times their normal size.[69] Given the results of animal studies and the

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[60] Position Paper, *supra* note 21.

[61] *See* Francis Fukuyama, Our Posthuman Future: Consequences of the Biotechnology Revolution 76 (2002).

[62] *Id.* at 77.

[63] Position Paper, *supra* note 21.

[64] BARUCH, *supra* note 22, at 11–20.

[65] POSITION PAPER, *supra* note 21.

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

increasing access and availability of IVF, "there appear to be no technical obstacles to initiating germ-line modification experiments in humans"[70] in order to achieve genetic enhancements.

There are a number of well-established, existing methods for germ-line gene modification that have been used in animal studies for several years.[71] Three such methods include (1) the introduction of a gene by direct pronuclear microinjection of DNA segments ("PMI"), the most frequently used method, (2) the use of a virus to carry the gene of interest to infect a target cell by delivering that gene, and (3), in recent years, a process where sperm is used as a vector to deliver the genes.[72] The first method, PMI, has actually been used to inject entire *artificial* chromosomes.[73] So, theoretically at least, the existing germ-line modification techniques could be used for genetic enhancement purposes in humans.[74]

However, the current methods for germ-line genetic modification have not yet been established "sufficiently reliable or safe to countenance their immediate use with humans"[75] and are not without issue. Both the viral and non-viral mechanisms for genetic modification pose issues with precise placement and expression of the modified genes.[76] The insertion of foreign genes into imprecise locations within a chromosome, either via direct injection or virus, may have unpredictable consequences. This is demonstrated by one experiment in which the offspring of a mouse injected with an extra copy of a gene were 40 times more likely to develop cancer than the control group of mice.[77] In another experiment, insertion of a gene substantially interfered with naturally occurring genes in mouse embryos, which resulted in mice with several physical deformities.[78] These results indicate that the techniques currently used for germ-line modifications can lead to

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[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] For a more comprehensive reading of these processes, *see* Kevin R. Smith, Sarah Chan, & John Harris, *Human Germline Genetic Modification: Scientific and Bioethical Perspectives*, 43 ARCHIVES OF MEDICAL RESEARCH 491, 493–96 (2012), *available at* http://www.arcmedres.com/article/S0188-4409(12)00244-5/pdf.

[74] *Id.*

[75] *Id.*

[76] BARUCH, *supra* note 22, at 14–15.

[77] Aya Leder et al., *Consequences of Widespread Deregulation of the c-myc Gene in Transgenic Mice: Multiple Neoplasms & Normal Development*, 45 CELL 485 (1986).

[78] A.J. Griffith et al.,. *Optic, Olfactory, and Vestibular Dysmorphogenesis in the Homozygous Mouse Insertional Mutant Tg9257*, 19 J. CRANIOFAC. GENET. DEV. BIOL. 157–63 (1999).

developmental disruptions in the modified embryo itself.[79] Unsuccessful attempts at germ-line genetic modification in animals indicate that such a technique on humans "can profoundly perturb ordinary biological function and introduce new, harmful genetic variants into the gene pool[.]"[80]

The aforementioned problems are primarily associated with gene *addition*[81]. But various techniques to introduce genetically modified DNA into gametes are continuously developing. For example, researchers are now able to insert a gene into a particular location on a chromosome, while simultaneously removing the unwanted gene — i.e. gene *replacement*.[82] While the Council for Responsible Genetics suggested that such a technique would increase accuracy of genetic modification, it also noted that this would not entirely eliminate the risk of the procedure.[83] One of these risks includes the lack of ability on the part of biologists to fully understand or predict the potential interactions of genes with one another within the environment of a specific individual.[84] Certain genetic combinations could prove harmful to the individual and, subsequently, to future offspring.[85] The risks associated with such harmful combinations would apply equally to germ-line genetic modification in the contexts of alleviating disorders and enhancing certain characteristics.[86]

In 2009, Japanese researchers successfully performed germ-line genetic modification in mammals when they produced the first genetically modified primates with the ability to pass the modified gene down to their offspring.[87] Researchers modified a virus to carry a gene known as green fluorescent protein ("GFP") found in jellyfish.[88] This virus was used to infect and transfer this gene to

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[79] POSITION PAPER, *supra* note 21.

[80] *Id.*

[81] To be clear, gene addition is the insertion of an *extra* copy of a malfunctioning or nonfunctioning gene. *See Gene Addition*, BIOCHEMISTRY, http://www.biochem.arizona.edu/classes/bioc461/Biochem499/RaymondCostantini/Pages/GeneAddition.htm (last visited Dec. 1, 2014).

[82] POSITION PAPER, *supra* note 21.

[83] *Id.*

[84] *Id.*

[85] *Id.*

[86] *Id.*

[87] Rob Stein, *Test Monkeys' Offspring Pick Up Genetic Modification*, WASH. POST, May 28, 2009, at A1 (detailing the first successful germ-line modification of a primate and hypothesizing that "[t]he approach could tempt some to use the technique to try to engineer desirable traits in people").

[88] *Id.*

the cells of several marmosets.[89] The jellyfish gene, which causes the cells to glow green when exposed to ultraviolet light, was present in four out of five offspring resulting from the implantation of marmoset embryos in female marmosets.[90] Researchers could identify the success of this genetic modification due to the fact that the marmosets actually glowed green when exposed to ultraviolet light.[91] Then, the researchers took gamete cells from two of the marmosets that carried the gene and, from them, were ultimately able to produce four offspring — three of which contained the jellyfish gene and glowed under ultraviolet light.[92] The success of this germ-line genetic modification of primates suggests the high likelihood that the same technique would be similarly effective on humans.

Ultimately, biologists and medical researchers may be able to draw on the scientific successes of somatic genetic modification in humans and the somatic and germ-line modification in animal cells to achieve successful germ-line modification in humans.[93] This would allow for genetic enhancement of humans, in addition to gene therapy — a distinction highly relevant to the following discussion. Gene *therapy* primarily focuses on curing or reducing human diseases and conditions, while genetic *enhancement* focuses instead on enhancing human characteristics.[94] Given the potential development and use of biotechnologies like human germ-line genetic modification ("HGGM"), it is necessary to address the legal implications posed by such technologies to the United States patent system.

II
THE SUPREME COURTS DECISION IN ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS, INC.

A. Procedural Posture of Myriad Genetics

After several years of research, Myriad Genetics, Inc. ("Myriad"), a molecular diagnostic testing and assessment company, obtained a number of patents based on the discovery of two human genes, mutations of which correlate with an increased risk of breast and ovarian cancer.[95] Specifically, the Patent and

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[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] BARUCH, *supra* note 22, at 13.
[94] Hanna, *supra* note 40.
[95] Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329, 1339 (Fed. Cir. 2011); *Myriad Genetics*, 133 S. Ct. at 2111. It is significant to note that there are several citations to this case in its various procedural postures.

Trademark Office specifically granted patents for the isolated BRCA1 and BRCA2 genes.[96] The patents essentially gave Myriad the exclusive right to isolate these genes from an individual's genome and also to synthetically create BRCA cDNA.[97] Given that isolation is necessary to conduct genetic testing, the patents effectively gave Myriad exclusive control of BRCA testing.[98]

The patents, however, did not stop others like the University of Pennsylvania's Genetic Diagnostic Laboratory ("GDL") from providing genetic testing services to women.[99] In fact, Dr. Harry Ostrer, former researcher at New York University School of Medicine, frequently sent DNA samples to GDL to be tested.[100] When Myriad learned that others were offering these services, it began to assert its rights over the isolated genes, claiming all genetic testing infringed upon its patents.[101] Myriad filed suit against various entities providing the BRCA testing and the litigation and threats thereof prevented several other medical practitioners and entities from providing BRCA testing.[102] Consequently, Myriad Genetics was left as the sole entity that could provide or license the service.[103]

Several years later, Dr. Ostrer, along with health care professionals, advocacy groups, and patients filed suit against Myriad Genetics seeking invalidation of their patents under § 101 in the United States District Court for the Southern District of New York.[104] The plaintiffs asserted that Myriad's claims cover patent-ineligible subject matter.[105] They alleged that the patenting of the BRCA genes impeded research on breast cancer, and restricts the "ease of access to genomic discoveries" and the dissemination of knowledge to patients.[106]

Approximately ten months after plaintiffs had filed their complaint, the District Court granted summary judgment in their favor, invalidating all of Myriad's claims to the isolated BRCA genes and testing methods.[107] Policy

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[96] *See Ass'n for Molecular Pathology*, 653 F.3d at 1339.
[97] *Myriad Genetics*, 133 S. Ct. at 2113–14.
[98] *Id.* at 2113.
[99] *Id.* at 2114.
[100] *Id.*
[101] *Id.*
[102] *Ass'n for Molecular Pathology*, 653 F.3d at 1340.
[103] *Myriad Genetics*, 133 S. Ct. at 2114.
[104] *Id.*
[105] Complaint at 3, Ass'n for Molecular Pathology v. USPTO, 669 F. Supp. 2d 365 (S.D.N.Y. 2009) (No. 09 Civ. 4515).
[106] *Id.* at 2 –4.
[107] Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010).

considerations, namely, what plaintiffs alleged to be the diminished availability of the testing for breast cancer, played into the court's consideration of the motion for summary judgment, but, ultimately, it decided that the issues were too complicated to address at that stage.[108]

On appeal to the Federal Circuit, the court affirmed the judgment of the lower court invalidating Myriad's method patents for comparison and analysis of DNA sequences, given that they covered abstract steps and were, thus, a subject matter ineligible for patent.[109] The court went on to reverse the district court's invalidation of the isolated DNA molecules on the grounds that the "the molecules as claimed do not exist in nature."[110] As a result, the patents on the isolated BRCA1 and BRCA2 genes were upheld.[111]

The Federal Circuit judges in this case each wrote separate opinions, in which each judge addressed their own perspective and concerns. Judge Alan D. Lourie wrote the opinion for the court, finding that the composition claims were in fact patentable and noting that the "isolated DNAs, not just cDNAs, have a markedly different chemical structure compared to native DNAs."[112] In her concurrence, Judge Kimberly A. Moore discussed the moral implications that the patents raised.[113] However, she declined to address the moral and ethical issues, noting that the job of the court is to interpret the words of the legislature, an inquiry, she suggests, which "[has no] moral, ethical, or theological components."[114]

In a separate opinion, Judge William C. Bryson concurred and dissented in part from the court's decision.[115] He disagreed with the court's holding that the isolated genes were a patent-eligible subject matter.[116] Judge Bryson explained that, given the established product of nature exception, the isolated genes were

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[108] *Id*. at 211.

[109] *Ass'n for Molecular Pathology*, 653 F.3d at 1334.

[110] *Id*. at 1334.

[111] *Id*. at 1365 ("[T]he mere fact that the larger chromosomal polymer includes the same sequence of nucleotides as the smaller isolated DNA is not enough to make it per se a law of nature and remove it from the scope of patentable subject matter.").

[112] *Id.* at 1353.

[113] *Id.* at 1371–73 (Moore, J., concurring in part).

[114] *Id.* at 1373 (discussing the notion *Chakrabarty* that these types of policy considerations are within the province of the legislature).

[115] *Id*. (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part).

[116] *Id.*

merely naturally occurring material and ineligible for patent.[117] He also suggested that a decision to the contrary "would likely have broad consequences, such as preempting methods for whole-genome sequencing . . . ."[118]

In 2012, the case was granted certiorari by the Supreme Court. However, the Court vacated the judgment and remanded to the Federal Circuit in light of the Court's holding in *Mayo Collaborative Services v. Prometheus Labs*.[119] In *Mayo*, the Court was confronted with patent claims for methods of determining effective dosages of autoimmune disease medications in treating patients.[120] Ultimately, the court invalidated the patent. In its opinion, the Court significantly relied on the public policy rationale that innovations restricting the ability to research and develop natural laws should not be eligible for patent.[121] The Court seemed to be expanding the "naturally occurring" exception through its application of the law of nature doctrine to a *non-natural* process. Justice Breyer discussed the Court's refusal to "uphold[] patents that claim processes that too broadly preempt the use of a natural law."[122] Allowing these patents would "disproportionately t[ie] up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."[123]

On remand, the Federal Circuit again upheld patents. The same three-judge panel reached the same legal conclusions, again allowing the isolated DNA patents given their nonexistence in nature.[124] Judge Lourie, again, delivered the opinion of the court. While indicating the concern that these patents "raise substantial moral and ethical issues related to awarding a property right to isolated portions of human DNA," Judge Moore indicated that these are issues that are more properly within

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[117] *Id.* at 1377–78 (citing Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

[118] *Id.* at 1373 (Bryson, J., concurring in part and dissenting in part).

[119] Ass'n for Molecular Pathology v. Myriad Genetics, 132 S. Ct. 1794 (2012).

[120] Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289 (2012). Prometheus was the exclusive licensee of a patent that's claims were directed to a method of determining dosages of drug to give to patients with particular autoimmune diseases. Effectiveness of dosages inherently varies with each patient given their unique metabolization rates. Having identified a threshold dosage for effectiveness, which was part of the claimed method, the plaintiffs argued that they could more efficiently determine whether to increase or decrease the dosage of the drug for individual patients. *Id.*

[121] *Id.*

[122] *Id.* at 1294 (citing O'Reilly v. Morse, 56 U.S. (15 How.) 62, 112–20 (1854)); *see also* Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972).

[123] *Mayo*, 132 S. Ct. at 1294.

[124] Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1337 (Fed. Cir. 2012).

the realm of Congress.[125] In a dissenting opinion, Judge Bryson reiterated his belief that the isolated DNA genes were not a patentable subject matter and allowing such patents would "likely have broad consequences."[126]

B. The Supreme Court's Decision

The Supreme Court once again granted certiorari in order to determine the validity of Myriad's patents on the isolated BRCA genes and cDNA. The primary issue before the Court was whether naturally occurring, but isolated DNA sequences were eligible for a patent under 35 U.S.C. § 101.[127] The Court also addressed the issue of whether synthetically created DNA, or cDNA was patent eligible.[128] Ultimately, the Court affirmed and reversed in part the Federal Circuit's opinion, holding that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."[129]

Given that Myriad neither created or altered the genetic structure of DNA nucleotides, the Court did not decide whether creation or alteration would lead to unpatentability.[130] Instead, it was first confronted with the question of whether the discovery of the precise location and the isolation of the DNA genes renders them patentable.[131]

In reaching its conclusion, the Court relied on *Diamond v. Chakrabarty*, in which a patent for a modified bacterium was in dispute.[132] In that case, scientists had added four plasmids to the bacterium allowing it to break down crude oil.[133] The Court explained that, prior to this patent claim, this was not a naturally occurring composition of matter, but rather a "product of human ingenuity having a distinctive name, character [and] use."[134] In *Myriad Genetics*, the Court noted that the bacterium at issue in *Chakrabarty* had "markedly different characteristics

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[125] *Id.* at 1346 (Moore, J., concurring in part).

[126] *Id.* at 1348 (Bryson, J., concurring in part and dissenting in part).

[127] *Id.*

[128] *Id.* Note that the cDNA created by Myriad "contain[ed] the same protein-coding information found in a segment of natural DNA but omit[ted] portions within the DNA segment that do not code for proteins." *Id.*

[129] *Id.*

[130] *Id.* at 2116, 2120 ("Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors.").

[131] *Id.* at 2116.

[132] *Chakrabarty*, 447 U.S. at 305.

[133] *Id.*

[134] *Id.* at 309–10 (internal quotation marks omitted).

from any found in nature," given its distinct chemical composition and its newfound ability to break down oil.[135] This was in stark contrast to Myriad's mere isolation of genes from its surrounding material.[136]

Justice Thomas went on to discuss *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[137], where the Court considered a patent for a resultant mixture of naturally occurring bacteria.[138] The mixture of bacteria was created as a way of improving the nitrogen intake of leguminous plants and was ultimately a more effective inoculant[139], given that other inoculants often mutually inhibited each other.[140] The Court nonetheless held that the mixture was not proper subject matter under § 101, finding that there had been no alteration to the bacteria.[141]

In *Myriad Genetics*, there was no alteration to the chemical composition of the genetic material, nor was there any change in the material as a result of isolation.[142] The Court stated that it was not enough that Myriad's isolation of DNA entailed the severance of the covalent bonds — holding the nucleotides of the DNA molecule in place — and effectively created a non-naturally occurring molecule.[143] The claims themselves simply focused on the genetic information contained in the isolated genetic sequence.

The Court then moved on to a discussion of cDNA, recognizing that the synthetic DNA did not pose the same legal challenges as the isolated DNA segments.[144] The cDNA that Myriad claimed was a sequence resulting in only the inclusion of exons, as opposed to naturally occurring sequences which include both exons and introns. While acknowledging that nature dictated the structure of the nucleotide sequence, the Court found that resulting cDNA was an

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[135] *Myriad Genetics,* 133 S. Ct. at 2217 (citing and quoting *Chakrabarty*, 447 U.S. at 310).

[136] *Id*. at 2117.

[137] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[138] *Id.*

[139] Inoculants are soil additives that serve to promote plant health when included in the surrounding soil or on the roots of the plant itself. *See generally id.*

[140] *Id*. at 129–30.

[141] *Id*. at 132 ("There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself.").

[142] *Myriad Genetics*, 133 S. Ct. at 2118.

[143] *Id*. To be clear, the genes are only non-naturally occurring in the sense that this particular genetic sequence is not found *isolated* in nature.

[144] *Id*. at 2119

"unquestionabl[e] creat[ion] of something new," since it was "distinct from the DNA from which it was derived."[145]

Myriad Genetics, in conjunction with *Chakrabarty*, could be read to suggest that the act of creating or altering of naturally occurring material are significant in determining patentability.[146] However, it seems that the Court is only willing to uphold a patent when claims deal with the creation or alteration of the essential nature of the original material, effectively crewating a "markedly different" material.

III
THE APPLICATION OF MYRIAD GENETICS TO GENETICALLY MODIFIED OR SYNTHETIC GAMETES AND EMBRYOS

As has been discussed, in the last three decades, biotechnology has been advancing at such a rate to make human genetic enhancement an actual reality.[147] For years, scientists have had the ability to screen developing human embryos for chromosomal abnormalities and genetic disorders.[148] It is not in the unforeseen future that parents will be able to hand-select the genes that their children will encompass. Developments in assisted reproduction technologies have led to the creation of new markets for things like gametes and embryos.[149] These new markets raise significant questions in patent law, regarding ownership and rights surrounding human genes, embryos, gametes, and the like.[150] The Supreme Court made clear the unavailability of patents on isolated human genes in *Myriad Genetics*, but a question remains as to patentability of the creation of synthetic DNA or the alteration of naturally occurring DNA in the context of genetic enhancement of human gametes and embryos. This section will address how this subject matter should be addressed in light of the Court's holding in *Myriad Genetics*.

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[145] *Id.*

[146] *See, e.g.*, *Myriad Genetics*, 133 S. Ct. at 2117 (contrasting the patent claims at issue in *Myriad* to those in *Chakrabarty* and finding that, unlike in *Chakrabarty*, "Myriad did not *create* anything" (emphasis added)); *Chakrabarty*, 447 U.S. at 310 (upholding patent on modified bacteria given the resulting bacterium's "markedly different" properties and abilities).

[147] POSITION PAPER, *supra* note 21. Genetic engineering procedures are conducted on animals, and these procedures have resulted in mice growing to twice their size and cows producing milk enhanced with pharmaceuticals. This testing may ultimately result in athletically gifted children, the physically attractive, or a math genius. *See id.*

[148] *See generally* REPRODUCTION AND RESPONSIBILITY, *supra* note 34, 89–104.

[149] *Id.* at 147.

[150] *Id.*

A. The Emergence of Human Genes as a Topic in Patent Law

Over the past several decades, the growing industry of biotechnology has left us with many questions about what can and cannot be afforded patent protection. While 35 U.S.C. § 101 defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," one of the provisions of the America Invents Act, passed by Congress in 2011, specifically prohibits the issuance of patents for inventions "direct to or encompassing human organisms."[151] This provision consequently puts a spotlight on many reproductive biotechnologies, including genetic modification techniques.

Until *Myriad Genetics*, courts had not addressed the issue of whether genetic material was a patent-eligible subject matter under § 101. Despite this fact, the first patents on human genes were issued by the PTO in the early 1980s.[152] By the time of the Supreme Court's decision, there were an estimated 2,645 issued patents claiming "isolated DNA."[153] By 2005, the PTO had issued close to 40,000 DNA-related patents that, in total, covered about twenty percent of the genes in the human genome.[154]

In the past, patents have been issued on modified human tissue, cell lines, and even DNA molecules of human origin.[155] It was not until recently, however, that patents for genetically modified gametes or embryos appeared to be on the horizon. In 2013, a personal-genomics company called 23andMe was issued a patent on a system of reproductive technology[156] for a process in which fertility clinic patients could identify certain characteristics that they would like their child to have.[157] Based on donors' and patients' genetic profiles, the program then runs an inheritance calculation, which can identify the preferred donors for the recipient. The patient can select for a child with a low risk of certain genetic conditions, or even request that the child have a high probability of a certain eye color.[158] Significantly, the issuance of this patent indicates a move in patent law towards the protection of genetic enhancement techniques and processes.

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[151] Leahy-Smith America Invents Act, § 33(a).

[152] *See* Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 28 (2011).

[153] *Ass'n for Molecular Pathology*, 689 F.3d at 1333.

[154] Rogers, *supra* note 152, at 19.

[155] REPRODUCTION AND RESPONSIBILITY, *supra* note 34.

[156] Naik, *supra* note 38.

[157] *Id.*

[158] *Id.*

According to Jacob Sherkow, formerly a biotechnology patent expert at Stanford University's law school and now an Associate Professor of Law at New York Law School, said that 23andMe's patent "is a shot across the bow — a signal to the world that this is what the future is going to look like."[159]

B. Judicial Precedent on the Patentability of Living Organisms

Existing case law in this area does not seem to produce a coherent rule of law with respect to patent eligibility of living organisms. It first began when the Supreme Court in *Diamond v. Chakrabarty* upheld a patent on a living bacterium organism.[160] In *Chakrabarty*, the Court determined that the scientific alteration of a bacterium sufficiently transformed it into a new chemical composition with new capabilities of breaking down crude oil.[161]

Since *Chakrabarty* was decided, patents have been issued on several human-made organisms, including multicellular organisms[162] and genetically altered mammals.[163] Nonetheless, the Supreme Court has continued to reiterate the limitations on the subject matter that is eligible for patent. Prior to *Myriad Genetics*, the Court in *Mayo* had previously concluded that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[164] In *Myriad Genetics*, the Court explained that it has "long held that [§ 101 of the Patent Act] contains an important "implicit exception" that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable."[165]

But in discussing this "rule against the patents on naturally occurring things," it noted that a balancing test limits the extent of this prohibition; that is, "a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur,

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[159] *Id.*

[160] *Chakrabarty*, 447 U.S. 303; *see also* Keay, *supra* note 15, at 421–30.

[161] *Chakrabarty*, 447 U.S. at 309–10.

[162] *See In re* Allen, No. 87-1393, 1988 WL 23321 (Fed. Cir. Mar. 14, 1988) (upholding a patent on a new type of oyster).

[163] *See* U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988).

[164] *Mayo*, 132 S. Ct. at 1300.

[165] *Myriad Genetics*, 133 S. Ct. at 2116 (citing Mayo Collaborative Servs. v. Prometheus Labs., — U.S. —, 132 S. Ct. 1289, 1293 (2012)). In stating the rule against patents on naturally occurring things, the Court in *Mayo* noted "[s]uch discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Mayo*, 132 S. Ct. at 1293 (quoting *Chakrabarty*, 447 U.S. at 309).

invention.'"[166] This was the standard governing the court's decision on the whether what Myriad had claimed was a proper subject matter for patent.[167]

To be clear, there are two separate holdings in *Myriad Genetics*. First, the Court held that an isolated, naturally occurring DNA segment is a product of nature and, as such, not eligible for patent.[168] Second, the Court fond that cDNA, or the lab created DNA, is eligible for patent, given that "it is not naturally occurring."[169] When looking closely at the holding in *Myriad Genetics*, the Court specifically identifying an exception to certain uses of natural phenomenon.[170] Consequently, "only an *innovative* or *inventive* use of a natural phenomenon" may be patentable.[171] The Court's opinion implicitly suggests that the *alteration* or *creation* of the information in the human genes or other material would a significant factor in determining whether the subject matter is "naturally occurring."[172] Given that Myriad neither altered or created the BRCA genes, and that its primary contribution was discovering the location and identifying the sequencing of the genes within particular chromosomes, the court found it patent-ineligible.[173] Simply "separating that gene from its surrounding genetic material is not an act of invention."[174]

Depending on the future technology involved in creating desirable genetic sequences with hand selected characteristics, there could be one of two legal possibilities for an application for patent protection. Should the biotechnology industry produce a technique for isolating particular genetic human traits, perhaps taken from embryonic stem cells, then it would seem to necessarily follow that the these isolated genes would nonetheless be naturally occurring and constitute a non-patentable subject matter. However, a new question arises should these isolated genes be used to create a synthetic genetic sequence that alters or replaces an existing sequence and is not naturally occurring.

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[166] *Myriad Genetics*, 133 S. Ct. at 2116 (quoting *Mayo*, 132 S. Ct. at 1305).

[167] *Id.*

[168] *Id.* at 2111.

[169] *Id.*

[170] *Myriad Genetics*, 133 S. Ct. at 2119 ("Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.").

[171] Ariosa Diagnostics, Inc. v. Sequenom, Inc., No. C 11-06391 SI, 2013 WL 5863022, at *9 (N.D. Cal. Oct. 30, 2013) (quoting *Myriad Genetics*, 133 S. Ct. at 2119).

[172] *Id.* at 2115–16.

[173] *Id.* at 2116.

[174] *Id.* at 2117.

C. The Demise of the "Beneficial Utility" Requirement and the Introduction of the America Invents Act

For patent eligibility, the innovation or invention must be (i) novel, (ii) nonobvious, (iii) useful.[175] Under the utility requirement, "beneficial utility" used to play a significant role.[176] Dating back to 1817, Justice Story recognized this doctrine in *Lowell v. Lewis*, where he stated the view that "the law requires . . . the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society."[177]

While previously a consideration under the utility prong, the Court by the mid-1990's no longer seemed interested in assessing the morality of inventions in patent law.[178] Since *Lowell*, federal courts have relaxed, if not dismissed, this additional requirement of beneficial utility. For example, the Federal Circuit in *Juicy Whip, Inc., v. Orange Bang, Inc.*, evaluated a case in which a patented product was misleading to customers as to the source of the product it was producing.[179] Nonetheless, the court stated that a doctrine invalidating patents serving immoral or illegal purposes "has not been applied broadly in recent years."[180] It also suggested that the legislature is free to prohibit patents on such deceptive devices but has not yet done so.[181] The Supreme Court conveyed a similar idea in *Chakrabarty*, when it noted that the Court was "without competence to entertain [arguments regarding the balancing of risks and benefits of inventions] . . . the contentions [before the Court] should be addressed to the political branches of Government . . . ."[182]

Despite the current broad interpretation of the bounds of patentable subject matter rejecting a beneficial utility doctrine, morality cannot be entirely dismissed from a discussion of patents on human gametes and embryos. As implied by the first Federal Circuit opinion in *Myriad Genetics*, one of the primary functions of the judiciary is to interpret federal statutory law and regulations governing the

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[175] 35 U.S.C. § 101.

[176] *See generally* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 216–28 (3d ed. 2002) (describing the history behind the doctrine of beneficial utility of the doctrine).

[177] *Lowell*, 15 F. Cas. at 1019.

[178] Keay, *supra* note 15, at 429.

[179] *Juicy Whip*, 185 F.3d at 1366–67.

[180] *Id.*

[181] *Id.* at 1368.

[182] *Chakrabarty*, 447 U.S. at 317.

realm of patent.[183] The Federal Circuit went on to suggest the inappropriateness of courts to intervene in policy decisions that are more adequately addressed by the legislature.[184] This indicates a key distinction between *Myriad Genetics* and any future case involving the patent – eligibility of human gametes or embryos. The distinction is one based on Congress's express recognition of the ethical and moral concerns regarding patent claims "directed to or encompassing human organisms" through the adoption of a federal statute excluding such subject matter from the realm of patentability.[185] The fact that Congress has spoken with regard to the patentability of this sort of subject matter should portend courts' adherence to this preference.[186]

1. The America Invents Act's Prohibition on Patents for Inventions "Directed to or Encompassing Human Organisms."

While the issuance of patents can potentially serve the significant purpose of encouraging innovation and the research and development of beneficial advances in the industry of biotechnology, patents on human gametes and embryos clearly raise a number of ethical concerns, which are expressly recognized by federal statute.[187] Prior to *Myriad Genetics*, Congress directly addressed the issue of patenting human organisms through the America Invents Act. Section 33(a) of the Act states, in relevant part, that "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[188]

It is significant that *Myriad Genetics* was not a case in which the court was confronted with the §33(a) of the America Invents Act discussed *supra*. To this extent, the holding should be properly narrowed to synthetic DNA which *does not* implicate this federal statute — e.g. medical uses and gene therapy, and not those materials that are so intimately related to human organisms and their creation and development. The statue itself makes no distinction between naturally occurring or

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[183] *Ass'n for Molecular Pathology*, 653 F.3d at 1353.

[184] *Id.* ("[T]he Supreme Court has 'more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed'" (quoting Bilski v. Kappos, 561 U.S. 593, 602 (2010)).

[185] Leahy-Smith America Invents Act, § 33(a).

[186] *See Chakrabarty*, 447 U.S. at 317 ("[T]he balancing of competing values and interests, which in our democratic system is the business of elected representatives . . . should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts."); *Juicy Whip*, 185 F.3d at 1366–68 (upholding patent on deceptive product, but noting that it would defer to Congress if it were to make the patenting of such devices illegal).

[187] Leahy-Smith America Invents Act, § 33(a).

[188] *Id.*

synthetic materials in its prohibition on patents "directed to or encompassing human organisms."[189]

Significantly, § 33(a) may serve to limit the extent of the impact that *Myriad Genetics* will have on the analysis on the patentability of modified gametes and embryos. The Court will be confronted with a case necessarily involving statutory construction, something that was *not* involved in *Myriad Genetics*. When this issue arises, undoubtedly much of the debate will surround the precise meaning of the phrases "directed to" and "human organism."[190] Unfortunately, the Act itself does nothing to precisely define either of these phrases, and its legislative history seems "riddled with internal contradictions, ad hoc exceptions, and, generally, a lack of any coherent guiding principle."[191] It is important to note that the phrase "human organism" seems to have been intended to have the same meaning as it did under the Weldon Amendment — off of which § 33 was modeled.[192] The Weldon Amendment was originally put forward by U.S. Representative Dave Weldon and passed as a part of the Consolidated Appropriations Act of 2004, which barred appropriated federal funds from their use in issuing patents "directed to or encompassing a human organism"[193] The legislative history of this amendment offers some guidance to the meaning of this prohibition in both the Appropriations Act and § 33:

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[189] *Id.*

[190] *See* Dennis Crouch, *Patents Directed to Human Organisms*, PATENTLYO (Sept. 9, 2011), http://www.patentlyo.com/patent/2011/09/patents-directed-to-human-organisms.html ("The phrase 'directed to' is not defined in the Patent Act or the USPTO Implementation Rules found at 37 C.F.R. § 1, *et seq.* However, the phrase [is] often used by patent attorneys to describe the coverage of a particular claim and the statutory category. Even amongst patent attorneys, the usage is not uniform.").

[191] Yaniv Heled, *On Patenting Human Organisms or How the Abortion Wars Feed into the Ownership Fallacy*, 36 CARDOZO L. REV. 241, 243–44 (2014).

[192] *Id.* at 261, n.86 ("The sponsors of Section 33 viewed the Section as mere codification of the Weldon Amendment and, as such, as a direct extension of the Weldon Amendment's jurisprudence, including the meaning of the term 'human organism.'"); *see* 157 Cong. Rec. E1177, E1177-78 ("Chairman Lamar Smith [included] in the manager's amendment to . . . the America Invents Act, a provision that will codify an existing pro-life policy rider included in the CJS Appropriations bill since FY2004. This amendment, commonly known as the Weldon amendment, ensures the U.S. Patent and Trade Office, USPTO, does not issue patents that are directed to or encompassing a human organism . . . . I also submit into the Record items from previous debate on the Weldon amendment that will add further clarification to the intent of this important provision.").

[193] Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3 (2004).

> [T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.[194]

The history of the Weldon Amendment helps delineate Congress's intended meaning of the statute. The congressional record further reveals that "the amendment applies to patents on claims directed to or encompassing a human organism at *any stage* of development, including a human embryo . . . *regardless* of whether the organism was produced by technological methods (including, but not limited to, *in vitro* fertilization, somatic cell nuclear transfer, or parthenogenesis)."[195] It, admittedly, goes on to note that the amendment should not preclude "*methods* for creating, modifying, or treating human organisms, including . . . through *in vitro* fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos."[196]

Nevertheless, given the text of the act and what legislative history is clear, it seems obvious that human embryos would not constitute a patentable subject matter under 35 U.C.S. § 101. Pursuant to the America Invents Act, no patents shall issue to inventions "directed to or encompassing a human organism."[197] Genetically engineered or altered human embryos are the epitome of what the America Invents Act sought to keep beyond the realm of patent. While no definition is provided for this phrase, a human embryo, including those genetically altered or synthetically created, contains all of the elements necessary for human life to form and develop and would undoubtedly "encompass a human organism."

It is less obvious, given the lack of clear guidance in interpreting this phrase, that gametes would fall into this category. But, within the Manual of Patenting

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[194] 157 CONG. REC. E1177-04 (testimony of Representative Dave Weldon previously presented in connection with the Consolidated Appropriations Act of 2004, Pub. L. 108-199, § 634, 118 Stat. 3, 101 (2004), and later resubmitted with regard to the America Invents Act; *see* 149 Cong. Rec. E2417-01).

[195] 157 Cong. Rec. E1177-04, E1180 (daily ed. June 23, 2011) (emphasis added) (statement of Rep. Dave Weldon).

[196] 157 Cong. Rec. E1182, E1183 (daily ed. June 23, 2011) (emphasis added) (statement of Rep. Lamar Smith).

[197] Leahy-Smith America Invents Act § 33(a); see also MPEP § 2105 (8th ed. Rev. 8, July 2010).

Examining Procedures, the PTO has indicated that a rejection will be made on the basis of non-statutory subject matter "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human organism[.]"[198] Given that gametes contain at least half of the genetic material that goes into the formation of a human embryo, it seems consistent that genetically altered or synthetic gametes, like embryos would "encompass[] a human organism" — thus, considered a non-patentable subject matter. At the very least, genetically altered gametes would be "directed to" a human organism. These cells are the building blocks of human life. Sperm and egg combine together to form an embryo, which has the potential to develop into a living, functioning human being. Consequently, even if they are genetically modified through germ-line modification or another technique, they do not lose their inherent capability of producing human life. Moreover, to the extent that scientists may create synthetic genetic material in order to alter gamete cells,[199] the gamete itself would still be ineligible for patent, and, arguably, so to would the synthetic genetic material itself.

Researchers and scientists may attempt to skirt this prohibition by receiving a patent on the process of modifying human gametes or embryos given the Weldon amendment's "methods" exception.[200] However, a patent application of this sort would nevertheless include claims *directed to* a human organism for the reasons described above. Furthermore, the excepted methods that are enumerated only encompass assisted reproductive technologies, somatic cell nuclear transfers, and genetic therapies.[201] While the legislative history does not provide an exhaustive list of exceptions, methods for genetic *enhancement* — distinct from genetic therapy — are not included and do not appear to have been contemplated.[202] The techniques and processes involved in altering gametes or embryos to achieve desired characteristics would be directly aimed at creating genetically *enhanced* human organisms; methods that are not explicitly protected in the legislative history.

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[198] MPEP § 2105 (8th ed. Rev. 8, July 2010).

[199] It does not seem scientifically impossible to synthetically create the desirable DNA characteristics and use those to modify existing human gametes and genes. *See Myriad Genetics*, 133 S. Ct. at 2112–13 (discussing the discussed the possibility of creating synthetic DNA through well-known scientific processes).

[200] 157 Cong. Rec. E1182, E1183 (daily ed. June 23, 2011).

[201] *Id.* (excepting methods including "in vitro fertilization, methods of somatic cell nuclear transfer, medical or genetic therapies, methods for enhancing fertility, and methods for implanting embryos").

[202] *Id.*

Admittedly, it is questionable whether legislative history will or should bear any weight in statutory construction. However, under the above formulations it would suggest that gametes and embryos would both be considered within the realm of human organisms, since it arguably encompasses organisms at *any stage* of development. Moreover, the methods for genetic enhancement techniques are distinct from medical or genetic therapy processes involving the creation of embryos, and is not expressly excluded from the realm of patentability.

It is significant to reiterate the distinction between genetic modification characterized as gene *therapy* and genetic *enhancement*.[203] What has been termed gene therapy is primarily focused on curing or reducing human diseases and conditions, where as genetic enhancement focuses in stead on enhancing human characteristics.[204] In analyzing the legislative history of the Weldon Amendment, it does not expressly exclude genetic enhancement from patent law's prohibition on claims "directed to or encompassing human organisms" but does address genetic *therapy*.[205] Accordingly, to properly adhere to legislative intentions, federal courts should view the impact of *Myriad Genetics* as limited in determining whether human gametes or embryos are patentable, either synthetic or natural. That is, when the patents at issue implicate § 33(a), *Myriad Genetics* should apply only in the limited context of the patentability of *medical* processes or genetic *therapies*,[206] and not in contexts of genetic *enhancement*.

For example, patents on synthetic DNA similar to that in *Myriad Genetics*, but used in germ-line genetic modifications or reproductive cloning might implicate the federal statute. As gametes have the ability to pass along hereditary genetic information from one organism to its offspring[207], any synthetic gene or DNA that is inserted into a gamete is essential to the ultimate function of that gamete or embryo. In other words, without the incorporated synthetic DNA, a modified gamete would not be able to ensure perpetuation of its genetic information. In this way, it would seem a claim for such synthetic genes or DNA sequences, like those that could be utilized in germ-line genetic modification, might well be an invention "directed to or encompassing a human organism," and, accordingly, prohibited by statute.[208]

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[203] *See* Hanna, *supra* note 40.
[204] *Id.*
[205] 157 Cong. Rec. E1182, E1183 (daily ed. June 23, 2011) (emphasis added).
[206] *Id.*
[207] BARUCH, *supra* note 22, at 11.
[208] Leahy-Smith America Invents Act § 33(a).

It is important to note that *Myriad Genetics* was considering a sort of gene therapy, where the location and isolation of the BRCA genes enabled testing for and treatment of certain health conditions within the human body; the Court was not considering genetic enhancement. But, in upholding the patents on Myriad's claims for cDNA, the Court's holding only specifically applied to cDNA, which did not encompass a human organism. These are synthetic materials that are entirely created and inserted by the scientists.[209] The synthetic DNA involved in *Myriad Genetics* was designed to to diagnose and target conditions *within* a human organism, but, admittedly, does not itself *encompass* one. However, gametes and embryos for all of the aforementioned reasons are fundamentally distinct from the type of material that Myriad was creating and should be treated as such in subsequent federal court cases involving such genetic material.

CONCLUSION

In sum, the advances of biotechnology and reproductive technologies invite the question of the patentability of human gametes and embryos. The challenges this question poses to patent law seems even more imminent given the Supreme Court's holding in *Myriad Genetics*. However, pursuant to the MPEP and the America Invents Act, no innovation or invention "directed to or encompassing a human organism"[210] will be considered for a U.S. patent, and the holding in *Myriad Genetics* does nothing to disturb this prohibition. While the phrase directed to is never precisely defined or used in any other section of the Act, the plain meaning of the phrases and legislative history may help to inform the analysis in federal courts. Ultimately, the Supreme Court's holding upholding patents on cDNA should be limited in its reach and should not apply in circumstances that are in direct contradiction to federal law — namely, section 33's express prohibition on patents "directed to or encompassing human organisms."[211]

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[209] The Supreme Court discussed the possibility of creating synthetic DNA through well-known scientific processes. "It is also possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The result is the inverse of the mRNA's inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as complementary DNA (cDNA)." *Myriad Genetics*, 133 S. Ct. at 2112.

[210] Leahy-Smith America Invents Act, § 33(a).

[211] *Id.*