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Personalized Medicine, Genetic Exceptionalism, and the Rule of Law: An Analysis of the Prevailing Justification for Invalidating BRCA1/2 Patents in *Association of Molecular Pathology v. USPTO*

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PERSONALIZED MEDICINE, GENETIC EXCEPTIONALISM, AND THE RULE OF LAW: AN ANALYSIS OF THE PREVAILING JUSTIFICATION FOR INVALIDATING BRCA1/2 PATENTS IN *ASSOCIATION OF MOLECULAR PATHOLOGY V. USPTO*

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ABSTRACT

As medicine advances toward a more personalized model, the significance of genetic information is growing exponentially. While unlocking the genetic code has advanced the state of medicine, it has also reinvigorated the debate over the boundaries of patentable subject matter. The potential clash between having access to state-of-the-art medicine and protecting intellectual property investments came to a head in the case, Association of Molecular Pathology v. USPTO *("*Myriad*"). This Article analyzes the legal opinion rendered by the district court through the unique lens of genetic exceptionalism—a concept previously reserved to social science and public policy. Then, this Article analyzes Judge Sweet's unprecedented incorporation of genetic exceptionalism into the Patent Act by first tracing the historical roots of the exceptionalism doctrine and then dissecting the* Myriad *decision through that historical lens. As it stands at publication, it has yet to be seen whether the Supreme Court will similarly adopting a novel interpretation of the*

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Patent Act that incorporates genetic exceptionalism into the Act's subject matter restrictions.

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INTRODUCTION

Judge Sweet's decision in *Association of Molecular Pathology v. USPTO* ("*Myriad*")[1] has reinvigorated the longstanding debate of whether genes qualify for patent protection and whether granting such protection does more harm to patients than good for innovation. In a health care system moving more toward personalized medicine, the resolution of these questions is vital for the stability—and possibly the survival—of genetic innovation. *Myriad* has the potential to greatly impact the way personalized medicine is administered to patients by increasing access to more at-risk patients and decreasing the cost of genetic testing. On the other hand, the decision could be a potential setback to genetic innovation that results in more harm to patients by stifling research incentives. Regardless, stakeholders on both sides of the debate are eagerly awaiting the appeal that will provide some stability in an unsettled area of patent law.

There is no disagreement that since its discovery, DNA has captivated audiences from the science, medical, ethical, and legal fields, at times rising DNA to a near-reverent status. Despite the promise that genetic science holds, the science is susceptible to abuse, as has been demonstrated by the history of eugenics and

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[1] 702 F. Supp. 2d 181 (S.D.N.Y. 2010). The procedural history of this case—following Judge Sweet's opinion in district court—is complicated. The Federal Circuit first affirmed in part and reversed in part the lower court's decision in Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (reversing the lower court's decision on gene patentability by holding, among other things, that human genes are eligible patent matter). Certiorari was granted by the United States Supreme Court, only to have the case remanded back to the Federal Circuit for reconsideration. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012). After the Federal Circuit reviewed the case, the Supreme Court again granted certiorari, limiting the issue to whether human genes are patentable. *See* Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) *and* Ass'n for Molecular Pathology v. Myriad Genetics, Inc, 133 S. Ct. 694 (Nov. 30 2012) (certiorari granted in part). As it stands, the parties have until March 2013 to file their briefs on the merit. For an up-to-date status of the case as it proceeds through the Supreme Court, visit the case on the Scotus Blog, available at http://www.scotusblog.com/case-files/cases/association-for-molecular-pathology-v-myriad-genetics-inc/.

ethnically targeted genetic screening programs. It is this unharnessed power to do both good and bad that has directed scientists, academia, and policy makers alike to treat genetic information differently than other scientific knowledge, resulting in "genetic exceptionalism." Until the *Myriad* decision, however, genetic exceptionalism did not exist as a legal principle under the Patent Act, but was instead relegated to areas of discrimination, privacy, and insurance.

To better understand *Myriad*'s impact on personalized medicine and the progeny of gene patents flowing from the genome, it is helpful to first understand basic genetic science, the development of genetic exceptionalism in other contexts, the various types of gene patents, and the existing law on subject matter patentability. Part I of this Article begins with an overview of personalized medicine and its relation to genetic science. Parts II and III discuss the impact of patenting these genetic tools and the types of patent protection falling within the catch-all category of "gene patents." In Part IV, the Article provides a summary of the precedent governing the subject matter patentability requirement. Finally, Part V addresses Judge Sweet's incorporation of genetic exceptionalism into the Patent Act by first tracing the historical roots of the exceptionalism doctrine and then dissecting the *Myriad* decision through that historical lens. After doing so, the Article concludes that the court in *Myriad* inappropriately adopted genetic exceptionalism as a legal principle on patentability instead of leaving the gene patent policy decision to Congress.

I. CHANGING THE FACE OF MEDICINE ONE STRAND AT A TIME: HOW GENETIC INFORMATION IS ALTERING THE PRACTICE OF MEDICINE

A. Defining Personalized Medicine

What does the ambiguous phrase "personalized medicine" actually mean? After all, doctor-patient relationships have traditionally been of a personal nature. New advances in technology have altered this traditional doctor-patient approach to

treatment[2] and solidified "personalized medicine" as a term of art. Building on the traditional doctor-patient relationship, personalized medicine moves health care one step further by providing physicians with a more precise tool to evaluate, diagnose, and treat patients. Beyond promising better health outcomes for individual patients, personalized medicine also has the potential to transform the entire health care delivery infrastructure into a more efficient, cost-effective system.[3]

Despite being a recognized term of art, "personalized medicine" has multiple definitions. On the literal end of the spectrum, personalized medicine refers to the development of stem cell based therapies that are specifically tailored to an individual.[4] In this context, doctors would use cloned stem cells—embryonic or adult—to generate additional cells, tissues, or organs to circumvent the inherent risks associated with individual transplantations.[5]

On the other end of the spectrum, personalized medicine is cast more broadly, referring to technologies and treatments that can be administered to a subset of the population based on common characteristics found in DNA and environmental factors. More in line with this broader definition, the Personalized Medicine

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[2] *See, e.g.*, Kent Bottles, *The Doctor/Patient Relationship for the 21st Century*, THE PHYSICIAN EXECUTIVE 10-14 (Sep.-Oct. 2001), available at http://www.kentbottles.com/pdfs/Doctor-Patient-Relationship-for-the-21st-Century.pdf (discussing different views of the doctor/patient relationship).

[3] *See generally* James P. Evans et. al., *Preparing for a Consumer-Driven Genomic Age*, 363 NEW ENG. J. MED. 1099 (2010) (discussing personalized health care in the direct-to-consumer genetic testing context); Eric D. Green & Mark S. Guyer, *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (February 2011) (discussing a 2011 vision for moving towards an era of genomic medicine); Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301 (2010) (discussing the hurdles in moving from concept to clinical use); The Case for Personalized Medicine, PERSONALIZED MEDICINE COALITION, http://cllcanada.ca/2010/pdfs/TheCaseforPersonalizedMedicine_5_5_09.pdf (discussing the benefits of personalized medicine and the necessary steps for widespread implementation).

[4] *See* Matthew Herder, *Patents & the Progress of Personalized Medicine: Biomarkers Research as Lens*, 18 ANNALS HEALTH L. 187, 190-91 (2009).

[5] *Id.* at 190. Currently embryonic stem cell therapy is in its nascent stage and not a realistic therapeutic option.

Coalition describes the emerging practice as follows:

> Personalized medicine uses new methods of molecular analysis to better manage a patient's disease or predisposition toward a disease. It aims to achieve optimal medical outcomes by helping physicians and patients choose the disease management approaches likely to work best in the context of a patient's genetic and environmental profile. Such approaches may include genetic screening programs that more precisely diagnose diseases and their sub-types, or help physicians select the type and dose of medication best suited to a certain group of patients.[6]

Other definitions go even further to dispel the potential misunderstanding surrounding the term "*personalized*." For instance, the President's Council of Advisors on Science and Technology stressed that personalized medicine "does not literally mean the creation of drugs or medical devices that are unique to a patient but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment."[7]

In other words, personalized medicine interpreted broadly enables physicians to provide better diagnoses and earlier interventions, to engage in more effective drug development, and to implement more effective therapies for various subsets of patients who share the same genetic variations.[8]

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[6] *Personalized Medicine: An Introduction*, PERSONALIZED MEDICINE COALITION, http://www.personalizedmedicinecoalition.org/sites/default/files/personalmed_backgrounder.pdf.

[7] Priorities for Personalized Medicine, President's Council of Advisors on Science and Technology (September 2008), http://www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v2.pdf.

[8] *Id.* Because this paper focuses primarily on gene patents, the term personalized medicine should be understood in the broader context as defined by the Coalition and the President's Council.

B. The Science Underlying Genetics and Personalized Medicine

Genetic science continues to revolutionize the practice of medicine by enabling treatment tailored to individual patients and providing insight to better therapeutic approaches. Although many patients utilize personalized medicine at some point over the course of their medical treatment, not all patients understand the science behind such treatment. While understanding the basics of genetic science and the types of patents currently available for the countless discoveries in the field would aid the reader's understanding of the genetic impact on medicine, an in-depth discussion of this complex science is beyond the scope of this paper.[9] Instead, this Article will provide a basic explanation from a patient's perspective: what are genes and how are they patented? This section will define the key terms and introduce the basic scientific foundations of genetics, moving into an overview of the various categories of patents that collectively are referred to as "gene patents."

The genomic structure is best understood by explaining the different parts of DNA and how its components direct the formation of proteins.[10] DNA (deoxyribonucleic acid) is a double helix structure created by two chemically-bonded strands that

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[9] *See, e.g.*, Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine – A Primer*, 347 N. ENG. J. MED. 1512-20 (2002); W. Gregory Feero & Alan E. Guttmacher, *Genomic Medicine – An Updated Primer*, 362 N. ENG. J. MED. 2001-11 (2010); Wylie Burke, Genetic Testing, 347 N. ENG. J. MED. 1867-75 (2002).

[10] Many articles go into great detail on the structure of DNA and its corresponding science. *See, e.g.*, Eric D. Zard, Note, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486-490 (2009); Lorelei Perez Westin, Note, *Genetic Patents: Gatekeeper to the Promised Cure*, 25 T. JEFFERSON L. REV. 271, 276-79 (2002). Similarly, the Federal Circuit has discussed molecular genetics in greater depth. *See, e.g.*, In re Deuel, 51 F.3d 1552, 1554-56 (Fed. Cir. 1995); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1207-08 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 895-99 (Fed. Cir. 1988). This Article will not rearticulate the scientific foundation in as great detail, but will rather provide sufficient background to understand the gene patents and their relationship with genetic exceptionalism.

stores and encodes an organism's genetic information.[11] Each DNA strand contains four base molecules (A, G, C, and T) that serve as the building blocks.[12] Before the cell can make the protein, the DNA strand must undergo three processes: (1) copying the DNA strand into RNA (transcription); (2) removing or splicing of the inactive regions (introns) and connecting the active regions (exons); and (3) translating the RNA (ribonucleic acid) into its corresponding amino acids.[13] When joined together, these amino acids fold into unique three-dimensional shapes that determine the property and function of the protein in the body.[14]

While the human genome contains more than three billion base pairs,[15] only two percent of these base pairs represent the 20,000 to 25,000 genes present in the human genome.[16] In comparing human

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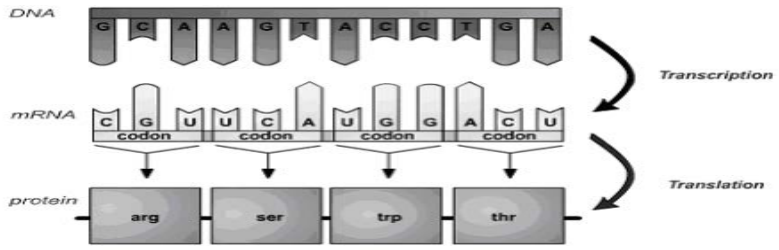
[11] Wylie Burke, *Genetics Primer*, NATIONAL ASSOCIATION OF WOMEN JUDGES, GENOME JUSTICE, September 2005, 1-14.

[12] *Id.*

[13] The following figure, a reproduction of Figure 14.5 from DAVID KROGH, BIOLOGY: A GUIDE TO THE NATURAL WORLD 249 (5th ed., 2005), depicts the two processes for decoding genetic information:



[14] There are typically three regions that are relevant to genetic patents: (1) the exon region (coding region of the gene); (2) the promoter and terminating regions of a gene (which mark the beginning and the end of gene); and the (3) intron region (non-coding regions that are spliced or removed during the transcription phase). See Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means*, 7 COMPUTER L. REV. & TECH. J. 255, 256 (2003).

[15] The human genome refers to the complete set of DNA from the combined chromosomes. *See The Science Behind the Human Genome Project: Basic Genetics, Genome Draft Sequence, and Post-Genome Science*, HUMAN GENOME PROJECT INFORMATION (Mar. 26, 2008) http://www.ornl.gov/sci/techresources/Human_Genome/project/info.shtml.

[16] *How Many Genes Are in the Human Genome?*, HUMAN GENOME PROJECT INFORMATION (Sept. 19, 2008) http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml. Currently, the average gene is

genomes, scientists have discovered that humans share approximately 99.9 percent of the same code, resulting in only .01 percent variation between human genomes.[17] Scientists have identified 1.4 million locations where these single-base variations occur.[18] These variations are referred to as single nucleotide polymorphisms, or "SNPs."[19]

Depending on where the variation occurs, the mutation(s) may result either in minor changes that account for the normal range of characteristic like hair color, height, or medication response, or in more profound changes that are responsible for various forms of genetic diseases.[20] While a single mutation may cause a handful of diseases, the majority of diseases are multifactorial, depending on a complex interaction of multiple genes and numerous environmental factors.[21]

II. PATENTING THE TOOLS OF PERSONALIZED MEDICINE: A LOOK AT THE IMPACT OF GENETIC PATENTS ON PATIENT CARE

Each step towards understanding the human genome fortifies the bridge between DNA code and a patient's bedside by creating new possibilities in personalized medicine. With the completion of the Human Genome Project, researchers have unlocked the key to a wealth of genetic information. But discovering the function and relationship of genes and translating these discoveries into

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approximately 3,000 bases, with the largest known gene having 2.4 million. And of the known genes, scientists can identify the function for only approximately 50 percent.

[17] Burke, *supra* note 9, at 4.

[18] *Id.*

[19] *Id.*

[20] *Id.* SNPs help determine the likelihood that a person will develop a disease during his or her lifetime.

[21] *See id.* at 7, 12. The media coverage has influenced the public's perception of genetic diseases, often oversimplifying the causation between a mutation and a disease and overemphasizing the determinative effect of a genetic mutation. Diseases caused by single gene mutations can be broken down into autosomal dominant, autosomal recessive, and X-linked recessive disorders. Chromosomal conditions, another subset of genetic diseases, are caused by a deficiency or excess of chromosomal material. *Id.* at 9-11.

beneficial treatment is an ongoing, complex endeavor. Currently, there are over 6,000 diseases that can be traced to a single gene,[22] while there are thousands of other conditions that are linked to genetic variations in multiple genes and interactions with environmental factors. As scientists better understand these complex genetic interactions, further progress can be made in the development of diagnostic tools, prevention techniques, and therapeutic treatments.[23]

With the progress in personalized medicine comes the desire to protect the intellectual property associated with such advancements. The impetus behind the U.S. patent law system has always been the careful balancing between the competing interests of incentivizing innovation, encouraging the disclosure of inventions for the public good, and fostering competition. The framers of the U.S. Constitution were mindful of these tradeoffs in drafting Article I § 8, which provides that Congress shall have the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[24] America's founding fathers understood that granting an exclusive right for a period of time may justify an otherwise undesired monopoly so long as the exclusive right provided sufficient incentives to invest in research and development that would otherwise not come to fruition absent the incentive. In exchange for this period of exclusivity, however, the patentee must contribute to the public a useful, novel, non-obvious invention–disclosing sufficient information for a person skilled in the arts to practice the invention.[25]

Understanding that innovation and ongoing discovery is

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[22] Melissa Conrad Stoppler, *Genetic Diseases Overview*, MEDICINENET.COM (May 11, 2010), http://www.medicinenet.com/genetic_disease/article.htm.

[23] Eric D. Green & Mark S. Guyer, *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204 (2011); see also Ethical, Legal & Social Issues: Gene Testing, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[24] U.S. CONST. art. I, § 8, cl. 8.

[25] *See* 35 U.S.C. §§101-103, 112 (2003).

imperative to personalized medicine's success, numerous stakeholders have raised concerns that granting genetic patents may substantially impede necessary scientific research and block access to therapeutic treatments.[26] As a basis for these public policy concerns, critics argue that the twenty years of protection provided to the patent holder from the date of filing enables the patent holder to prevent others from researching the patented gene and from performing diagnostic testing procedures on patented variations of the gene.[27] Critics maintain that even if a patent holder is willing to license the patent(s), researchers have a difficult time locating the owner of the patent rights.[28] Moreover, because U.S. patent law permits patent issuance for gene fragments and single nucleotide variations (see discussion on the types of gene patents, *infra*), critics argue that licensees incur higher transaction costs to obtain multiple licenses associated with one gene.[29]

In an effort to assess whether gene patents truly inhibit research, health and science researcher David Blumenthal[30] conducted several surveys that targeted both academics and commercial scientists involved with genetic research. He found that "[o]ne of every five medical scientists has delayed publication of research results for at least half a year in order to protect

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[26] *See* Marisa Noelle Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377 (2010).

[27] *See* Eric Zard, Comment, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology's Clash With the Public Good*, 6 U. ST. THOMAS L.J. 486, 504 (2009).

[28] *Id.*

[29] *Id.*

[30] David Blumenthal, M.D., M.P.P., was appointed on March 20, 2009, by the Obama Administration to serve as the National Coordinator for Health Information Technology. In this capacity, Dr. Blumenthal will lead "the implementation of a nationwide interoperable, privacy-protected health information technology infrastructure." U.S. Dept. of Health & Human Services, *HHS Names David Blumenthal As National Coordinator for Health Information Technology* (March 20, 2009), available at http://www.hhs.gov/news/press/2009pres/03/20090320b.html.

financial interests."[31] He also found that "twenty-eight percent of the geneticists surveyed reported that they were unable to duplicate published research because other academic scientists refused to share information, data, or materials,"[32] thereby preventing scientists from verifying the studies.

Further compounding the problem of gene patents is the "patent thicket"—a term critics use to refer to the multiple patents on various components of a gene—which, according to some critics, "may be stifling life-saving innovations further downstream in the course of research and product development."[33] In other words, if research scientists must acquire multiple licenses from multiple parties to conduct research on any given gene, then the cost of researching gene therapy is greater and the research itself is at risk of being derailed by a patent holder who refuses to license a necessary input to the research.[34]

While some critics concede that a level of patent protection is necessary for incentivizing research, they suggest that the patent system is offering protection at the wrong stage in the development process.[35] By issuing patents early in the development process when little is understood about the role the gene plays, a patent holder can assert the patent against later discovered mutations or genetic associations when more is understood about the gene's role in genetic diseases.[36] Arguably, the patent system grants the equivalent of a "hunting license" to the pioneering scientist, rewarding the search without compensating later discoveries that

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[31] Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 81 (2002) (summarizing findings in David Blumenthal et al., *Withholding Research Results in Academic Life Sciences*, 277 JAMA 1224, 1224 (1997)).

[32] *Id.* (citing David Blumenthal et al., *Data Withholding in Academic Genetics*, 284 JAMA 473, 477 (2002)).

[33] *Id.* at 85 (quoting Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 701 (1998)).

[34] *See id.* at 85-86.

[35] *See id.*

[36] *See id.* at 87-88. But consider that some people, including Steven Shavell, argue that awarding patents early in the process prevents excess duplicative investment.

result in a useful application.[37] As Justice Abraham Fortas once summarized, "a patent may confer power to block off whole areas of scientific development, without compensating benefits to the public."[38]

Finally, gene patents arguably deprive patients the access to reliable genetic tests and therapies that would otherwise be available. Because some patent holders exclusively license their patent, a genetic test may be permitted at one laboratory, leaving the patient with no means for getting a second opinion.

III. GENE PATENTS: DOES ONE SIZE FIT ALL?

This Article's genetic primer has focused thus far on how DNA works in its natural, non-patentable state. To be patentable, an inventor must "transform" genetic information into a non-natural form to circumvent the rule against patenting products of nature.[39] After taking steps to isolate, purify, or modify the genetic information, the inventor can claim the resulting product as an invention because the resulting product is chemically different from the product in nature.[40] In other words, the patent is not issued on the gene found in the body, but rather on man-made DNA molecules.[41]

Generally, genetic patent claims relate to one of the following four categories found to satisfy the patentability standards prior to *Myriad*:

> (1) Whole genes or parts of them, (2) proteins that the genes encode as well as their function in organisms, (3) vectors used for the transfer of genes

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[37] *Id.* at 88.

[38] *Id.* at 88 (quoting Brenner v. Manson, 383 U.S. 519, 536 (1966)).

[39] *See, e.g.*, Parker v. Flook, 437 U.S. 584 (1978); Diamond v. Diehr, 450 U.S. 175 (1981).

[40] *Id.* Isolating DNA refers to the process of removing the DNA from its natural environment in the body, while purifying DNA refers to removing the non-coding regions of the DNA (e.g. cDNA). *See* John Conley & Dan Vorhaus, *When the Grass Eats the Cows*, 23 GENEWATCH 8 (Oct.-Dec. 2010).

[41] *See* Sharon Terry, *Why Banning Patents Would Hurt Patients*, 23 GENEWATCH 24 (Oct.-Dec. 2010).

> from one organism to another, or (4) genetically modified cells or organisms, processes used for the making of genetically modified products and the uses of genetic sequences or proteins for genetic tests.[42]

The patents are generally issued as "compositions of matter" or "method-of-use" patents, and although sometimes erroneously interpreted as patenting the gene itself, the patent only covers genetic information that has been isolated and purified.[43]

A. cDNA Patents

Complementary DNA (cDNA) is a synthetic copy of an isolated section of DNA that includes only the coding-region for a protein as opposed to the entire gene as it is found in the body.[44] Scientists take the mRNA (which is copied DNA minus the non-coding regions) and convert it into a new DNA molecule through reverse transcription (cDNA).[45] Structurally and functionally different from genes found in nature, cDNA molecules can be used to produce large quantities of human protein in non-human species, to identify disease-causing mutations for diagnostic testing, to treat genetic disorders (gene therapy), and to enable new discoveries with their use as chemical reagents and research tools.[46] Although critics of cDNA patents assert that the information contained in cDNA is identical to naturally occurring DNA, even those critics acknowledge that naturally occurring DNA cannot be used for commercial diagnostic testing and research.[47]

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[42] E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Political Storm*, http://www.theinnovationpartnership.org/data/ieg/documents/cases/TIP_Myriad_Legal.pdf (working document).

[43] *Id.*

[44] *See* Kevin Noonan, *Why Genes Must Remain Eligible for Patenting*, 23 GENEWATCH, 24, 30 (Oct.-Dec. 2010).

[45] *Id.*

[46] *See* Terry, *supra* note 41.

[47] See Magdalina Gugucheva, *The Physical Embodiment of Information*, 23 GENEWATCH 26-27 (Oct.-Dec. 2010). Vectors, which are larger molecules with integrated cDNA, that can be used to insert genes into other cells, are also patentable.

B. EST Patents

Expressed sequence tags (ESTs) are fragments of the cDNA molecule that are approximately 300-500 base pairs long, representing approximately 10 to 30 percent of the average cDNA molecule.[48] In practice, ESTs are used as research tools to map and discover entire genes in a fraction of the time it would take without the aid of these markers. Advocates for EST patenting claim that there are several uses for ESTs, which include: (1) serving as a molecular marker for mapping genomes; (2) measuring the level of mRNA in a tissue sample; (3) providing primers for polymerase chain reaction processes; (4) identifying polymorphisms; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.[49] In 2005, the Federal Circuit addressed the patentability of ESTs in *In re Fisher*.[50] Focusing on the utility requirement under § 101 of the Patent Act, the court invalidated the patent for lacking "specific and substantial utility."[51] Without digressing into a utility discussion, it is sufficient for this Article's purpose to understand that EST patents must claim a known correlation between the EST and an identified underlying gene to be patentable.[52] Strictly speaking, the EST must be more than a mere research intermediary with no immediate, well-defined benefit to the public.[53]

C. SNP Patents

Of the patents that are collectively referred to as "gene patents," SNP patents are arguably the most controversial because

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[48] *Genetics and Patenting*, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[49] *See* In re Fisher, 421 F.3d 1365, 1369-74 (Fed. Cir. 2005) (discussing the uses for ESTs proffered by Fisher).

[50] *Id*.

[51] *Id*.

[52] *See id.* at 1372-73.

[53] *Id.*

SNP patents permit the patentee to claim one "letter" of a sentence. As previously discussed, SNPs are unlike cDNA and EST fragments because they represent a genetic mutation (or variation) in only one nucleotide base in a genetic sequence.[54] These minor variations can have a major impact on the way that humans respond to disease, environmental factors, or pharmaceuticals and medical treatment.[55] Typically, SNP patents include claims for the method of determining a patient's susceptibility to a disease by detecting a particular SNP in a known gene and for the isolated SNP molecule itself.[56]

D. Patents on DNA Tests

The relationships between genetic mutations and diseases allow practitioners to tailor medical diagnoses and treatment to individual patients. Once a gene is discovered, scientists then work to develop a complementary test to screen individuals for the genetic mutation associated with a disease.[57] Genetic tests offer a window to a person's genetic make-up, making it possible to confirm suspected diagnoses, to predict likelihood of future illness, to detect carrier status in unaffected individuals, and to evaluate a person's response to medical treatment.[58] The tests differ in the manner by which they identify genetic variations. For example, some tests utilize short pieces of DNA, called probes, to seek out a complementary sequence to the mutated gene which then binds to the sequence if present.[59] Another type of genetic testing directly compares the patient's DNA sequence to a normal version of the sequence, looking for any differences between the two sequences.[60] Finally, other genetic tests detect gene products, such

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[54] *See* Genome Project Information, *Ethical, Legal & Social Issues: Gene Testing*, HUMAN GENOME PROJECT INFORMATION (July 7, 2010) http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml.

[55] *Id.*

[56] *Id.*

[57] *Genetic Testing*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Jan. 10, 2013), http://www.genome.gov/10002335.

[58] *Id.*

[59] *Id.*

[60] *Id.*

as an enzymes or proteins, for determining whether a gene variation is present.[61] Beyond method patents for analyzing a person's DNA, genetic testing patents may also cover the physical testing kits that contain the necessary materials to perform the test.[62]

E. Patents on DNA Diagnostic Algorithms

Genetic patents have also been issued for algorithms that compare known risks with multiple genetic variations.[63] These method patents straddle the line between an abstract idea and an invention.[64] When the algorithm uses information derived from multiple variations and gives different weight to known risks, the algorithm is likely to be patentable subject matter.[65] In this case, scientists can invent around the patented algorithm by creating a different model of analysis.[66] The issue of patentability is more questionable when the diagnostic algorithms use an "assay-and-correlate" model, which analyzes simple levels of physiological substances.[67] For these algorithms, it much more difficult—if not impossible—to design around the patented method.

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[61] *Id.*

[62] Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 846 (2008).

[63] Michael J. Shuster & Pauline Farmer-Koppenol, *Patent Strategy for Personalized Medicine in Light of* Bilski, BILSKYBLOG.COM (2010), http://www.bilskiblog.com/files/07-19-10_patent-strategy-for-personalized-medicine-bilski-3.

[64] *Id.*

[65] *Id.*

[66] *Id.*

[67] *Id.* Algorithms are also used in developing synthetic DNA with computer software and are patentable. For example, "patents have already been granted on many of the processes and products involved in synthetic biology, including patents on methods for building synthetic DNA, synthetic genes and DNA sequences, synthetic pathways, synthetic proteins and amino acids, and novel nucleotides that replace the letters of DNA." Eric Hoffman & Jaydee Hanson, *Synthetic Biology: The Next Wave of Patents on Life*, 23 GENEWATCH 39, 40 (Oct.-Dec. 2010).

IV. GENETICS AND THE LAW: AN OVERVIEW OF SUBJECT MATTER PATENTABILITY PRECEDING *MYRIAD*

The watershed case invalidating Myriad Genetics' gene patents was not the first to address gene patents, albeit perhaps the first to directly attack the patents under the subject matter requirement.[68] Patent law's history is fraught with cases that courts can draw on for the gene patentability analysis, dating as far back as the late 1800s.[69] The earlier cases addressing biotechnology patents focused primarily on the novelty and obviousness prongs of patentability.[70] It was not until after the Patent Act of 1952, however, that courts recognized the requirements of subject matter, novelty, and non-obviousness were wholly separate inquiries.[71]

The purification doctrine[72] has long been the linchpin for justifying gene patents. In 1874, the Supreme Court addressed the validity of a patent on purified cellulose used to make paper.[73] The Court reasoned that because the product was not substantially different than the naturally occurring product either in form or substance, the patent was invalid for lack of novelty.[74]

Subsequent courts interpreted this decision to mean that inventors could potentially patent purified or isolated products of nature with a new commercial or therapeutic use. In the early 1900s, *Parke-Davis & Co. v. Kalo Inoculant Co.*, decided whether purified adrenaline could be patented.[75] In upholding the validity

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[68] Myriad Genetics is the company that holds the patents on BRCA1/2, which are the patents the plaintiff sought to invalidate in the case referred to herein as *Myriad*.

[69] *See* Ashley McHugh, *Invalidating Gene Patents: Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 62 HASTINGS SCI. & TECH. L.J. 185, 191-92 (2010).

[70] *See id.*

[71] *See id.*

[72] The purification doctrine states that naturally occurring substances may still be patentable, despite being products of nature, if the substance can be isolated and purified from its naturally occurring state. *See, e.g.*, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).

[73] American Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566 (1874).

[74] *Id.* at 593-96.

[75] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911).

of the patent, the court reasoned that although the product was naturally occurring, the purified version of adrenaline was "a new thing commercially and therapeutically."[76]

Despite the trend of expansive subject matter, the Supreme Court reigned in the scope of patentable subject matter for naturally occurring products in its 1948 opinion in *Funk Brothers Seed Co. v. Kalo Inoculant Co*.[77] At issue in *Funk Brothers* was the validity of a patent held for a mixture of isolated bacterium, which unlike its predecessor products, could be mixed without the inhibitory effects owing to the inventor's method of testing and selecting noninhibitive strains.[78] The Court evaluated the patent under the requirements set forth in 35 U.S.C. § 31, which permitted issuance of a patent to, "[a]ny person who has *invented or discovered* any new and useful *art, machine, manufacture, or composition of matter* . . . ."[79] Interpreting the requirement of "invention or discovery," Justice Douglas provided that "[t]he qualities [of the invention at issue] are the work of nature. Those qualities are, of course, not patentable. For patents cannot issue for the discovery of the phenomena of nature."[80] The Court focused on the properties of the bacterium, namely that they performed no new function when mixed together and merely provided a more efficient means of packaging for the purchaser.[81]

Although seemingly supporting the position that genes (and fragments) are entirely outside the scope of patentability as products of nature, Justice Douglas' oft-quoted statement for this proposition must be narrowly read in light of the limited question presented: whether the mixture was an "invention or discovery" within the meaning of 35 U.S.C. § 31. The way the act was written, the "invention or discovery" requirement stands separate from the patentable subject matter requirement, which is embodied in the

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[76] *Id.* at 103.

[77] 333 U.S. 127 (1948).

[78] *Id.* at 130-31.

[79] 35 U.S.C. § 31 (2000) (emphasis added).

[80] *Funk Brothers*, 333 U.S. at 130.

[81] *Id.* at 131-32 ("[T]he packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like.").

"art, machine, manufacture, or composition of matter" language. The Court also provided additional language that suggests it was not deciding the case on the subject matter prong of patentability:

> Each of the species of root nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a *different use*. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the *range of their utility*. . . . Their use in combination does not *improve in any way their natural functioning*.[82]

Because the *Funk Brothers* analysis was directed at the invention or discovery prong—not the subject matter prong—the holding should be narrowly construed in subsequent cases.[83] Opponents of gene patents should not be quick to conclude that the case prohibits patenting naturally occurring biological products since the likely correct interpretation invalidates only those patents that fail to apply the naturally occurring substance in a non-obvious way.[84]

Indeed, *Funk Brothers* did not foreclose the door for patents on naturally occurring substances despite Justice Douglas' "phenomena of nature" reasoning.[85] In 1980, the Supreme Court

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[82] *Id.* at 131 (emphasis added).

[83] *See id.* at 132 ("[W]e conclude that the product claims do not disclose an invention or discovery within the meaning of the patent statutes, we do not consider whether the other statutory requirements contained in 35 U.S.C. § 31, R.S. § 4886, are satisfied.") (emphasis added).

[84] *See* John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 301 (2003).

[85] *See, e.g.*, Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 164 (4th Cir. 1958). In 1958, the Fourth Circuit Court of Appeals upheld a patent on purified vitamin B-12 based on the therapeutic and commercial value of the biological product, noting that nothing in the language of the Patent Act of 1952 prohibited the patenting of naturally occurring substances. *Id.* The court found that compositions of matter necessarily included products of nature, stating:

> All of the tangible things with which man deals and for which

decided the question whether a *genetically modified* organism was patentable subject matter under the current Patent Act, 35 U.S.C. § 101.[86] Drawing from the purification doctrine, the Supreme Court held that a genetically altered organism was patentable as a "nonnaturally occurring" biological product.[87] The Court reasoned that the genetically engineered bacterium—developed to break down oil—was patentable under § 101 as a "manufacture" or "composition of matter" because the altered product had characteristics that did not exist in its native environment.[88] Specifically distinguishing *Funk Brothers*, the *Chakrabarty* Court held that the bacterium had "markedly different characteristics from any found in nature and one having the potential for significant utility."[89] Unlike in *Funk Brothers*, the *Chakrabarty* decision clearly speaks to the subject matter requirement.

Marking a turning point for the biotechnology industry, *Chakrabarty* has since provided gene patent advocates with fodder in the patentability debate.[90] By the close of the 20th century, the patentability of isolated (or purified) naturally occurring products was well-established, providing the biotechnology industry with much-needed assurance that its emerging discoveries would be protected by the U.S. patent system.[91] The USPTO issued numerous gene patents under the purification doctrine without dispute as to whether the subject matter was beyond the scope of patentability, granting over 5,000 DNA patents and 16,000 relating

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> patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed are composed necessarily includes naturally existing elements and materials.

Id. at 161-62.

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

[87] *Id.* at 303.

[88] *See id.* at 308-09.

[89] *Id.* at 310.

[90] *See* Gold, *supra* note 42; DAVID B. RESNIK, OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING 1 (2004).

[91] *See id.*

to DNA in the two decades that followed this revolutionary decision.[92]

Despite the proliferation of DNA patents, none have been invalidated for lack of subject matter. Instead, challenges to gene patents focus primarily on the novelty, utility, and non-obviousness requirements for patentability.[93]

V. BEGGING THE QUESTION: DOES GENETIC EXCEPTIONALISM HAVE A PLACE IN THE PATENT ACT?

A. The History of Genetic Exceptionalism in Social Science and Public Policy

Several bioethicists and legal commentators have discussed the role of genetic exceptionalism in the areas of privacy, insurance, and discrimination laws, with some questioning whether the special treatment of genetic information is necessary or even beneficial.[94] Despite the body of literature replete with arguments for and against gene patentability, genetic exceptionalism is conspicuously absent from the debate. The recently decided case invalidating Myriad's BRCA1/2 patents, however, arguably opened the door to a more nuanced application for genetic exceptionalism: invalidating gene patents based primarily on a gene's unique function in nature as an information carrier. To better understand how Judge Sweet's legal analysis effectively directs gene patents down the road to exceptionalism, it is first

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[92] *Id.*

[93] Because this Article focuses solely on genetic exceptionalism's influence on the subject matter requirement for gene patents, the court decisions regarding utility, novelty, obviousness, and enablement will not be discussed here. Recognizing these requirements are equally important to gene patentability, the Author suggests reading Lauren M. Nowierski, Note, *A Defense of Patenting Human Genome Sequences Under U.S. Law: Support For the Patenting of Isolated and Purified Substances*, 26 CARDOZO ARTS & ENT. L.J. 473 (2008), for an in-depth overview of genetic patent challenges under these patentability prongs. *See also* Conley, *supra*, note 40.

[94] *See, e.g.*, Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669, 671 (2001).

necessary to understand the principle of genetic exceptionalism and its historical development in American culture.

Genetic exceptionalism is a term that refers to the idea that genetic information is qualitatively different from other health information and raises separate social, ethical, and legal issues.[95] Both a fascination with the inherent power of genetic information and the historical fear from genetics' role in eugenics arguably spawned the principle of genetic exceptionalism.

Despite its potential for providing improved patient care, genetic information can be both "uniquely threatening and susceptible to misuse."[96] In an article assessing its allure, Professor Sonia M. Suter traced genetic exceptionalism's development from its historical roots through the eyes of four key stakeholders: the public, the media, scientists, and policy makers.[97] Since the discovery of genes, the public and media have together elevated genes' status to an arguably overstated position of the "Holy Grail" of predictive traits and patient well-being. Since the early 1960s, the media has run rampant with coverage that suggests single genes alone determine characteristics ranging from everything like aggression to homosexuality, while often understating the role of multi-gene and environmental interactions.[98]

In the 1980s, popular culture was fixated on the advent of gene therapy that promised to treat or prevent disease altogether, but three decades later the public and medical community are still

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[95] *Id.* at 671.

[96] *Id.*

[97] *Id.* at 674-75.

[98] *See, e.g.*, Robert Wring, *Our Cheating Hearts*, TIME MAGAZINE, Aug. 15, 1994 ("[Genes] affect behavior by creating feelings and thoughts--by building and maintaining the brain."); DOROTHY NELKIN & M. SUSAN LINEE, THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON 85 (1995) (quoting a New York Times reporter as having said "evil is 'embedded in the chromosomes that our parents that our parents pass to us at conception.'"). In their book, authors Nelkin and Linee suggest that popular culture's "love affair" with the gene draws from scientific principles, but fails to confine itself to DNA's technical boundaries. The authors detailed the debate over the criminal gene, which gained traction in the early 1960s and continued throughout the decades in media's coverage of seemingly unexplainable crimes. *See id.* at 83-86.

waiting for the promise to come to fruition.[99] As one author comments, "Science reporters must first and foremost attract readers, a difficult task when competing with more attention-grabbing topics like war and pop culture. Likely in response to this pressure, two trends have emerged in media coverage of genetics: oversimplification and sensationalism."[100]

Prior to 1993, media coverage focused on newly discovered genes, but as these discoveries became "old news," the stories lost their luster.[101] The media responded by shifting their angle to the pitfalls and perils of genetics, reporting on cautionary tales of discrimination and the proliferation of designer babies.[102] Regardless of whether the undulating media coverage currently paints genetics with a brush or negative, the public's impression that genetics deserves a unique, tailored discourse has already been solidified in the collective mind.

Throughout the ongoing discourse, the public and media have not ignored the other side of the proverbial genetic coin. Simultaneous with genetics' elevation to its "Holy Grail" status was the emergence of a historically-based distrust of genetics' misuse. While the majority of the public most readily identifies the eugenics movement's apex with the Nazi experiments of World War II, the principles of reproductive selection have existed since the days of Darwin.[103]And as evidenced by the oft-reviled United

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[99] See *Gene Therapy*, HUMAN GENOME PROJECT INFORMATION (Aug. 24, 2011), http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml. Gene therapy remains in the experimental stage and has yet to have a solidly successful clinical trial. The technology has not overcome the difficulties presented by the short-lived nature of gene therapy, immune responses in recipients, problems with viral vectors, and the complex nature of multigene disorders.

[100] Ellen Dupont, *Diagnosing the Geno-Hype: Genetic Determinism in the Mass Media*, 5 THE SCI. IN SOC'Y REV. 20, 21 (Spring 2009).

[101] Suter, *supra* note 94, at 678 n.1.

[102] *See* Dupont, *supra* note 100; *see also* David A. Hyman, *Lies, Damned Lies and Narrative*, 73 IND. L.J. 797 (1998) (discussing the power of anecdotal evidence to shape public opinion); Mike Snider, *How Genetics Can Be Used Against You*, USA TODAY, Nov. 17, 1993, at 9D, available at 1993 WL 6726460; Lisa Goldstein, *If You Knew Your Child Would Be Born Deaf*, S.F. CHRON., Feb. 1, 1999, at A19.

[103] Although deemed most prolific implementation of eugenics practice, the

States Supreme Court case *Buck v. Bell*,[104] the eugenics movement did not culturally confine itself. In fact, eugenics' principles manifested themselves as the underpinning rationale for the Court's upholding of compulsory sterilization in America.[105] Not only did courts promulgate eugenics principles, so too did the legislatures at both the federal and state level. In 1924, Congress adopted the Federal Immigration Restriction Act to curb the migration of persons thought to have defective genes.[106] States, on the other hand, began implementing mandatory genetic screening programs for African Americans in the 1970s, resulting in the unintended, yet harmful stigmatization of the African American population.[107] This brief history of the eugenics movement serves only to illustrate the imbedded distrust present in the public's perception of genetic science.

Many scholars, researchers, and law makers alike have been influenced by the media and the history of genetics as an exceptional science in their quest for solutions to social issues and policy making. As early as the 1970s, legislatures have crafted laws that regulate genetic information separate and apart from other medical information,[108] the most recent genetic-specific legislation being the Genetic Information Nondiscrimination Act signed into law by President Bush in 2008.[109] Contributing to the

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Nazi regime by no means created the practice. The word "eugenics" was coined in 1883 by Francis Galton to refer to the practice of improving the human race by controlling reproduction. Martin S. Pernick, *Eugenics and Public Health in American History*, 87 AM. J. PUB. HEALTH 1767 (1997). In 1922, the American Society for Eugenics was founded in the United States to "stem the tide of threatened race degeneracy," and in 1927, the Supreme Court of the United States justified the use of compulsory reproductive eugenics to sterilize those deemed unfit for reproducing. *Id.* at 1769.

[104] 274 U.S. 200 (1927).

[105] *See id.*

[106] Paul Lombardo, *Medicine, Eugenics, and the Supreme Court*, 13 J. CONTEMP. HEALTH L. & POL'Y 2 (1996).

[107] Howard Markel, *The Stigma of Disease: Implications of Genetic Screening*, 93 AM. J. MED. 209, 210-11 (1992).

[108] Suter, *supra* note 94 at 670 n.1.

[109] Genetic Information Nondiscrimination Act, H.R. 493 (110th Cong. 2008). GINA prohibits health insurance companies and employers from discriminating against individuals based on genetic information, which includes

driving force of the exceptionalism movement was the dedication of "the largest expenditure of money for biomedical ethics and health law in the country" to the study of the ethical, legal, and social issues (ELSI) in genetic research.[110] This unprecedented expenditure generated a vast body of literature and countless studies dedicated exclusively to genetic issues, and "even if much of the scholarship is not explicitly premised on notions of genetics exceptionalism, . . . [it] intensifies the media's attention to genetics issues and public fear about genetics."[111] While many of the same threats for misuse and potential social consequences exist in other disciplines, no other science has captivated the public with equal pervasiveness as genetic science.[112]

The confluence of lofty promises for cures, the trendy appeal of the ethical issues, and the sordid history of misuse can explain genetic exceptionalism in American culture. Traditionally, scholars have analyzed genetic exceptionalism in the areas of employment discrimination, insurance discrimination, and privacy laws.[113] The

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family medical histories and information pertaining to an individual or family member's genetic tests and genetic services. Although several states had already acted to protect against genetic discrimination, GINA served to set the minimum level of protection afforded to individuals.

[110] Suter, *supra* note 94, at 685 n.1 (quoting Robert Weir, *Why Fund ELSI Projects?*, *in* GENES AND HUMAN SELF KNOWLEDGE: HISTORICAL AND PHILOSOPHICAL REFLECTIONS ON MODERN GENETICS 189 (Robert F. Weir et al. eds., 1994)).

[111] Suter, *supra* note 94, at 685-86.

[112] *See* Thomas H. Murray, *Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information*, *in* GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 60, 61 (Mark A. Rothstein ed., 1997); Suter, *supra* note 94. *But see* Eric T. Juengst, *FACE Facts: Why Human Genetics Will Always Provoke Bioethics* 32 J.L. MED. & ETHICS 267 (2004) (arguing that genetic information's intrinsic moral value justifies the continued prominence of genetic exceptionalism in bioethics).

[113] *See* Suter, *supra* note 94; see also Trudo Lemmens, *Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?*, 45 MCGILL L.J. 347 (2000) (discussing the desirability of genetic-specific legislation in the insurance context); Douglas H. Ginsburg, *Genetics and Privacy*, 4 TEX. REV. L. & POL. 17 (2000); Mark A. Rothstein, Genetic Exceptionalism and Legislative Pragmatism, 35 J.L. MED. & ETHICS 59 (2007); Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End to Genetic Exceptionalism*, 40 JURIMETRICS J. 21 (1999) (arguing that there

literature is silent, however, on whether genetic exceptionalism applies with equal force to the patentability of genes debate. In other words, assuming that the statutory requirements for patentability can otherwise be satisfied, should the law reject gene patents based solely on genetic exceptionalism's justification that genes unique characteristics warrant different protections than do other fields of science?

B. Power Play from the Bench: Myriad*'s Insertion of Genetic Exceptionalism into the Patent Act*

The previous sections provide background information to the reader with regard to the law on gene patents and the story of genetic exceptionalism's impact on insurance, discrimination, and privacy laws. In the recent controversial case on gene patents, *Association for Molecular Pathology v. U.S. Patent and Trademark Office*,[114] patentable subject matter collides with genetic exceptionalism for the first time, transforming genetic exceptionalism into a legal principle. In the opinion, Judge Sweet singles out DNA from other isolated products based purely on DNA's information carrying characteristics, while attempting to invalidate DNA patents under a "product of nature" analysis.[115] The court falls short in its explanation of why other purified or isolated products of nature continue to be patentable subject matter. Perhaps influenced by DNA's mystique, the court reasoned that genetic patents differ from patents on antibodies, antibiotics, hormones, metabolites, biologic drugs, and the like, because DNA is solely the "physical embodiment of information."[116] Rather than purely focusing on the chemical makeup of DNA (after all, DNA is comprised of chemically bound strands of molecules), the court

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is no clear demarcation between genetic data and other health information).

[114] 702 F. Supp. 2d 181 (S.D.N.Y. 2010); referred to herein as "*Myriad*."

[115] *See id.*

[116] *See* Noonan, *supra* note 44, at 30 n.17. As Noonan points out, these naturally occurring, isolated products are in "substantially homogenous form, are structurally unchanged from their sources in blood and other bodily fluids, and are less altered than the cDNAs that are the subject of the claims to isolated human DNA invalidated by the district court." *Id.*

embraces the genetic exceptionalism ideals by finding that genes are *inherently different* and thus deserving of unique treatment under the Patent Act.[117] Despite whether genetic information should be treated differently in other contexts—for example with insurance, discrimination, and privacy laws—Judge Sweet overlooks the fact that the genetic information itself is not patented. As such, researchers are able to utilize the genetic information disclosed in the patent for purposes such as performing sequence comparisons or detecting genetic polymorphisms.[118] This section dissects the law on patentable subject matter from the opinion's genetic exceptionalism components, and then evaluates whether the holding can stand based purely on the legal arguments that remain.

1. Background of BRCA1/2 and the *Myriad* Litigation

In 1990, a team of geneticists discovered that a mutation in the BRCA1 gene was linked to an increased risk for developing breast and ovarian cancers.[119] Of the patients with hereditary breast cancer, five to ten percent have a substituted allele that inactivates the BRCA1 gene, leading to an abnormal cellular gene expression of the protein.[120] If a patient has a mutated gene, she has a lifetime risk of 40 to 85 percent for developing breast cancer and a risk of 16 to 40 percent for developing ovarian cancer.[121] Other known factors, such as the type of mutation (e.g., insertion, deletion, or rearrangement of codons) and family history can impact the lifetime risk of developing cancer, as well as the likely interaction

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[117] Some philosophers have viewed genes as more than the "common heritage of mankind," arguing that genes are an "un-encloseable commons-by-necessity . . . . free for use by any and all." David Koepsell, *Naturally Occurring Genes and the Commons by Necessity*, 23 GENEWATCH 32, 34 (Oct.-Dec. 2010).

[118] *Id.* at 31.

[119] Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123, 131 (2002).

[120] *Id.* at 127.

[121] *Id.*

with other genes.[122] The BRCA2 gene is also thought to be a similar acting tumor-suppressing gene.[123]

Mark Skolnick, the co-founder of Myriad, sequenced the BRCA1 gene in August 1994 with the help of a team of researchers from NIH, the University of Utah, and McGill University.[124] Following this discovery, Skolnick and Myriad filed for a U.S. patent claiming the isolated sequence and the associated mutations as both a "composition of matter" and a "method-of-use."[125] The USPTO was quick to issue the patents to Myriad, but further complicated the patentability of BRCA1 by issuing a similar patent to OncorMed.[126] OncorMed's BRCA1 patent differed only slightly with respect to the mutations claimed, overlapping in both the diagnostic and therapeutic applications of the patent.[127] As a result, both patent owners filed infringement suits against the other, but instead of litigating the issue, OncorMed settled by selling Myriad its patent on BRCA1 in 1998.[128]

Understanding the importance of locating and patenting BRCA2, Myriad embarked on a race to discovery against a group of U.K. scientists who were also highly invested in locating the sequence. On December 21, 1995, the day before the U.K. scientists were scheduled to publish its discovered BRCA2 sequence in *Nature* magazine and the day of the U.K.'s planned press conference, Myriad notified the public that they had sequenced BRCA2 and had filed for a U.S. patent.[129] Having now secured patents to both the isolated BRCA1 and BRCA2 genes, Myriad was poised to control the testing market for breast and

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[122] *Id.*

[123] *Id.*

[124] *Id.* at 131. The founders of Myriad were "focused on the discovery and commercialization of genes involved in major common disorders including cancer and heart disease." *Id.* at 129 (citation omitted). Myriad now offers an array of services, ranging from research and development to diagnostics.

[125] *Id.*

[126] *Id.* at 132.

[127] *Id.*

[128] Williams-Jones, *supra* note 119, at 132.

[129] Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 202 (S.D.N.Y. 2010).

ovarian cancer and the market for developing therapeutics to treat patients with one of the mutations.[130]

Over the course of the 1990s, Myriad did not assert its exclusivity rights over its BRCA1/2 patents, but instead allowed researchers to use the tests under certain circumstances. Myriad offered to license its patents to the University of Pennsylvania Genetic Diagnostic Laboratory so that the laboratory could continue its screening program on BRCA1 and BRCA2.[131] Not satisfied with the scope of the license, the University and its physicians rejected the licensing proposal.[132] Myriad subsequently sent cease-and-desist letters to the University of Pennsylvania and on August 26, 1998, sent notice that the physicians were infringing Myriad's patents and filed the infringement suit in November of the same year.[133] Although the laboratory was forced to stop performing tests, Myriad informed the University that it was free to continue academic research on the genes.[134] A similar course of conduct—Myriad offering a license and the plaintiffs rejecting the license—occurred with the other plaintiffs in the case.[135]

Myriad asserted seven patents against the plaintiffs, identifying fifteen claims within those patents that the plaintiffs allegedly infringed.[136] The claims fell into one of two categories: composition claims or method-of-use (or process) claims.[137] Because there were several composition claims within the patent,

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[130] In the years following the issuance of the patents, Myriad developed a host of tests to screen and diagnose patients with an increased risk for breast cancer. Among the tests (listed from least to most expensive) include: (1) a single site test for patients having a family history of the mutation, designed to identifies carriers; (2) a multisite test that searches for three common mutations in the Ashkenazi Jewish population; (3) a comprehensive test identifying the full gene sequence; and (4) a rapid test designed to return the full gene sequence within seven days. Williams-Jones, *supra* note 119, at 133-34. Myriad's tests were arguably more sensitive than other tests offered at the time because Myriad's tests identified each base-pair within the gene. *Id.*

[131] *Myriad*, 702 F. Supp. 2d at 205.

[132] *Id.*

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.* at 212.

[137] *Id.*

the court provided one composition claim as the categorical representative, which read: "An *isolated DNA* coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2."[138]

Similarly, the court provided a representative methods-of-use claim for Myriad, which reads: "A method for detecting a germline alteration in a BRCA1 gene . . . in a human which comprises *analyzing a sequence* of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA . . . ."[139] In layman's terms, the first category of claims at issue covers any use of the isolated gene itself and the second category of claims at issue covers methods used to analyze mutations in the gene that correlate with a predisposition for breast and ovarian cancer.[140]

The plaintiffs brought an action for summary judgment against the USPTO & Myriad asking the court to declare these patents relating to BRCA1/2 invalid for lack of patentable subject matter.[141] The plaintiffs urged the court to find that the patents were improperly issued to cover products of nature, laws of nature, physical phenomena, and abstract ideas, which offend Article I, § 8, Clause 8 of the United States Constitution.[142]

2. A Closer Look at Judge Sweet's Analysis in the *Myriad* Decision

Judge Sweet crystallized the issue before the court as whether "isolated human genes and the comparison of their sequences [are] patentable."[143] He embarked on his legal inquiry by first constructing the claims at issue to determine the scope of the patent protection. The first claim dispute to be resolved involved the terms "DNA" and "isolated DNA."[144] The plaintiffs argued

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[138] *Id.* (emphasis added).
[139] *Id.* at 213 (emphasis added).
[140] *See id.* at 211-17.
[141] *Id.* at 184.
[142] *Id.*
[143] *Id.* at 185.
[144] *Id.* at 216. In construing a patent claim, the court applies several cannons of construction to arrive at a final interpretation. These canons can be broken

that the term "DNA" should be construed to mean "a sequence of nucleic acids, also referred to as nucleotides."[145] As Myriad pointed out, this definition implies that DNA refers to a description of the sequence of nucleic acids (i.e., information only).[146] Myriad contended that "DNA" encompasses a "real and tangible molecule, a chemical composition made up of deoxyribonucleotides linked by a phosphodiester backbone."[147] In resolving this dispute in Myriad's favor, the court looked at the specification of Myriad's patent, which explicitly referred to DNA as a *physical manifestation* of the nucleotides such that the DNA *could be separated* from the other components of the cells that naturally accompany DNA.[148] Similarly, the court adopted Myriad's definition of "isolated DNA" as set forth in the specification, which defined isolated DNA as "a DNA molecule which is substantially separated from other cellular components which naturally accompany a native human sequence . . . ."[149]

The second claim concerned the definition of BRCA1 and BRCA2. The plaintiffs argued that each meant "a particular fragment of DNA found on chromosome 17 [13 for BRCA2] that relates to a person's predisposition to develop breast and ovarian cancer."[150] Once again, however, Myriad acted as its own lexicographer, defining in the patent specification each gene as "a human breast cancer predisposing gene . . . some alleles of which

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down into two categories, intrinsic and extrinsic evidence, with more weight given to the former. Some of the intrinsic evidence considered by a court includes: words of the claims themselves, the written description, and the prosecution history of the patent. *Id.* at 214-15. In looking at this evidence, the court will not read a limitation in a dependent claim into the independent claim, nor will the court read a limitation from the specification into the claim (but does read the claim "in light of" the specification). Finally, if the patentee acts as its own "lexicographer," then the court will use the patentee's definition for a disputed term. The court may also look at the extrinsic evidence available: dictionaries, treatises, and expert testimony. Usually, extrinsic evidence is used to inform the judge of the field of science and technology. *Id.* at 215-16.

[145] *Id.*

[146] *See id.*

[147] *Id.*

[148] *Id.* at 216.

[149] *Id.* at 217.

[150] *Id.*

cause susceptibility to cancer, in particular breast and ovarian cancer."[151] While noting that BRCA1 and 2 are genes normally integrated into chromosomes 17 and 13 respectively, the court again adopted Myriad's construction of the definition.[152]

Having construed the claim language, the court moved into the heart of the analysis: subject matter patentability under § 101 of the Patent Act, which provides, "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 . . . ."[153] Although Congress intended to grant patent protection broadly, § 101 is not without limits. Specifically, the Supreme Court has carved out three categories of non-patentable subject matter: laws of nature, natural phenomena, and abstract ideas. The reasoning behind these exclusions is that although each may be "discovered" in a sense, each comprises the basic tools of science and technological work.[154]

Under the heading, "Patentable subject matter must be 'markedly different' from a product of nature," Judge Sweet emphasized that questions of utility and statutory subject matter patentability are wholly separate inquiries, and only cases decided on subject matter grounds are binding on the court.[155] Judge Sweet relied on *Funk Brothers*, which he described as holding that the mixture of bacteria was not patentable subject matter because it "did not create a state of inhibition or of non-inhibition," but rather maintained qualities that were a work of nature.[156] Despite ample

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[151] *Id.*

[152] *Id.*

[153] *Id.* at 218 (emphasis added).

[154] *Id.* at 218-219 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)). Recall from discussion *supra*, *Chakrabarty* held that a genetically altered bacterium was patentable subject matter because it had "markedly different characteristics from any found in nature and one having the potential for significant utility."

[155] *Id.* at 219, 222.

[156] *Id.* (citing Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 128-31 (1948)). Recall that *Funk Brothers* was deciding the issue whether the mixture was an "invention or discovery," not necessarily whether the mixture was patentable subject matter. Prior to the Patent Act of 1952, "invention or discovery" was interpreted as the non-obvious prong for patentability. *See* Brief

evidence that *Funk Brothers* was decided on grounds other than subject matter patentability,[157] however, the court interpreted the case as standing for the exclusion of natural phenomena from subject matter patentability.[158]

The court next turned in passing to *Chakrabarty*, which is arguably more controlling in *Myriad* since it was decided under § 101 of the current Patent Act.[159] While he included some of the language of the opinion, Judge Sweet omitted any meaningful discussion on the analysis underlying the Court's holding. For instance, he seemingly glossed over the part of the *Chakrabarty* opinion that states that without a specifically designed exception from Congress, § 101 should be construed broadly and in such a way that includes living things.[160] Since the decision, *Chakrabarty* has supported patenting living products that have "markedly different characteristics from any found in nature and one having the potential for significant utility."[161]

Throughout the next several pages of the *Myriad* opinion, Judge Sweet proffered a litany of cases that essentially require "something more" than merely isolating or purifying a substance from its native state to fall within the scope of statutory subject matter.[162] Read collectively, these cases require that a patentable product have qualities or characteristics that were absent in its

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for Alnylam Pharmaceuticals, Inc. as Amici Curiae Supporting Defendants-Appellants, Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 133 S.Ct. 694 (2012) (No. 12-398) at 8 ("Debunking myths of Funk Bros. Seed Co. v. Kalo Inoculant Co."), available at http://patentdocs.typepad.com/files/alnylam-amicus-brief.pdf. There is ample language in the *Funk Brothers* opinion that suggests the mixture was not patentable because the proffered "invention" conferred no new quality or use (i.e., obvious) for any one bacterium in the mixture or for the collective whole. Rather, the mixture merely provided consumers with a more convenient way to purchase the component bacteria.

[157] *See id.* For a discussion on this very issue, visit the 37 Thoughts legal blog, available at http://37thoughts.wordpress.com/2010/03/30/save-the-funk-brothers/.

[158] *Myriad*, 702 F. Supp. 2d at 222.

[159] *Id.* at 223.

[160] *Chakrabarty*, 447 U.S. at 318.

[161] *Id.* at 310.

[162] *Myriad*, 702 F. Supp. 2d at 223-28.

natural form.[163] As examples, the court cited to refined cellulose, artificial alizarine dye, purified tungsten, and isolated pine needle fibers, all of which were rejected as non-patentable subject matter.[164]

Turning to precedent relied on by Myriad, Judge Sweet summarily rejected the applicability of *Parke-Davis*, which Myriad asserted as establishing that the purification of a naturally occurring product (i.e., adrenaline) was patentable subject matter.[165] He noted that *Parke-Davis* was decided on novelty—not subject matter—grounds and was therefore not applicable to the present case being decided under § 101.[166] In so doing, he cast the language in *Parke-Davis*, which stated that "even if [adrenaline] were merely an extracted product without change, there is no rule that such products are not patentable," as dicta.[167] Judge Sweet went on to distinguish other cases cited by Myriad based on similar reasoning.[168]

Finally, almost as an afterthought, Judge Sweet briefly addressed *Merck & Co., Inc. v. Olin Mathieson Chem. Corp.*,[169] which held that a higher concentration of purified Vitamin B12—capable of treating anemia—was a patentable composition of matter.[170] The purified B12 was created through an artificial fermentation process that allowed for the production of a greater concentrated product than the naturally occurring B12 produced by cows.[171] Because of the different concentration and effectiveness as a therapeutic agent, the *Mathieson* court reasoned that the new product was not the same as the old naturally occurring product, but rather a "new and useful composition entitled to the protection

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[163] *See id.*

[164] *See id.*

[165] *See id.* at 225.

[166] *Id* at 225-26.

[167] *Id.* at 226 (quoting Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911)).

[168] *Id.* at 225-27.

[169] 253 F.2d 156 (4th Cir. 1958).

[170] *Myriad*, 702 F. Supp. 2d at 227.

[171] *Mathieson*, 253 F.2d at 165.

of the patent."[172] Without scratching the surface of the case, Judge Sweet merely pointed out the court's conclusion that purified Vitamin B12 was more than a "mere advance in the degree of purity of a known product."[173]

3. Genetic Exceptionalism Transcribed into Legal Principle: Isolated DNA is not "Markedly Different" from Native DNA

After setting forth the legal precedent, Judge Sweet identified the applicable test for determining the subject matter patentability of Myriad's isolated BRCA1 and BRCA2 gene patents. Namely, whether the isolated DNA claimed in the patent possesses "markedly different characteristics" from the native (or genomic) DNA.[174] Focusing on the chemical make-up of DNA, Myriad argued that the isolated DNA *is* markedly different because it differs both structurally and functionally from genomic DNA.[175] Instead of looking at the similarities and the differences between the two compositions, Myriad argued the court should look exclusively at the differences.[176] Judge Sweet rejected this approach, citing Supreme Court precedent that requires claims be considered as a whole.[177] While a correct statement of the law, the law may be misapplied; reading the claim as a whole means looking at the entire claim regarding *isolated* DNA, not the genomic DNA that falls outside the scope of the patent.[178]

At this point in the opinion, Judge Sweet diverges from a purely legal argument into what is viewed by some as carving out an exception for gene patents based on the inherent information carrying function of genes themselves. He explained that focusing on the chemical nature of DNA "fails to acknowledge the unique characteristics of DNA that differentiate it from other

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[172] *Id.*
[173] *Myriad*, 702 F. Supp. 2d at 227 (quoting *Mathieson*, 253 F.2d at 164).
[174] *Id.* at 227-28.
[175] *Id.* at 229.
[176] *Id.*
[177] *Id.*
[178] *See id*. at 228.

compounds."[179] Without citing any legal authority justifying why DNA *should* be considered differently under the Patent Act, he goes on to explain that even if other chemical compounds contain information, the information encoded in DNA reflects its primary biological function: "[DNA] direct[s] the synthesis of . . . proteins, biological molecules of enormous importance, which catalyze biological chemical reactions and constitute the major structural materials of the animal body."[180] Thus, DNA could be seen as the "physical embodiment of laws of nature."[181]

Given the unique nature of DNA, Judge Sweet reasoned that the structural and functional differences raised by Myriad were not "markedly different."[182] Rather than explaining why the differences are not relevant to an inquiry into the nature of native versus isolated DNA, he jumped to the conclusion that neither is relevant because of the "overriding importance of DNA's nucleotide sequence to both its natural biological function as well as the utility associated with DNA in its isolated form."[183] In other words, because isolated DNA preserves the important characteristics of native DNA, isolated DNA can never be "markedly different."[184] He goes on to state that the "defining characteristic of DNA in its native and isolated forms *mandates the conclusion* that the challenged composition claims are directed to unpatentable products of nature."[185]

In its attempt to persuade the court, Myriad delineated several distinctions between isolated DNA and native DNA. First, they argued, there are structural differences because isolated DNA is

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[179] *Id.* In response to biotech's assertion that invalidating gene patents will lead to invalidating pharmaceuticals, Judge Sweet states: "The conclusions reached in this opinion concerning the subject matter patentability of isolated DNA . . . are based on the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature." *Id.* at 228 n. 51 (emphasis added).

[180] *Id.* (internal quotations omitted).

[181] *Id.*

[182] *Id.* at 229.

[183] *Id.*

[184] *See id.*

[185] *Id.* (emphasis added).

not associated with chromosomal proteins.[186] The court rejected this argument, stating it was only a matter of purity.[187] Next, Myriad asserted that native DNA contains introns (noncoding regions) that are absent from the isolated or purified DNA, which only contains the exons (coding regions).[188] However, Judge Sweet found that because the isolated DNA contains *some* of the same gene fragments (e.g., the same fifteen nucleotide sequence), the two are not sufficiently different.[189] Judge Sweet stated that the claims covering the compositions of matter for BRCA1/2 (i.e., cDNA molecules) cover the same product that is produced by naturally-occurring splicing within the cell.[190] Yet he failed to recognize that the isolated DNA—as a chemical molecule—is much smaller, not three dimensional, and lacks the chemical complexity of genomic DNA, all properties which permit novel and innovative uses.[191]

Arguably, Myriad's strongest argument rested with isolated DNA's ability to be practically applied in ways that native DNA cannot. By extracting and significantly altering native DNA, scientists are able to use the isolated molecules to improve patient health care.[192] With the adapted DNA, scientists are able to perform diagnostic tests using the molecule as a probe, primer, or template for sequencing genes.[193] Likewise, isolated DNA opens the door to medical treatment options ranging from preventative care to gene therapy.[194] Without the isolated DNA molecules, none of these health care innovations would be possible.[195]

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[186] *Id.* at 228-29.
[187] *Id.* at 229.
[188] *Id.* at 230.
[189] *Id.*
[190] *Id.* at 229-230.
[191] *See* Brief for Am. Intellectual Prop. Law Ass'n as Amici Curiae Supporting Neither Party, Ass'n for Molecular Pathology v. USPTO, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010–1406) at 14, available at http://www.aipla.org/Advocacy%20Shared%20Documents/AIPLA-Myriad-Amicus-filed.pdf [hereinafter "AIPLA Brief"].
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] *Id.* at 14-15.

Finally, Judge Sweet hypothesized that a "time may come when the use of DNA for molecular and diagnostic purposes may not require such purification."[196] This consideration runs contrary to patent law, which requires the evaluation for patentability to take place at the time of the invention, regardless of any subsequent innovations.[197]

Notwithstanding the newly derived capabilities of isolated DNA, the court erroneously rejected these differences, instead electing to focus on the information carrying characteristics of inherent in the nucleotide sequence. In so doing, Judge Sweet elevates DNA to a greater status than other chemical molecules—excepting genetic science from other fields of discovery. There is nothing in precedent or the Patent Act that demands DNA be treated differently than the molecules which comprise it. It follows that if Judge Sweet had not cast DNA as an elite chemical substance, the decision may have fallen more in line with that of the Court of Customs and Patent Appeals in *In re Bergy*.[198]

In *Bergy*, the court was presented with the question whether the discovery of a biologically pure bacterium for pharmaceutical use, providing an indispensable medical tool, was patentable.[199] The court reasoned,

> [M]icroorganisms have long been important tools in the chemical industry, especially its pharmaceutical branch, and when such a *useful, industrial tool* – [the tools used by chemical manufacturers in the same way as they use chemical elements, compounds, and compositions] – is invented which is new and unobvious, so that it complies with those conditions for patentability, we see no reason to deprive it or its creator or owner of the protection

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[196] *Myriad*, 702 F. Supp. 2d at 232.

[197] *See* 35 U.S.C. § 103 (stating the time for evaluating obviousness against prior art is at the time of invention, not the time of the patent application's evaluation).

[198] 596 F.2d 952 (C.C.P.A. 1979) (affirmed sub nom Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

[199] *Id.*

> and advantages of the patent system by *arbitrarily excluding* it at the outset from the § 101 categories of patentable invention on the *sole ground that it is alive*. It is because it is alive that it is useful. . . .[200]

By analogy, DNA's chemical characteristics enable it to be used as a medical tool, but not unless it is isolated and purified. Without the man-made changes, the DNA molecule is unable and unreliable as a diagnostic tool. Thus, neither law nor fact supports arbitrarily excluding isolated DNA from patent protection owing to the fact that it carries the same information as genomic DNA. As an *Amicus Curie* brief eloquently summarized, "By selectively assigning dispositive importance to one shared characteristic of the claimed purified/isolated DNA molecules and discounting all the differences, the District Court adopted precisely the rationale that *Bergy* rejected."[201]

CONCLUSION

After reviewing Judge Sweet's 152-page opinion, the Author would argue that there is no legal or factual basis for declaring isolated DNA outside the scope of patentable subject matter. Instead, it appears that the impetus behind the *Myriad* decision is rooted in genetic exceptionalism. By adhering to the principles of genetic exceptionalism, the opinion tends to overlook legal precedent to arrive at a conclusion that the nature of DNA as information carriers naturally exempts itself from patent protection absent an express exclusion from Congress. One could conclude that the *Myriad* decision was largely influenced by the societal, moral, and ethical issues—not by the legal precedent—raised by the plaintiffs. The opinion devoted several pages to the negative impacts that gene patents have on costs and access to health care as well as the possible chilling effect on research innovation. While these are important considerations in determining patent *policy*, they are not factors to be applied under the Patent Act. If such was the case, patented and statutorily permissible subject matter—such

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[200] *Id.* at 975 (emphasis added) (internal citations and quotations omitted).
[201] AIPLA Brief at 17 (citing *Bergy*, 596 F.2d at 975).

as pharmaceuticals example—could be invalided solely based on similar policy concerns. Whether one agrees that genetic information should be treated different, almost reverently, deciding whether to adopt genetic exceptionalism is a matter of public policy rather than legal principle.[202] Thus mandating that the Patent Act subject matter patentability requirement be interpreted through the lens of genetic exceptionalism is a power not conferred to the bench, but rather to Congress.

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[202] Perhaps Chief Justice Burger stated it best in *Chakrabarty*, when addressing the judicial branch's place in making policy decisions:

> The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

447 U.S. at 317.