Every Woman Deserves Her Own Pair of Genes: The Constitutionality of Patenting the BRCA Genes in Association for Molecular Pathology v. U.S. Patent & Trademark Office

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EVERY WOMAN DESERVES HER OWN PAIR OF GENES: THE CONSTITUTIONALITY OF PATENTING THE BRCA GENES IN ASSOCIATION FOR MOLECULAR PATHOLOGY V. U.S. PATENT & TRADEMARK OFFICE

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I. INTRODUCTION

Every person’s body contains an array of complex and unique information, known as DNA. These segments of proteins and molecules instruct the body how to develop and function, and are the most basic ingredients of every person’s individuality and distinct life experience. Genetic discoveries and identification of specific mutations have even contributed to the academic, corporate, and health communities in uncovering secrets and insight into the human body, health, and disease. An example of a recent genetic breakthrough was the identification of the human genes associated with hereditary breast and ovarian cancer, known as BRCA1 and BRCA2, which can help patients gain insight as to whether they are at risk of developing these diseases. In maximizing the benefits and possibilities of genetic discoveries for public health, ease of access “is crucial if basic research is to be expeditiously translated into clinical laboratory tests that benefit patients in the emerging era of personalized and predictive medicine.”

In an effort to reward and protect this new wealth of information and scientific advancements, the U.S. Patent and Trademark Office (USPTO) has granted thousands of patents on human genes, including BRCA1 and BRCA2, which give patent holders “the right to prevent anyone from studying, testing or even examining a gene.” While the public can in fact benefit

1. See AMERICAN CIVIL LIBERTIES UNION, LEGAL CHALLENGE TO HUMAN GENE PATENTS 2 (May 27, 2009), available at http://aclu.org/pdfs/freespeech/brca_qanda.pdf [hereinafter LEGAL CHALLENGE TO HUMAN GENE PATENTS].
3. See Laurie L. Hill, The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs, 11 TEX. INTELL. PROP. L.J. 221, 222 (2003) (“In order to understand health and battle disease, scientists seek an understanding of [human] genes, hoping to improve our lives and cure the diseases that plague us. The complete sequencing of the human [genes] offers unprecedented opportunities for scientific advancement and medical breakthroughs.”).
5. Complaint, supra note 2, at 2; see also Hill, supra note 3, at 228 (Proliferation of diagnostic genetic testing “will undoubtedly aid physicians in diagnosing patients and in practicing more effective preventative medicine.”).
7. LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 1. Because patent holders have exclusive rights over the genes themselves, they essentially have “a monopoly over the patented genes and all of the information contained within them.” Id.
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from an efficient patent system, unsound patents or "government sanctioned restraints on freedom and competition" can also "harm the public by making products and services more expensive, if not completely unavailable, by preventing scientists from advancing technology, by unfairly prejudicing small businesses, and by restraining civil liberties and individual freedoms." 8

Association for Molecular Pathology v. United States Patent & Trademark Office 9 was originally filed on May 12, 2009 by the American Civil Liberties Union (ACLU) and the Public Patent Foundation, on behalf of numerous patients and researchers; and it is a new demonstration of concern for the non-patent holding public, whose interests and voices have been absent in the decision-making about the current patent system. 10 One of the plaintiffs, Genae Girard, was diagnosed with breast cancer at the age of thirty-six, 11 and in an effort to gain information about treatments and medical decisions, she stated:

I... decided to be diligent about getting second opinions along the treatment path ... [but] one company has a monopoly on genetic testing of the BRCA genes. After I was diagnosed with cancer, I was tested for hereditary risk for breast and ovarian cancers. Mutations on [those] genes can show if you are at higher risk for these cancers. I tested positive. ... [O]nly one company... has the ability to sequence them. I can’t get a second sequencing done at a different company to validate my results. I am thinking about having my ovaries removed... It is uncomfortable making such an important decision based on only one test... Having... your ovaries removed [is a] serious procedure[] that cannot be undone. Patents on human genes should not block patients’ ability to get second opinions. 12

10. Id. at 369–72; see American Innovation at Risk, supra note 8, at 2 ("[T]he patent community culture tends to dismiss and exclude the opinions of those it sees as unsophisticated outsiders, but it is mostly because the general public does not yet realize how much the patent system actually affects them.").
12. Id. (statement of Genae Girard). Genetic studies “will likely continue to identify many... genetic risk factors for common diseases. To continue translating these genetic discoveries into improved health and quality of life, it is critical to ensure that affordable,
The federal case of Association for Molecular Pathology, filed in the Southern District of New York, attempts to attack genetic patenting through theories and policies behind patent law, medicine, science, breast cancer activism, and "unusual civil liberties argument[s] in ways that could make it a landmark case."\[^{13}\]

With the advent of technology, patent law addresses many things which the Framers of the Constitution surely did not anticipate. Nevertheless, "[p]atent law should not trump [c]onstitutional rights nor be used to impede its own goal of advancing technology."\[^{14}\] This article will analyze the validity of DNA patents, specifically the patent on the genes associated with breast cancer, by applying the novel legal arguments raised in the pending case of Association for Molecular Pathology, as well as suggest the need for an exemption from infringement liability for exercising constitutional rights such as freedom of speech, expression, privacy, and bodily integrity. Section II of this article will begin with background information and history behind patent law, its constitutional purpose, and how it has been applied to DNA. It will also discuss the formation and opposition to the BRCA gene patents by explaining the causes of action in the Association for Molecular Pathology complaint. Furthermore, Section II will address the need for a new interpretation of gene patents by addressing the problems with the current laws and precedents, as well as the controversy and debate of patenting something which is naturally part of the human body. Section III will look to theories and interpretations of the First and Fourteenth Amendments as new grounds for attacking patents on human genes. Finally, Section IV will conclude by discussing the recent cases and how they have changed the analysis of patent claims in the Federal Circuit courts. It will also anticipate the defenses the patent holder of the BRCA may raise, as well as the implications of the Association for Molecular Pathology lawsuit and how patent law might be affected in the future.


\[^{14}\] *American Innovation at Risk*, supra note 8, at 16.
II. History and Constitutional Principles of Patent Law, DNA, and the BRCA Genes

A. Defining and Interpreting Genes and Patentable Subject Matter

Under section 101 of the Patent Act, there is no specific subject matter proscription on what is patentable.\footnote{See 35 U.S.C. § 101 (2006).} “[L]aws of nature, physical phenomena, and abstract ideas” are not patentable subject matter.\footnote{Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). “A principle, in the abstract, is a fundamental truth.” Parker v. Flook, 437 U.S. 584, 589 (1978) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)) (internal quotations marks omitted); accord Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948). Such discoveries “are manifestations of... nature, free to all men and reserved exclusively to none.” Id.} While a mathematical formula is not a patentable invention, a patent may exist where there is a new function produced with the aid of knowledge of such a mathematical formula.\footnote{Diamond v. Diehr, 450 U.S. 175, 192 (1981).} Consequently, patents may be obtained for any new or useful process, machine, manufacture, or composition of matter.\footnote{See Flook, 437 U.S. at 588–89.} However, it is not always clear how to distinguish an unpatentable principle from a patentable process.\footnote{Id. at 589; see also Lab Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 134 (2006) (per curiam) (Breyer, J., dissenting) (“[M]any a patentable invention rests upon its inventor’s knowledge of natural phenomena; many ‘process’ patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process.”).} Because of the lack of legislative guidance, courts have extreme difficulty in determining “what a patent does and does not cover,” and the discretionary “‘broadest reasonable construction’ standard” is often used to evaluate the validity of a patent claim.\footnote{Id. at 589; see also Lab Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 134 (2006) (per curiam) (Breyer, J., dissenting) (“[M]any a patentable invention rests upon its inventor’s knowledge of natural phenomena; many ‘process’ patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process.”).} As a result, quality of patent law has suffered, and private patent holders have the potential ability to deny the American people of significant advances that may benefit and address the needs of the public.\footnote{Id. at 15. “That fundamental limitation on the scope of what can be patented is needed to protect the public domain of science and nature from being appropriated through private property rights.” Id. at 17.}

Underlying the constitutional tests and congressional conditions for patentability is the balancing of two interests—the interest of the public in being protected against monopolies and in having ready access to and use of new items versus the interest of the country, as a whole, in encouraging invention by rewarding creative persons for their innovations. By declaring a constitutional
standard of patentability, however, the Court, rather than Congress, will be doing the ultimate weighing.\textsuperscript{22}

Currently, the USPTO awards patents on human genes,\textsuperscript{23} usually meaning that the patent holder prevents laboratories from analyzing “the gene for mutations in order to diagnose the presence of a disease or condition, such as breast cancer,” without permission and a high priced licensing fee.\textsuperscript{24} Approximately twenty percent of all human genes are patented, including those associated with Alzheimer’s disease, asthma, and some forms of colon cancer.\textsuperscript{25} Ever since the Supreme Court held that a genetically altered bacterium could be patented in the case of \textit{Diamond v. Chakrabarty},\textsuperscript{26} courts have interpreted patent law to “include anything under the sun that is made by man.”\textsuperscript{27}

The Supreme Court has recognized the danger of granting patents that cover broad subject matter through application—especially in areas that are vast and unknown.\textsuperscript{28} Defining the term “gene patent” and what it encompasses is not an easy task, and is open to interpretation.\textsuperscript{29} With the increase in knowledge regarding genes, the term “gene” does not only cover the genetic material that encodes a protein in the human body, but also would include that broad sense of genetic sequencing of the entire segment of the relevant DNA.\textsuperscript{30} Some argue that gene patents cover molecular constructions that do not exist in nature and are corresponding structures that are derived from naturally occurring genes.\textsuperscript{31} The debate over patenting genes derives from the fact that “naturally occurring genes as they exist in their native state—as they exist in the human body—are unpatentable . . . raw genetic sequence information;” but the irony of precedent is that the isolation and “purification of a natural product from its native environment can confer patentability on the purified [gene].”\textsuperscript{32}

\textsuperscript{22} S. Doc. No. 108-17, at 315 (2004).
\textsuperscript{23} LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 3.
\textsuperscript{24} Hearing: Stifling or Stimulating, supra note 12, at 3 (statement of Marc Grodman).
“[E]xcept when blocked by exclusive licenses, clinical laboratories compete. We compete on service. . . . We compete on quality. . . . We compete on price. . . .” \textit{Id.}
\textsuperscript{25} LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 3.
\textsuperscript{26} 447 U.S. 303 (1980).
\textsuperscript{27} \textit{Id.} at 309 (quoting S. Rep. No. 1979, at 5 (1952); H.R. Rep. No. 1923, at 6 (1952)).
\textsuperscript{30} \textit{Id.}
\textsuperscript{31} \textit{See id.} at 313 (emphasis added).
When patent claims are drafted so that they cover any "recombinant or isolated form of naturally occurring gene sequence,... they would appear to cover any biotechnological product or process making or using the claimed sequence," thereby having a patent over the gene per se.33 In this way, courts are treating genes "as products in and of themselves, instead of guides to future product discovery."34 Accordingly, many argue that granting private property rights over "such a fundamental aspect of our common human heritage strikes some as an affront to human dignity."35

B. Myriad Problems

[A] "useful" invention is one "which may be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous and insignificant"—and upon the assertion that to do so would encourage inventors . . . to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge.36

The patent over the BRCA genes held by Myriad Genetics, a private biotechnology company in Utah, is an example of a detrimental broad patent claim.37 As researchers around the world were getting closer to isolating the first gene to be associated with hereditary breast cancer, researchers from Myriad applied for the patent, claiming they were the first to discover the genetic sequencing.38 The patent relates "generally to the field of human genetics," covers "methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene," and "also relates to the therapy of human cancers which have a mutation in the [patented] gene, including
gene therapy [and] protein replacement therapy." Unfortunately, Myriad's broad patent claim also covers the ownership over the rights to screening for drugs relating to cancer therapy, as well as screening for gene mutations, which are essential to understand a person's predisposition to breast and ovarian cancer.

The suit filed against the USPTO and Myriad asserts that the patent over the naturally occurring genes should not be patented simply because they are "'isolated from their natural state and purified.'" A gene that is isolated and removed from a human body functions the same exact way as does a non-isolated gene inside the body. Therefore, removing the gene—a product of nature—does not change the fact that it still remains and functions as a product or law of nature. Furthermore, by patenting a correlation of certain mutations with a high risk of breast or ovarian cancer, Myriad has an unlawful patent over an abstract idea or principle, which allows them to gain a monopoly over a scientific fact.

Because the patent is over the actual genes, rather than a genetic test, scientists and laboratories are prevented from performing alternative testing on the genes. Breast cancer is not a rare disease, but instead is one of the leading causes of death among women. Right now, there are about two thousand different mutations along the BRCA genes, but because of Myriad's broad patent claim and its incomplete genetic testing, little is known

40. See id.
41. Complaint, supra note 2, at 19.
42. Id.
43. Id.
44. See LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 4. Laboratory Corp. of America Holdings involved the natural relationship between elevated hormone deficiencies in B vitamins in human blood, but Justice Breyer and the dissent would have held that such a correlation is merely an observable aspect of biology and the human body. See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 135 (2006) (per curiam) (Breyer, J., dissenting). The patent merely covered instructions for reading and understanding the significance of numbers in light of already acquired medical knowledge. Id. at 137.
45. LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 3.
about this vast array of information which may be vital to a woman deciding to undergo preventative surgery.  

Researchers and clinicians cannot develop or implement new tests for breast/ovarian cancer linked to BRCA1 or BRCA2 if development or implementation involves looking at [the genes]. Women cannot give their blood or DNA to a researcher or clinician and obtain a second opinion. The effect is to infringe on quality medical practice and to compromise quality assurance and improvement of testing.

C. Impeding the Progress of Science and the Useful Arts

Article I, Section 8 of the Constitution gives Congress the broad 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." Patent law, therefore, is aimed at fostering productive efforts by providing inventors exclusive rights as an incentive for their research and intellect. The rationale behind the purpose and efficiency of patents is that competitors will be encouraged "to 'invent around' the patented invention, avoiding wasteful duplication of efforts, and insuring the eventual dedication of invention to the public with the expiration of the patent." Particularly in the field of diagnostic testing, competition is "critical to protection of the public health." The Framers of the Constitution, therefore, were concerned with "promoting certainty" in addition to the federal policy objectives.

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With the breast cancer test, more reliable laboratory tests will enable better treatments or at least enable more rational decisions about electing experimental treatments. . . . There is a large number of diseases that could be potentially diagnosed and treated more effectively through improved diagnostic testing . . . . However, researchers [cannot improve a genetic test] if broad diagnostic claims are allowed to remain valid, even when there is a[n] . . . unmet need for such an improvement.

Id. at 172–73.

49. Complaint, supra note 2, at 18–19.


52. Hill, supra note 3, at 236.

53. Hearing: Stifling or Stimulating, supra note 12, at 3 (statement of Marc Grodman).

The underlying policy behind patent law is that discoveries and inventions should be used fully and freely. Genes are at the forefront of public interest, considering that many of them may hold the keys to life-saving medical and scientific discovery and innovation. Unlike other patents on more tangible and concrete inventions, genetic discoveries have been publicly funded through initial research, but private biotechnology companies, such as Myriad, and the pharmaceutical industry are those that perform private research under a patent in order to strive towards a commercially viable use. However, some argue—such as those parties opposed to Myriad's exclusive rights—that these privately funded patent holders are usually not interested in making any further end product, or do not have the capability of doing so. When this happens, further development is prevented because intellectual property rights in genes and diagnostic testing are being protected too early in the research process.

In a survey of clinical laboratory directors that perform DNA-based genetic tests—including members of the Association for Molecular Pathology—a study analyzing the effects of patents on genetic testing revealed that laboratories were being prevented from continuing already developed genetic tests because of gene patents. Because genetic laboratories have the ability and knowledge to perform and translate clinical tests without the publication of data supplied by gene patents, there is the argument that these gene patents are not necessary to provide the incentive for others to develop new innovations in genetic discoveries. On the contrary, when a genetic variant is discovered and sequenced, such as the BRCA genes, patents are not crucial for the development of the initial invention.

The patent held by Myriad makes ease of access to genomic discoveries restricted, and the BRCA genes have been underused in medical and scientific breakthrough as a result of the over-exclusive use of the patent holder. If the potential uses and benefits of these genetic discoveries are not made available to the public, access to personalized and predictive medicine is

55. See id. at 338.
56. Horn, supra note 34, at 262.
57. See id. at 263.
58. See id. at 265.
59. See id.
61. See id. at 8.
62. See id.
63. See Complaint, supra note 2, at 2; see also American Innovation at Risk, supra note 8, at 14 ("[T]here does come a point at which over rewarding patent holders can in fact retard technological development.").
Because the BRCA genes are not the only genes or factors associated with breast cancer, there is still a lot to be uncovered about the disease in order to maximize the benefits of genetic testing and technology. However, because Myriad can decide how many tests will be done, and who is entitled to receive and perform the tests, only a limited number of individuals are using and testing the new information. In a statement regarding the danger of patents on patients' rights by prohibiting medical innovation, the American Society for Clinical Pathology reported:

[Myriad's] gene patents limit the broad availability of diagnostic tests due to the simple fact that laboratory scientists are prohibited from performing genetic tests because of patent enforcement and the threat of litigation. As a result, the market is dominated by a single provider, eliminating competition and scientific diversity, which ultimately drives up costs. Such patents stifle the innovative process, negating further refinement in test methodology, improvements in quality, and access to testing.

Perhaps the most disturbing effect of the Myriad patent over the BRCA genes is that because there is little incentive for competition due to fear of litigation, there is little incentive to improve the quality of testing performed by Myriad. As a consequence, the company continues to deliver confusing and ambiguous results. Because of the limited avenues of testing provided by Myriad, women and their families are left without knowing whether they should make a life-altering decision affecting their bodies, health, and value of life.

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64. Complaint, supra note 2, at 2.
65. See Horn, supra note 34, at 272–73 (“Science has moved away from thinking that one gene is responsible for each disease. . . . [M]ultiple genes work in coordination; therefore, in order to treat or cure a disease, research and experimentation upon many genes and their functions is necessary.”).
66. Id. at 269, 275.
67. Plaintiff Statements, supra note 11. “In breast cancer genetic testing, . . . we have seen no innovation in the past five years—since Myriad Genetics introduced its most recent test.” Id. (statement of Dr. Harry Ostrer).
68. Hearing: Stifling or Stimulating, supra note 12, at 4 (statement of Dr. Wendy Chung).
69. See id.
70. See id.
I. The Need for Dynamic Constitutional Interpretation

As those in the medical profession continue to be cooperative and open about their intellect and ideas within their studies, the case against Myriad demonstrates the need to interpret gene patent claims through a new alternative means of constitutional purpose.\(^{71}\) When the Framers of the Constitution drafted the provision regarding congressional authority over patents, the science of genetic sequencing was surely not in their field of thought or imagination.\(^{72}\) Therefore, like the Constitution itself, patent claims are drafted broadly to adapt to current social and legal issues in light of precedents that are already understood and well known.\(^{73}\) Patent holders should not be able to construct their own claims and laws in order to fulfill their own private interests; rather, only Congress holds the broad power to grant patents to fulfill the constitutional intent of "promoting the sciences and useful arts."\(^{74}\)

When patents no longer function as the Framers intended, patents are unconstitutional. As the plaintiffs in Association for Molecular Pathology contend, patent law affects many fundamental rights.\(^{75}\) Awarding a patent for a human gene, such as those associated with breast cancer, prevents scientific advancement and intellectual freedom by obstructing the free exchange of information that is vital to the workings of democracy.

III. NOVEL LEGAL CHALLENGES: GENE PATENTS AS A CIVIL LIBERTIES ISSUE

In order to uphold the validity of the plaintiffs’ unprecedented constitutional challenges against patenting genes in Association for Molecular Pathology, one must understand the inner workings of the relationship between patent law and constitutional rights in order to appreciate these novel arguments, keeping in mind that the Constitution, as a political invention, and patents, as a physical invention, are both, in some sense, a source of intellectual, social, and human development.\(^ {76} \) Because Congress’ power over patents derives from the Constitution itself, "constitutional interpretation must be freed from the [past] circumstance[s] of the Framers,” in order to allow

\(^{71}\) See Katopis, supra note 54, at 387.

\(^{72}\) See Thomas K. Landry, Constitutional Invention: A Patent Perspective, 25 Rutgers L.J. 67, 92–94 (1993) (“It has been necessary to adapt the Constitution to our advancing technologies . . . . The case for accommodation of progress without originalist objections . . . is supported by the interpretative accommodation of progress in patent law.”).

\(^{73}\) See id. at 90–91.

\(^{74}\) U.S. CONST. art. I, § 8.

\(^{75}\) See generally Plaintiff Statements, supra note 11.

\(^{76}\) See Landry, supra note 72, at 97 (emphasis added).
modern interpreters and judges to accommodate the changes caused by the new unknown realm of intellectual property that is engraved in genetic sciences.\textsuperscript{77} The power granted to a patent holder is created by constitutional power.\textsuperscript{78} Thus, constitutional law demands the flexibility and endurance of protections of fundamental liberties and core principles of a democratic society. To achieve the constitutional requisites of patent law, one must develop new conceptions of constitutional rights as exemptions from governmental power.\textsuperscript{79} Patents exist only for a limited lifetime.\textsuperscript{80} The Constitution lives forever. The enumerated power granted to Congress in Article I "is not an end in itself for the typical citizen in whose name the Constitution was ratified as supreme law."\textsuperscript{81}

A. \textit{Granting Exclusive Licenses Infringe on First Amendment Rights}

Although the First Amendment states, "Congress shall make no law . . . abridging the freedom of speech, or of the press,"\textsuperscript{82} the text also applies to other forms of conduct and communication, such as expression of ideas and knowledge, self-expression, and the dissemination of information.\textsuperscript{83} Patent law serves the same purpose as does the First Amendment—to place knowledge and innovation on an equal playing field in order to develop new ideas based on actual merit and effort, and not based on what is dictated by more powerful organizations and the government.\textsuperscript{84} Therefore, if a gene patent prevents the progress of scientific and medical breakthroughs and innovations, the First Amendment is inevitably implicated because the federal government has awarded the patent holder with the exclusive rights to deny others from researching the genetic sequences, which results in the silencing of future knowledge, ideas, and expression.\textsuperscript{85} After all, "[t]he first amendment is there so as to enrich the gene pool of ideas."\textsuperscript{86}

\textsuperscript{77} Id.
\textsuperscript{78} See U.S. CONST. art. I, § 8.
\textsuperscript{80} See Hill, supra note 3, at 233.
\textsuperscript{81} BARBER, supra note 79, at 106.
\textsuperscript{82} See generally FARBER, supra note 83. It is important to "preserve a predominantly free enterprise economy, [and] the allocation of our resources . . . will be made through nu-
In the case of Association of Molecular Pathology, the patent for the BRCA genes is drafted in such a way that it gives Myriad not only exclusive rights but also exclusive license, which makes it more difficult for others to express opinions and share ideas regarding the breast cancer enigma. If patents such as the one held by Myriad are an unconstitutional private ownership of a basic idea or human knowledge, then the gene patent therefore infringes on the First Amendment rights of researchers, doctors, patients, and the American public, who have a fundamental right to access known, beneficial public information. There are thousands of physicians, researchers, pathologists and scientists who are able and willing to look at and sequence a person’s BRCA genes and determine whether a mutation exists that would increase that person’s risk of breast or ovarian cancer. Genes contain the necessary information towards developing cures and therapies for diseases; however, “[t]he only thing that prevents those doctors and scientists from looking at the human BRCA1 and BRCA2 genes is Myriad’s patents.”

1. Self-Realization Values and the Attainment of Truth in the Marketplace of Ideas

Intrinsic in the First Amendment is the importance of attaining truth through the exchange of facts and personal fulfillment. “If people lack numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.” Id. at 152 (quoting Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976)) (emphasis added).

86. Heckel, supra note 84 (emphasis added).
87. See Plaintiff Statements, supra note 11.
88. See LEGAL CHALLENGE TO HUMAN GENE PATENTS, supra note 1, at 7 (The public has a “right to benefit from scientific breakthroughs that advance medical research.”).
89. Id. (statement of Elsa Reich, Dep’t of Pediatrics at N.Y. Univ. School of Med.); see also Hill, supra note 3, at 233. Since Myriad holds a patent on the molecule itself, this “confers the broadest protection to the patentee because the claimed molecule will fall within the scope of the patent regardless of what process is used to make the product.” Id.
90. Id. The BRCA genes are pure information—not inventions—and in order to invent around them, the actual sequences must be freely available to utilize. Id. (emphasis added).
91. FARBER, supra note 83, at 4.
access to a wide range of ideas, they are prevented from imagining the full range of possibilities in their lives."\(^{92}\) From the viewpoint of those wishing to study and research BRCA genes, and other genetic disorders and treatments related to them, the repressive nature of the patent system can confine their ability to express their perspectives, thereby taking a sense of self-ownership away from them.\(^{93}\)

The Supreme Court once said that "[o]ur [n]ation is deeply committed to safeguarding academic freedom, which is of transcendent value to all of us and not merely to the teachers concerned. That freedom is therefore a special concern of the First Amendment . . . ."\(^{94}\) For those who have devoted their lives and studies to uncovering the endless possibilities in the field of genetic science, the patent law system seems to work against their devotion for their work and desire to acquire knowledge.\(^{95}\) Patents are economically driven, but in the world of science and research, personal wealth often takes a back seat to recognition among peers and self-gratification.\(^{96}\) Therefore, in the case of the plaintiffs opposing the BRCA gene patent, the patents are unnecessarily restrictive in that they deny the personal quest for scientific truth and progress in answering a usually narrow question with a specific answer.\(^{97}\) By patenting the BRCA genes, the government is sanctioning the patenting of useful scientific information and the abstract idea that mutations occur outside of the body.\(^{98}\) In fact, little is known to certainty regarding

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92. Id.

93. See id.; see also Brian C. Murchison, Speech and the Self-Realization Value, 33 Harv. C.R.-C.L. L. Rev. 443, 446 (1998) (explaining that the freedom to participate in decisions is a necessary ingredient to a democratically-governed society).


95. See generally Plaintiff Statements, supra note 11. There is a "strong disincentive to perform translational research, [which] applies to many other academically based genetics testing laboratories, thus depriving patient populations from the active research involvement of some of the best scientists and institutions in the world." Id. (statement of David H. Ledbetter, Ph.D.).

96. See Hill, supra note 3, at 243. Although there might be some underlying economic incentive behind genetic sciences, the foremost goal of scientists is defining individual achievement. Id. (citing John M. Golden, Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System, 50 Emory L.J. 101, 147-49 (2001)).

97. See id. at 244. The validation of scientific findings, which are confirmed by others in the field, are vital in searching for scientific truth among different techniques and ways of approaching the scientific enigma in question. Id. (citing Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1048-53 (1989)).

98. See Complaint, supra note 2, at 23 (What is patented is that the two forms of the BRCA1 and BRCA2 genes have been made different because of nature—an abstract idea not known to be true.).
breast cancer genetics, and if these ideas are treated as any other traditionally patented products, the public "marketplace of ideas" will be burdened by patent regulations.\textsuperscript{99}

Because the significance of the test results of BRCA genetic tests are often unclear and meaningless, the results lack an objective quality—even though other physicians who actually interpret these results have the ability to perform further testing.\textsuperscript{100} When a patient or a physician receives a test result of "variants of unknown significance," it can be confusing because there is no way to acquire a definite answer whether the patient can surely be at a higher risk of developing cancer.\textsuperscript{101} Especially in the realm of medicine and health, the providers of beneficial services should act with the patients' best interests in mind.

Progress in the natural sciences is not remotely confined to findings made in the laboratory. Insights into the mysteries of nature are born of hypothesis and speculation. The more so is this true in the pursuit of understanding in the groping endeavors . . . the concern of which is man and society. . . . [I]f understanding be an essential need of society—inquiries into these problems [by those in their respective occupations], speculations about them, stimulation in others of reflection upon them, must be left as unfettered as possible. Political power must abstain from intrusion into this activity of freedom [that is a special concern of the First Amendment].\textsuperscript{102}

By allowing Myriad Genetics to hold the power and wealth of vital information to sick patients, the quality of health care inevitably suffers. The complaint of Association for Molecular Pathology points to the fact that "[f]or at least some portions of the life of the [BRCA genes], Myriad did not perform certain tests that were known to reveal additional mutations that

\textsuperscript{99} See \textit{Farber}, supra note 83, at 5 (noting that society can benefit from a wide array of ideas in order to conceptualize and confirm true ideas by disproving false, or bad, ones).

\textsuperscript{100} See generally \textit{Cho} et al., supra note 60 (finding that genetic laboratory directors felt that gene patents delayed or inhibited research, especially regarding genetic testing they had already been performing before the issuance of a gene patent). While there exists an experimental use exemption for infringement liability, it has been interpreted to have no significant effect on the patent system and researchers’ rights. \textit{See American Innovation at Risk, supra} note 8, at 16 (noting that "it seems perverse to subject scientific research to the risk of infringement liability. . . . [but] legislative action is now [needed] to restore the proper balance between the private rights of patent holders and the public interest in advancing technology.").

\textsuperscript{101} Plaintiff Statements, \textit{supra} note 11 (statement of Harry Ostrer, M.D.).

increased the risk of breast and/or ovarian cancer.” Myriad’s patent over the BRCA genes, therefore, does not coincide with the constitutional purposes behind the Patent Act and merely has the effect of prohibiting others in the medical and scientific fields from disseminating useful knowledge and ideas. Contrary to what proponents of patents on genes may argue about negative impacts of duplicative research, multiple teams of researchers can actually scrutinize the same problems in order to efficiently reach and validate a particular result. In fact, it is likely that when multiple individuals research the same subject matter—BRCA genes and the significance of their mutations—the “marketplace of ideas” can be filled with new implications and conclusions arising from the initial discovery.

2. Chilling Effects Doctrine and the Public’s Right to Know

Today, doctors are viewed as individuals who are part of a prestigious team and work together by sharing insights and intellectual honesty, in order to inform each other and their patients. However, because Myriad does not share the information that is personally held in its large database of BRCA1 and BRCA2 data, researchers are “chilled from engaging in research on other genes,” despite the fact that it is well-known that the BRCA genes “interact with other genes in ways that are not yet fully understood.” Up until this point in time, there have only been two lawsuits involving Myriad and its BRCA patents, but neither proceeded far enough to reach a substantive ruling. Consequently, “none of the fears” and potential harm caused by gene patents have materialized, despite the fact that many would agree that declaring private ownership of a human gene is morally inappropriate. One lawsuit for infringement involved the University of Pennsylvania, which had been providing commercial genetic testing for the BRCA1 gene, but decided to cease testing in order to avoid litigation. This demonstrates the

103. Complaint, supra note 2, at 26.
104. See Brenner v. Manson, 383 U.S. 519, 536 (1966) (Congress did not intend for a patent to be “a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”) (emphasis added).
105. Katopis, supra note 54, at 390.
106. See id. (“The benefits of the parallel research strategy include, increased returns corresponding to the number of alternatives; [as well as] a higher rate of ‘learning’. . . .”) (citing Eisenberg, supra note 97, at 1065).
107. Id. at 388.
108. Complaint, supra note 2, at 28.
109. Holman, supra note 29, at 346–47.
110. Id. at 352.
111. Id. at 347.
“chilling effect of gene patents” and the negative impact on access to health-care and genetic testing.112

The chilling effect doctrine, as a basis for protecting First Amendment rights, understands that when the expression of viewpoints and freedom to engage in certain activities is limited because of indirect government regulation, a chilling effect occurs because of the abridgment of First Amendment freedoms.113 Myriad, as the exclusive holder of the rights to the BRCA genes, charges approximately $3000 for a genetic test, and charges high amounts for licensing fees.114 However, even if these licensing practices are available, the high prices and fees have led researchers to shut down labs and halt research efforts.115 Lab shut-downs result in the chilling effect of not being able “to gain access to the latest information [and] can result in a discovery . . . not being made at all.”116 Plaintiff Arupa Ganguly is an Associate Professor in the Department of Genetics at the Hospital of the University of Pennsylvania whose field of study involved clinical practice relating to breast cancer, but she was forced to discontinue her research because of a cease-and-desist letter from defendant Myriad.117 “If [Myriad’s patents] are invalidated now, she would seriously consider resuming clinical practice that is now prohibited.”118 First Amendment rights, and the chilling effect doctrine, are implicated through the exercise of patent rights held by Myriad because it affects those who have put time and effort and devoted their lives to studying breast cancer and related genetic disorders.

When there is a lack of competition in diagnostic testing, such as the current situation of BRCA genetic testing, different viewpoints and avenues for testing are chilled, as many providers have been prevented from providing genetic testing for breast cancer.119 Because Myriad has the ability to refuse to offer certain diagnostic testing, there is a reduction in possible accumulated knowledge. The chilling effects do not only harm certain individuals wishing to assemble together in order to acquire, share, and reap the benefits of their knowledge and viewpoints, but also harms society and the general public—especially in the world of health care—because “[t]he great-

112. Id.
114. Complaint, supra note 2, at 27; Horn, supra note 34, at 275.
115. Horn, supra note 34, at 275.
116. Id.
117. Complaint, supra note 2, at 6.
118. Id.
119. See Plaintiff Statements, supra note 11 (statement of Stephen T. Warren, Ph.D.) (“Even if an improvement in testing methodology is available, another laboratory is prohibited by the exclusive license from implementing the testing refinement.”).
The most benefit DNA patents bring is the promise and potential of curing, treating, diagnosing, and eliminating medical conditions that afflict all.  

When patents on DNA have the effect of privatizing biomedical research, they chill upstream and downstream research. Where clinical laboratory directors and genetic physicians would otherwise have the right to freely practice their own trade, patents on DNA force them to deal and license with the private patent holders. Therefore, the monopoly of the BRCA genes held by Myriad preempts any alternative avenues for communicating related expression and viewpoints regarding breast cancer and genetic disorders, effectually chilling, undermining, and blocking the public’s right to benefit from better medical care for hereditary forms of breast cancer. "As it currently stands, because of exclusive gene testing patents, no single laboratory in the United States could offer full genome sequencing for clinical purposes." Therefore, by raising First Amendment challenges to the patents held by Myriad, the plaintiffs in Association for Molecular Pathology have the ability to prove that the BRCA gene patents hamper the progress of useful arts and sciences on new legal bases that voice concern for the chilling effects of restricting the bounds of practicing medicine and silencing new research. "What they have really patented, . . . is knowledge."
B. **Fourteenth Amendment, Fundamental Rights, Privacy, and Informed Consent**

"Imagine if one of your family members was making a decision about surgery to remove her breasts [or ovaries] after a gene test result placed her at high risk for breast [or ovarian] cancer and there was no place to get an independent test done to confirm the results . . . ."\(^{127}\) This is the disturbing situation of many patients looking for some insight into their own personal diseases or those of family members. The rapid pace at which scientific and genetic technology are advancing foreshadows the continuing concerns over "genetic privacy, informed consent, and the ownership and custodianship of patient data . . . ."\(^{128}\) When a person is denied the information that might be readily available concerning his or her own health, the exclusion has an effect of taking away a person's constitutional right to control over his or her own life and liberty.

The Fourteenth Amendment states that a person shall not be deprived of "life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."\(^{129}\) The Supreme Court has recognized that individual rights and liberty interests encompassing individual sovereignty, bodily integrity, and informed consent are vital in order to protect and guarantee the most important decisions a person will make in her lifetime.\(^{130}\) The freedom over one's own body and health has been characterized as being pivotal to the liberties encompassed in the Fourteenth Amendment.\(^{131}\) Modern constitutional analysis, in addition, encompasses certain "zones of privacy, which were evident and sustained under law since before the nation's founding."\(^{132}\)

In the world of therapeutic and non-therapeutic medical experimentation, a patient has the fundamental right to be informed through disclosure of the benefits and risks of medical procedures—including complete and accurate information containing a full description of a patient's condition—to inclusive rights over "fundamental pieces of knowledge infringes on First Amendment rights, which protect the freedom of scientific inquiry and the free exchange of knowledge and ideas." \(^{Id.}\)

129. U.S. Const. amend. XIV, § 1.
132. *Id.*
maintain autonomy over his or her body. In the case of Myriad Genetics and its patents to the BRCA genes, breast cancer victims and those whose family members have succumbed to the disease have been excluded from information regarding personal information and the use of personal data. When people are excluded from participating in how their personal data contained in their genes can be used, there is an effectual feeling of uncertainty. The lack of ability to maintain knowledge of one’s own bodily and genetic information can make a person powerless. In the realm of possibilities genetic information can reveal, the patent on the BRCA genes prevents the discovery of new personal facts about a person that result from the aggregation of information taken from the original, isolated gene. Information contained in a person’s genes is vital to understanding how the body functions and reacts. Therefore, in order to make intelligent and informed decisions about one’s body, one must have the most accessible and accurate information. The women who are denied testing because they are unable to afford Myriad’s exorbitant diagnostic fees are therefore denied their fundamental rights to make informed decisions regarding choices over their body and health.

1. Reproductive Liberty and Gender Discrimination

Reproductive liberty is a certain autonomy encompassed in privacy over certain intimate decisions. By focusing on the general realm of reproductive health and freedom, discrimination and subordination of women can be found because the patents restrict a woman’s freedom to choose to reproduce at her will. Because reproductive liberty is a non-express fundamental constitutional right, some scholars believe it falls under a penumbra of rights under a right of privacy. However, “even if privacy is taken to mean [reproductive] autonomy, that kind of freedom of decision making presupposes that the one exercising it has control over the . . . act or its effects.” Breast cancer and ovarian cancer are diseases that mainly affect women, who as a

134. See Complaint, supra note 2, at 2, 18.
136. Id.
137. See Complaint, supra note 2, at 2, 18.
138. See id. at 2, 16.
139. Id. at 2–3.
141. See Marcia Mobilia Boumil et al., Law and Gender Bias 20 (1994).
142. Id.; see, e.g., Roe, 410 U.S. at 152–53.
class, are unequally burdened by Myriad's patents. "Because of this, reproductive liberty must be found in the Equal Protection Clause of the Fourteenth Amendment."  

Because of the patent over the BRCA genes, the collaboration of some of the nation's most experienced people in the world of cancer and genetics are missing, and these women are suffering as a result. Therefore, a woman who is denied the completely informed decisional authority to remove her ovaries is inevitably denied her fundamental right to choose freely whether or not to have a child. One of the plaintiffs in Association for Molecular Pathology, Lisbeth Ceriani, submitted a blood sample, as recommended by her oncologist, in order to determine if she should undergo surgery in order to reduce her risk for ovarian cancer.

However, she was notified that Myriad would not process the sample. Even though her insurance has informed her that it would cover the BRCA genetic test, Myriad will not accept coverage. Ms. Ceriani is unable to pay the full cost out-of-pocket and, to date, has not been tested. Without the genetic test results, she cannot determine the best medical course for herself. If the patents are invalidated, Ceriani is ready, willing, and able to utilize additional resources for testing and research.

For a woman who is deciding to remove her ovaries, it is essentially a decision to terminate her ability to give birth to a child. Something that the Supreme Court has also recognized as part of substantive due process is a fundamental right to be free from governmental interference affecting a person's decision whether or not to terminate—or in this case, prevent—a pregnancy. The possibility of unnecessarily preventing someone from having children brings back thoughts of Social Darwinism and the theory of eugenics, which has been held to be morally unacceptable and inhumane. When a woman is not informed to a sufficient degree to make a completely voluntary decision to make herself infertile, but a more knowledgeable physician and genetic counselor is able to make such a recommendation for her, the

144. See Complaint, supra note 2, at 26, 29; BOUMIL ET AL., supra note 141, at 20.
145. BOUMIL ET AL., supra note 141, at 20.
146. Complaint, supra note 2, at 2, 18–19.
147. See id. at 2.
148. Id. at 10.
149. Id.
151. See BOUMIL ET AL., supra note 141, at 57.
right to procreate is no longer a fundamental choice to uphold the existence and survival of one's familial line.\textsuperscript{152}

2. Family Rights

In the doctor-patient relationship, there are many issues regarding disclosure to family members regarding knowledge of a certain genetic condition.\textsuperscript{153} The genetic information of patients wishing to access BRCA testing may not only reveal information regarding their own personal risks of developing cancer, but also may answer questions about relatives who have died of breast or ovarian cancer.\textsuperscript{154} Currently, Myriad only offers genetic testing on blood samples and has not developed any other methods of testing through human tissue.\textsuperscript{155} If the family members have passed away due to breast or ovarian cancer, the only available specimen available for testing is human tissue from a previously removed cancerous tumor because the blood is no longer available.\textsuperscript{156} Therefore, family members wishing to have Myriad perform genetic testing are denied from doing so, despite the fact that other laboratories in the country are able to do so.\textsuperscript{157} The family, as a collective unit, has a common public interest and private right to claiming the information in question.\textsuperscript{158}

3. Equal Protection as a Basis for Discriminatory Genetic Testing Quality

In 2005, approximately 1,433 BRCA1/BRCA2 genetic tests resulted in genetic variations of unknown significance.\textsuperscript{159} Unfortunately, the problematic test results provided by Myriad disproportionately affect African Americans, Hispanics, and Asian women, who have been less likely to volunteer in research studies to add information to genetic databases.\textsuperscript{160} "[T]here are mul-

\textsuperscript{152} See id. at 20.
\textsuperscript{153} See Dean Bell & Belinda Bennett, Genetic Secrets and the Family, in GENETICS AND GENE THERAPY 209, 209 (Sheila A.M. McLean ed., 2005).
\textsuperscript{154} See id. at 210. "[E]ven if family members are not actually tested, in order to verify a diagnosis clinical practice normally entails obtaining information about family members in successive generations leading to the creation of a family pedigree." Id.
\textsuperscript{155} Hearing: Stifling or Stimulating, supra note 12, at 4 (statement of Dr. Wendy Chung).
\textsuperscript{156} Id.
\textsuperscript{157} See id.
\textsuperscript{158} See Lawrence O. Gostin, Genetic Privacy, in GENETICS AND GENE THERAPY 241, 304 (Sheila A.M. McLean ed., 2005).
\textsuperscript{159} Hearing: Stifling or Stimulating, supra note 12, at 3 (statement of Dr. Wendy Chung).
\textsuperscript{160} Id.
ultiple links among race, gender, and genetics, . . . [but] genetic differences, too, are typically regarded as biological and ‘real,’ justifying differences in treatment, with too little attention to the social choices involved.' 161 Under Susan M. Wolf’s approach to an antidiscrimination approach, the lack of knowledge of genetic information of minority populations results because “a norm exists . . . that all should be treated in conformance.” 162 The Myriad genetic testing:

counsels that people of color should be treated like whites . . . . It bifurcates the world into those who nonproblematically fit the norm . . . and those who are problematically different . . . . In genetic terms, this means bifurcating the world into those with nonproblematically “normal” genotypes and those with problematically “abnormal” ones. 163

Because no person has the same exact genetic makeup, it is important to have a genetic database containing variants in a wide range of ethnicities, in order to analyze and conserve the information to compare and correlate these variants. 164 The Myriad gene patents, however, result in disproportionate medical exclusion of minorities. 165 Because Myriad faces no competition in the market, “there is no incentive for them to improve the quality of data interpretation . . . .” 166

IV. CONCLUSION: CASE IMPLICATIONS AND SUGGESTIONS FOR FUTURE APPROACHES

The outcome of Association for Molecular Pathology is still indefinite. 167 “The rock was tossed into the biotech pond on March 29, 2010, when

162. Id. at 161.
163. Id. at 161–62.
164. See Hearing: See Stifling or Stimulating, supra note 12, at 3–4 (statement of Dr. Wendy Chung).
165. See id. at 3.
166. Id. at 4.
167. See Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 369–70 (S.D.N.Y. 2009). Since completion of this paper in the summer of 2009, Defendants moved to dismiss, and Plaintiffs moved for summary judgment on August 26, 2009. Id. at 370. ‘Defendants’ motion to dismiss, and Plaintiffs’ motion for jurisdictional discovery were heard and marked fully submitted on September 30, 2009, and Plaintiffs’
Judge Robert W. Sweet issued a 156-page opinion holding that the purification of a natural product (in this case, human BRCA1 and BRCA2 genes), without more, could not transform it into patentable subject matter.168 In reaching the conclusion, Judge Sweet relied on Supreme Court precedent, and determined that the proper test to analyze the patents was "whether the invention had 'markedly different characteristics' from the natural product."169 The court ultimately invalidated the human gene claims by looking "at the isolated DNA for the BRCA1 and BRCA2 genes as claimed in the patents, and held that it was unpatentable as it was not markedly different from native DNA as it exists in the human body."170 With regards to Myriad's method claims, Judge Sweet sided with the plaintiffs and ruled that the patents were indefinite and "were directed to an unpatentable abstract mental process."171

The case is surely to have an effect in the world of policy and law as it relates to the world of intellectual property and medicine.172 Because of the future wealth that awaits in the pharmaceutical and health care industries as a result of genetic discoveries, it is unlikely that a court would completely ban...

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169. Id.

170. Id.

171. Id.

172. Ass'n for Molecular Pathology, 669 F. Supp. 2d at 370. The challenges to the BRCA patents "raise questions of difficult legal dimensions concerning constitutional protections," as well as "the need to adopt policies that promote scientific innovation in biomedical research." Id. The outcome of the case against the USPTO and Myriad, and the resolution of the novel legal issues "will have far-reaching implications, not only for gene-based health care, . . . but also for the future course of biomedical research." Id.
the patenting of genes, in general. However, in order to maximize the benefits to the public, it is necessary that genetic testing is widely available with the greatest possible quality. The case against the USPTO and Myriad is rather a way to demonstrate the actual harms of broad patenting and licensing schemes in such an unknown yet valuable realm of information and sciences.

A recent case, Prometheus Laboratories, Inc. v. Mayo Collaborative Services, held that a correlation between metabolite levels and toxic results from metabolic activity in the human body were natural, unpatentable, phenomena, that would have existed without human intervention. Certain natural metabolites were not patentable on their own because the correlation was a result from a natural body process. However, with Judge Sweet’s new opinion, there might be hope that an appeals court may still hold that the mutations on the BRCA genes—while believed to be environmentally caused in an isolated, purified gene—are naturally correlated with a higher risk of breast cancer, and are therefore not patentable. It will likely take years of litigation to see whether Myriad’s patents will meet whatever standard the Supreme Court devises in the future.

Perhaps the answer to gene patents might be to develop a patenting scheme where there would still be incentive for intellectual efforts by ensuring financial merit; but, instead of granting exclusive rights and licenses, the patent would allow certain health-care providers access without infringement, or perhaps setting limits on licensing fees so that there would be decreased insurance barriers to patient access to quality healthcare. Further-

173. Because only some of Myriad’s claims were invalidated, while some remained unchallenged. Ramage, supra note 168.
175. Id. at *6-9.
176. Id. at *7.
178. After completion of author’s own research, conclusions, and recommendations—as stated in Part IV of this article—the Secretary’s Advisory Committee on Genetics, Health and Society (SACGHS) for the Department of Health and Human Services (HHS) issued a revised draft report, entitled Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, which includes six recommendations that stress equal and uninhibited access to the benefits of genetic testing and research for Plaintiffs like those affected by the broad BRCA patents. See SECRETARY’S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY, REVISED DRAFT REPORT ON GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 2 (Feb. 5, 2010), available at http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Patents%20Report%20Approved%202-5-2010.
more, if the same genetic test could be performed with better quality and knowledge by someone who has greater skills than that of Myriad, the government should not allow the public to suffer as a result. The personal right of those wishing to exercise their constitutional rights to access and share information and make informed decisions over their body should not be abridged simply because a court has read a patent too broadly.

pdf. The most controversial recommendation is “Recommendation 1: Support the Creation of Exemptions from Infringement Liability,” which suggests carving out statutory “exemption[s] from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes,” and “for those who use patent-protected genes in the pursuit of research.” Id. at 90. The other recommendations are as follows: “Recommendation 2: Promote Adherence to Norms Designed to Ensure Access”; “Recommendation 3: Enhance Transparency in Licensing”; “Recommendation 4: Establish an Advisory Body on the Health Impact of Gene Patenting and Licensing Practices”; “Recommendation 5: Provide Needed Expertise to USPTO”; and “Recommendation 6: Ensure Equal Access to Clinically Useful Genetic Tests.” Id. at 91–93.