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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

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NOTES

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

Marisa Noelle Pins

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I. INTRODUCTION

There are places where the patent system has gone too far... [T]oo much patent protection can in fact trample our civil liberties.

Tania Simmonelli

The story is becoming an all too familiar tale. What was once described as an innovation in women’s cancer research has turned into a nightmare for many of the women it was intended to help. For the women named as plaintiffs in the latest lawsuit against the United States Patent and Trademark Office (USPTO) and Myriad Genetics Laboratories, Inc. (Myriad Genetics), the tale has hit especially close to home. Each plaintiff’s story is different, but the offenders, the USPTO and Myriad Genetics, are the same. One woman, Lisbeth Ceriani, developed breast cancer in May 2008. After her physician advised that she be tested for BRCA1 and BRCA2 gene mutations to determine whether she was at an increased risk of developing ovarian cancer, she was informed that Myriad Genetics would not accept her insurance, MassHealth. Unable to pay out-of-pocket for the procedure, she has not been tested to date. As Ms. Ceriani sees it, “Myriad holds [her] fate and future in its administrative hands.”

Another woman, Genae Girard, was also diagnosed with breast cancer and underwent BRCA1 and BRCA2 gene testing. When she sought out a second opinion upon receiving a positive result for a mutation, she was told that receiving a second opinion would not be possible. Ms. Girard is now “forced to make, and continues to make, significant medical decisions for herself based on a test result that has not been verified by another laboratory.” Four additional women, who joined the lawsuit as plaintiffs, echo similar struggles to those of Ms. Ceriani and Ms. Girard. The ties that bind each of these women to Myriad Genetics are the

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3 Id.
4 Id.
6 Complaint, supra note 2, at 11.
7 Id.
8 Id.
9 Id. at 10–13.
seven United States patents that the USPTO granted Myriad Genetics on the BRCA1 and BRCA2 genes.¹⁰

Patents have been granted on approximately 4,382 human genes to date, which accounts for about twenty percent of all genes in the human body.¹¹ Two such genes are BRCA1 and BRCA2, which are proven indicator genes linked to breast and ovarian cancer.¹² The determination that a woman has one of these mutations allows the patient and her physician to plan ways to combat the heightened possibility of future cancers.¹³ These indicator genes have been preliminarily linked to several other types of cancers in both men and women, as well as to other familial genetic diseases.¹⁴ The testing for these gene mutations is performed through a simple blood sample taken at a physician's office.¹⁵ Individual results are then analyzed against other known mutations to determine an individual's susceptibility.¹⁶ Just because a woman tests positive for the mutation does not mean that she will develop cancer, however because these mutations tend to be hereditary, an individual's genetic testing can determine the risk of a mutation not only in the person being tested but also in that person's relatives.¹⁷

On May 12, 2009, the plaintiffs filed a lawsuit against the USPTO, Myriad Genetics, and ten directors of the University of Utah Research Foundation (the entity that sponsored the research).¹⁸ The lawsuit was brought on behalf of four professional associations, eight researchers and professors, and six current or potential breast and ovarian cancer patients.¹⁹ The complaint challenges the gene patents covering BRCA1 and BRCA2 that were granted to Myriad Genetics by the USPTO.²⁰ The plaintiffs claim that the patents granted unnecessarily restrict ease of access to the genetic material needed for additional research.²¹ The plaintiffs

¹⁰ U.S. Patent Nos. 5,747,282 (filed June 7, 1995); 5,837,492 (filed Apr. 29, 1996); 5,693,473 (filed June 7, 1995); 5,709,999 (filed June 7, 1995); 5,710,001 (filed June 7, 1995); 5,753,441 (filed Jan. 5, 1996); 6,033,857 (filed Mar. 20, 1998).
¹³ Id.
¹⁴ Id.
¹⁵ Id.
¹⁶ See id. (showing that the test determines whether that mutation has been associated with cancer in other people).
¹⁷ Id.
¹⁸ Complaint, supra note 2, at 13–14.
¹⁹ Id. at 3–13.
²⁰ Id. at 2.
²¹ Id.
allege these patents violate both the First Amendment and Article I, section 8, clause 8 of the United States Constitution. The plaintiffs also allege that these gene patents violate “long established legal principles that prohibit the patenting of laws of nature, products of nature, and abstract ideas.” As stated by the ACLU’s Science Advisor, Tania Simoncelli, “[Myriad Genetics owns] not only the gene, they own any future tests, any future drug, any future therapy, so it means we are putting our trust in one single company.” Thus, the plaintiffs are attacking four separate categories of patents held by Myriad: (1) patents on “natural human genes”; (2) patents on “genes with natural mutations”; (3) patents on “any method, including non-patented methods, of looking for mutations in natural human genes”; and (4) patents over the “thought that two genes are different or have different effects, including but not limited to the thought that the differences correlate with an increased risk of breast and/or ovarian cancer.”

The lawsuit notes the implications that these patents have on patients and researchers. The plaintiffs allege that unlike other patents, gene patents do not allow non-patent holders to “invent around” the patents; their inability to do so impedes scientific research. Because of these patents, the only supplier of BRCA1 and BRCA2 testing in the United States is Myriad Genetics. Additionally, as the exclusive source of the test, Myriad Genetics holds a large amount of data compiled through testing. Myriad Genetics has not, to date, shared this database with the National Institute of Health’s Breast Cancer Mutation Database, which would “ensure the widest possible distribution of information about genes and breast cancer.”

Thus, Myriad Genetics has impeded access to information that could help researchers in future genetic discoveries. The “chilling effect” of possible patent infringement enforcement likely leads many researchers to refrain from conducting research on these patents, possibly preventing future genetic breakthroughs.

Myriad Genetics, a Utah-based genetics company, won the race to find and patent the BRCA1 and BRCA2 genes. The founder of Myriad Genetics, Dr.

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22 Id. at 3.
23 Id.
24 Liberating The Breast Cancer Genes, supra note 1.
25 Complaint, supra note 2, at 15.
26 Id. at 25–29.
27 Id. at 25.
28 Id.
29 Id. at 26.
30 Id.
31 Id. at 28.
32 Memorandum of Law in Support of Defendants’ Motion to Dismiss at 3, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 09 Civ. 4515 (S.D.N.Y. July 13, 2009), 2009 WL 3269109 [hereinafter Motion to Dismiss].
Mark Skolnick, believes that Myriad has a right to the patents because the company "[made] this huge multi-tens-of-millions dollars investment" so "don't [they] have the right to deliver the test?" And they do deliver the test, receiving about 350 new samples per day. These samples are analyzed using one or both of the two tests that Myriad performs: the comprehensive BRACAnalysis test and the expanded BART test. Dr. Skolnick claims that no women would have been tested for the BRCA mutations if not for Myriad. He also states that the commercial interest afforded to the company through the issuance of the patents encourages the company to solve any problems that may arise. Myriad claims that without patent protection the company would not have been founded because the necessary funding would not have been made available by investors.

Therefore, the plaintiffs asked: (1) that the patents granted to Myriad Genetics for the BCRA1 and BRCA2 genes be invalidated or deemed unenforceable, or (2) that Myriad Genetics be enjoined from enforcing these patents. On March 29, 2010, Judge Sweet, presiding over the District Court for the Southern District of New York, granted the plaintiffs' motion for summary judgment, holding Myriad Genetics BRCA1 and BRCA2 gene patents invalid. The day after the decision was handed down, Myriad Genetics announced its plans to appeal the decision. Thus, the battle between the plaintiffs and Myriad Genetics is far from over, with a final resolution of gene patentability likely years down the road.

This Note will consider the ways in which the patents granted to Myriad Genetics have affected access to quality patient care, as well as the effect on patient rights not only in the United States, but on an international scale. Part II will examine how, under the current patent system, Myriad was granted a patent on human genes, seemingly natural products. This Part will evaluate the decision.

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33 In the Family: A Visit to Myriad Genetics, http://www.youtube.com/watch?v=wffdT0T3wgw (last visited Feb. 27, 2010).
34 Id.
37 In the Family: A Visit to Myriad Genetics, supra note 33.
38 Id.
40 Complaint, supra note 2, at 30.
of the District Court for the Southern District of New York; a decision which will be appealed by Myriad Genetics in a fight to keep their gene patents valid. Part II will then consider the handling of gene patents in other countries where Myriad Genetics holds BRCA patents, including those of the European Union. Various proposals that have been made by professional organizations and federal agencies in the United States will also be discussed in the event Myriad Genetics wins on appeal. Part III will examine the potential efficiency of these systems. Additionally, this Part will look at how the court’s resolution of this case could affect gene patents in other countries. Part IV will address the insufficiency of the current patent process for protecting the rights of patients in the United States and worldwide. Part IV will also discuss options for possible agreements or standards concerning gene patents that would address not only the concerns that have arisen in the United States, but those that have arisen under the laws of other affected nations.

II. BACKGROUND

A. DNA AND GENES: THE NATURAL BUILDING BLOCKS OF EVERY BODY

Each person has a unique genome, although 99% of a person’s genome is identical to that of any other individual. 43 Each genome consists of genes, which are sections of DNA that contain “instructions for making a specific protein or set of proteins.” 44 DNA is the building block of each person’s cells. 45 It contains a set of instructions that tell the cells in a living organism how to develop and function. 46 DNA is made up of four different nucleotides (those chemical units that form the basis of the DNA molecule) codified as adenine (A), thymine (T), guanine (G), and cytosine (C). 47 The order in which these nucleotides appear is a naturally occurring phenomenon. 48 The arrangement of these nucleotides on the DNA double-helix determines the traits a person will receive, as well as any possible hereditary diseases a person may develop. 49 Genetic mutations occur

45 Id.
46 Id.
47 Id.
48 See id. (demonstrating that these nucleotides systematically pair off to form the DNA sequence).
49 Id.
where one or more of the aforementioned nucleotides is missing or out of sequence. These mutations may be inherited or may occur naturally during one’s lifetime. Some of these mutations may have an impact on an individual’s health, increasing that person’s risk for a variety of serious diseases, while others are innocuous.

Approximately 5%–10% of all women who develop breast cancer have a BRCA1 or BRCA2 gene mutation. Women who have one of these mutations have a 40%–85% risk of developing breast cancer at some time in their lives. About 15%–40% of women with a BRCA mutation will develop ovarian cancer, compared to 1.4% of the general female population. The scientific community, recognizing the indispensable benefit of genetic testing, has begun to intensify focus on research in this area.

In order to read an individual’s DNA sequence (the order of the As, Ts, Cs, and Gs), a process called genetic sequencing is used. Scientists and clinicians regularly perform this sequencing process as part of their routine research. The resulting sequenced gene “is informationally and functionally identical to the sequence found inside the body,” as none of the “informational content” of the gene is changed during the sequencing process.

The process of sequencing a gene generally begins with the purification and isolation of the gene. A purified gene is one that has been “isolated from its natural state.” An isolated gene is one “that has been removed from the body and separated from surrounding cellular material.” The sequence of the DNA in the isolated and purified gene is the same as the sequence in the naturally occurring gene. Thus, an isolated and purified gene is “functionally and

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50 Id.
51 See id. (explaining that “[v]irtually every human ailment, except perhaps trauma, has some basis in our genes”); see also Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment at 2, Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09 Civ. 4515 (S.D.N.Y. Aug. 26, 2009), 2009 WL 3269113 [hereinafter Motion for Summary Judgment].
52 National Human Genome Research Institute, supra note 44.
53 Motion to Dismiss, supra note 32, at 3.
54 Id.
55 National Cancer Institute, supra note 13.
56 National Human Genome Research Institute, supra note 44.
57 See id. (explaining that researchers commonly perform a sequencing technique called “chain termination method”).
60 Motion for Summary Judgment, supra note 51, at 4.
61 Utility Examination Guidelines, supra note 59, at 1093.
informationally identical to [the gene] in the body." Under the current USPTO Utility Examination Guidelines, an isolated and purified gene may be patented. The genes at issue in the Myriad case have been labeled as isolated DNA.

The sequencing of DNA for genetic testing purposes is not limited to the breast cancer genes discussed here. Patents for genetic testing have also been granted to individual companies testing for long QT syndrome, the HFE gene that is linked to hereditary hemochromatosis, and the CFTR gene that is linked to cystic fibrosis. Thus, final resolution of the Myriad case could have far-reaching effects on the entire biotechnology industry.

B. PATENT PROTECTION FOR BIOLOGICAL MATERIALS IN THE UNITED STATES

To be eligible for a United States patent, biological material, genetic or otherwise, must meet three separate conditions: (1) it must be novel, (2) it must have utility, and (3) it must be nonobvious. The USPTO is the entity empowered in the United States to grant biological patents under these terms. Utility patents, such as those patents on the genes at issue in the Myriad case, are valid for twenty years from the date of the patent application.

1. The Utility Requirement Under 35 U.S.C. § 101. To meet patentability requirements, a potentially patented item must have "utility." While the Supreme Court has not historically held that the standard for utility is particularly high, the Federal Circuit has held that the item must have "specific and substantial" utility in order to be patented. The Court has not explicitly defined either "specific" or "substantial" utility. However, the Federal Circuit, along with the Court of Customs and Patent Appeals, provides that to meet the substantial utility requirement "an asserted use must show that the claimed invention has a significant and presently available benefit to the public." According to the Federal Circuit, the patent application must have sufficient detail and "disclose a

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62 Motion for Summary Judgment, supra note 51, at 4–5.
63 Utility Examination Guidelines, supra note 59, at 1093.
64 Motion for Summary Judgment, supra note 51, at 4–5.
70 In re Fisher, 421 F.3d 1365, 1370 (Fed. Cir. 2005).
71 Id. at 1371.
72 Id.
73 Id.
use which is not so vague as to be meaningless” in order to be specific.74 Despite being potentially useful for research purposes, if an application contains only “hypothetical possibilities” that are not presently beneficial to the public, an application may still be denied for not meeting the utility requirement.75 

The present benefit to the public is of particular concern to the biotechnology industry, where the present public use of the gene or DNA sequence may not be known at the time the patent application is filed.76 This concern was addressed in the USPTO’s 2001 Utility Examination Guidelines, which states that a patent application that “discloses only [the] nucleic acid molecular structure for a newly discovered gene, and has no utility for the claimed isolated gene” cannot be patented.77 However, if the application describes how the “purified gene isolated from its natural state” will be used, and there is “specific, substantial, and credible utility,” then the utility standard is satisfied and the item may be patented.78

To further clarify this requirement, in 2001 the USPTO established a new set of Utility Examination Guidelines for patent examiners to use when determining whether the patent application meets the utility requirement under 35 U.S.C. § 101.79 Despite the title, the Guidelines tend to speak more to the novelty requirement, however to correspond to the language used by the USPTO the term “utility” will be used throughout this Note. When the USPTO requested public comments regarding the proposed Guidelines, it received several comments stating that genes are products of nature and as such do not constitute a “new” entity.80 Others argued that isolating a gene does not equate to an invention or discovery because genes are products of nature.81 The new Guidelines, rejecting these arguments, state that isolated and purified genes may be patented despite the fact that the isolated and purified gene has the same sequence of DNA molecules as a natural gene would.82 The USPTO gave two alternate grounds for allowing patents for isolated and purified genes: (1) the “DNA molecule does not occur in that isolated form in nature,” or (2) “synthetic DNA preparations” may be patented because “their purified state is different from the naturally occurring

74 Id.
75 Id. at 1373 (showing how the asserted uses of expressed sequence tags at issue in Fisher only represented what could be achieved).
77 Utility Examination Guidelines, supra note 59, at 1093.
78 Id.
79 Id.
80 Id.
81 Id.
82 Id.
compound." The USPTO cited several cases to support its theory that the patenting of isolated compounds was "well-established." The Guidelines primarily rely on *Parke-Davis & Co. v. H. K. Mulford.* In that case, the court found a patent for adrenaline valid because it was isolated from nature; even though the chemical was not changed from its natural structure, it was a new entity. The Guidelines additionally rely on *In re Bergstrom.* In that case, the court found that products extracted from prostate glands were patentable because the compounds being patented did not naturally occur in a purified form. Thus, the applicants did not simply discover the compounds, but invented them. The USPTO does make clear in the Guidelines that the standards for patenting, while covering isolated and purified genes, do not expand patent protection to "cover the gene as it occurs in nature."

The USPTO directly addressed how DNA sequencing could be patented under the new Guidelines. The Guidelines state that the "fundamental sequence data," or the sequence of the As, Ts, Cs, and Gs, is not in and of itself patentable because it is simply "nonfunctional descriptive information." However, the Guidelines affirm that the "new and useful purified and isolated DNA compound described by the sequence is eligible for patenting," as long as it meets all of the other requirements of patentability. In light of the decision by the District Court for the Southern District of New York in the Myriad case, however, the Guidelines as they relate to gene patents are now invalid on their face.

2. History of U.S. Patent Protection for Biological Materials. Whether or not a human gene may be patented is a question of first impression. Up until this point, the closest the Supreme Court has gotten to answering this question was in the landmark case of *Diamond v. Chakrabarty,* which focused on the patentability of a living organism. However, because a gene is not a living organism per se, *Diamond* is distinguishable from the current controversy.

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83 *Id.*
84 *Id.*
85 196 F. 496 (2d Cir. 1912).
86 *Parke-Davis & Co. v. H. K. Mulford,* 189 F. 95 (S.D.N.Y. 1911).
88 *Id.*
89 *Utility Examination Guidelines,* supra note 59, at 1093.
90 *Id.*
91 *Id.*
92 *Id.*
Until 1980, the USPTO had not granted a patent on a living thing. However, that changed with the decision in *Diamond*. In that case the Supreme Court was asked to determine whether a “live, human-made micro-organism” could be patented under 35 U.S.C. § 101. The Court determined that the live organism at issue was patentable. After the Court’s decision in *Diamond*, approximately three million gene-patent applications were filed with the USPTO. Out of these applications approximately 52,800 gene-related patents have been granted.

Before *Diamond*, the case law concerning the patentability of biological materials historically shied away from offering these materials patent protection. A long line of cases, beginning as early as the late 1800s, have shaped the patentability of biological materials, as well as addressed the effects of purification of compounds on the product’s patentability.

The vast majority of cases leading up to *Diamond* focused on the patentability of materials that have been derived from natural products through extraction and purification. The first such case arose in 1874 when the Supreme Court decided *American Wood-Paper Co. v. Fibre Disintegrating Co.* The Court voided the paper company's patent for extracted wood-pulp, stating that the extract was the same as the natural product. In a refrain that would be repeated throughout this line of purification cases, the Court did note that the process for extracting the material from the natural product may be patented if it is a new invention, “but the thing itself when obtained cannot be called a new manufacture.” The Court came to a similar conclusion in *Cochrane v. Badische Anilin & Soda Fabrik* when it held that a synthetic dye, even though it was being produced for the first time, was not a new composition because it had the same chemical compound as the original. The reliance on the purification doctrine became more apparent in *Ex parte Latimer* when the patent commissioner rejected a patent for fibers that were extracted or purified from the needles of the longleaf pine tree. The commissioner held that despite the purified nature of the fiber, the plant was still

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95 447 U.S. at 305.
96 Id. at 313.
97 Boyd, supra note 94.
98 Id.
99 90 U.S. (1 Wall.) 566 (1874).
100 Id. at 596.
101 Id. at 594.
102 111 U.S. 293, 311 (1884).
103 Application of Bergy, 596 F.2d 952, 982 (C.C.P.A. 1979) (citing *Ex parte Latimer*, 1889 Dec. Comm'r Pat. 123 (1889)).
a product of nature and could not be patented.\textsuperscript{104} However, one lower court challenged this precedent in \textit{Parke-Davis & Co. v. H. K. Mulford, Co.}, where it found that an extract of adrenaline derived from the suprarenal gland was patentable.\textsuperscript{105} The district court claimed the extract was separate from the gland from which it was derived, and was different “not in degree, but in kind.”\textsuperscript{106}

Despite this detour, other courts continued to abide by the Supreme Court’s decisions in the earlier purification cases, holding those materials unpatentable. In \textit{General Electric Co. v. De Forest Radio Co.} the Third Circuit struck down a patent for a purified form of tungstic acid.\textsuperscript{107} While the company found a way to make the naturally brittle compound more ductile, the district court held the patents invalid because “they cover an element of nature with characteristics which nature alone has given it.”\textsuperscript{108} The Third Circuit held that General Electric had not discovered a new compound, but had simply discovered the natural qualities of the pure form as it existed in nature.\textsuperscript{109} In two additional cases with striking factual similarity to \textit{General Electric}, an appellate court held that patents could not be maintained on products that simply exposed the natural elements’ hidden qualities.\textsuperscript{110}

Similarly, the Supreme Court has continued to require that a product be novel to be patented. In \textit{American Fruit Growers, Inc. v. Brogden Co.} the Supreme Court found that the process of retaining the freshness of fruit through the use of borax was not patentable.\textsuperscript{111} The patent was voided for lack of novelty, because “[t]here must be transformation; a new and different article must emerge ‘having a distinctive name, character, or use.’”\textsuperscript{112} In its decision, the Court noted that the fruit itself retained the same form and possessed the same uses as it did prior to the addition of the borax compound.\textsuperscript{113}

Simply having a commercial advantage has also been held to be insufficient if there is no enhanced utility or if the product is not novel. While a product may be commercially valuable, the product cannot be patented if it is not novel.\textsuperscript{114} This

\textsuperscript{104} Id.
\textsuperscript{105} \textit{Parke-Davis & Co. v. H. K. Mulford Co.}, 189 F. 95, 103 (S.D.N.Y. 1911).
\textsuperscript{106} Id.
\textsuperscript{107} 28 F.2d 641, 642 (3d Cir. 1928).
\textsuperscript{108} Id.
\textsuperscript{109} Id. at 643.
\textsuperscript{110} \textit{See In re Marden, 18 C.C.P.A. 1046 (C.C.P.A. 1931)} (finding a patent for ductile uranium void because it was a product of nature); \textit{In re Marden, 18 C.C.P.A. 1057 (C.C.P.A. 1931)} (finding a patent for purified ductile vanadium void because it was a product of nature).
\textsuperscript{111} 283 U.S. 1 (1931).
\textsuperscript{112} Id. at 13 (quoting Hartranft v. Wiegmann, 121 U.S. 609 (1887)).
\textsuperscript{113} Id. at 12.
\textsuperscript{114} \textit{See In re Bergy, 596 F.2d 952, 982 (C.C.P.A. 1979)} (quoting \textit{Ex parte Latimer, 1889 Dec. Comm’t} \textit{Pat.} 123, 125 (1889)) (finding that while the fiber extracted from the natural product was
theory was reiterated in In re Merz, where the purified substance's brighter hue had a slight commercial advantage for pigmenta- tion purposes. However, the patent court held that despite any advantages of the purified form, if it does not have any new utility the "product which has been purified is not patentable over the unpurified product." The Supreme Court weighed in on this discussion in Funk Brothers Seed Co. v. Kalo Inoculant Co., where it held that a combination of natural bacteria was not patentable despite its commercial advantage. The Court found that the aggregation of species did not constitute a new product because there was no enlargement of utility. The Court noted that while there may be certain commercial advantages, a "product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery."

The most recent in this line of cases decided by the Supreme Court was Diamond v. Chakrabarty in 1980. The Court was asked whether a man-made, engineered bacterium capable of breaking down crude oil could be patented, or whether it was a product of nature and unpatentable. Looking at past precedent, the Court reiterated that products of nature are not patentable. Providing a few examples, the court noted "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." Even if useful, some theories and products cannot be patented. Providing an example, the Court noted, "Einstein could not patent his celebrated law that E=mc² nor could Newton have patented the law of gravity." In the case at hand, the Court noted that to determine whether the bacterium could be patented, it had to decide whether it was a " 'manufacture' or 'composition of matter' " under 35 U.S.C. § 101. The Court determined that the bacterium had "markedly different characteristics from any found in nature." In a 5–4 decision, the Court held that the organism claimed was not an "unknown natural phenomenon, but . . . a nonnaturally occurring manufacture or composition of matter — a product of

commercially advantageous, it lacked novelty).
The Court held bacterium patentable deeming the creation of a new bacterium a manufacture or composition of matter under 35 U.S.C. § 101 and having found the requisite utility.\(^{129}\)

As seen in the purification line of cases, the Court has typically refused to grant patent protection to purified compounds. The cases have reiterated that patents cannot be issued for products of nature, or products that simply uncover a product's natural quality. However, they also demonstrate that a patent may be granted on the process for purifying a compound if that process is new and inventive.\(^{130}\) Even if the product has the potential of being commercially valuable, if the product does not meet the requisite patent eligibility requirements the patent will not be granted.\(^{131}\) A product purified from a natural source is only patentable if it has the required utility, and is different from the natural source from which it was acquired.\(^{132}\)


a. The Myriad Genetics' Decision. The latest decision in the isolation and purification line of cases came with the swift decision of the District Court for the Southern District of New York in the Myriad Genetics case. On March 29, 2010, Judge Sweet granted the plaintiffs' motion for summary judgment, holding Myriad Genetics' BRCA1 and BRCA2 gene patents invalid.\(^{133}\) The decision invalidating the gene patents stunned many lawyers who follow such issues. One such lawyer, Rebecca S. Eisenberg, a law professor at the University of Michigan, stated, "it's really quite a dramatic holding that would have the effect of invalidating many, many patents on which the biotechnology industry has invested considerable money."\(^{134}\) Judge Sweet summed up his decision by stating that "the identification of the BRCA1 and BRCA2 gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that is not the same as concluding that it is something for which they are entitled to a patent."\(^{135}\)
Keenly aware of the breadth of any potential decision, the court named various professionals, organizations, and other individuals whom invalidation would directly affect. The court then outlined its decision by dividing the case into two claims: (1) composition claims and (2) method (process) claims.

One of the first issues to be resolved by the court was the meaning of DNA. Myriad Genetics claimed that the plaintiffs' definition "suggests that the term 'DNA' refers merely to information," whereas Myriad argues it refers to "a real and tangible molecule, a chemical composition." The court sided with Myriad Genetics noting that DNA is "a tangible, chemical compound." However, that distinction did not save Myriad Genetics from ultimate defeat.

The bigger issue the court had to address was whether the composition "claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception to §101." The court first dismissed Myriad Genetics' reliance on the Utility Examination Guidelines put forth by the USPTO, arguing that they owe the USPTO's Guidelines "no deference" and reiterating that the courts have the ability to review patents granted by the USPTO (showing the court's superior position over the decisions of the USPTO). The court was challenged with the application of the term 'isolated DNA.' The court noted that Myriad's case was based on a mere "lawyer's trick." Lawyers have long claimed that isolating DNA makes it patentable subject matter "by transforming it into something distinctly different in character." However, the district court rejected this argument. The court noted that DNA is different from many other chemicals and compounds that are regularly patented because it is based upon information, thus "represent[ing] the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature." Because these isolated genes are merely sources of information, the isolated nature of the gene "neither [alters the] fundamental quality of DNA as it exists in the body nor the information it encodes." As a product of nature, the subject

136 Id. at *3 (noting the "resolution of the resolution of the issues presented to [the Court] deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health").
137 Id. at *80.
138 Id. at *90.
139 Id. at *90–91.
140 Id. at *91.
141 Id. at *103.
142 Id. at *104.
143 Id. at *104–05.
144 Id. at *3.
145 Id.
146 Id. at *3–4.
147 Id. at *4.
matter is not patentable under U.S.C. § 101.148 Verifying the contention of the plaintiffs that a sequenced gene "is informationally and functionally identical to the sequence found inside the body,"149 the court held that the "sequencing process, by design, does not alter the information content of the native DNA sequence."150

The court acknowledged that "purified or synthesized DNA may be used as tools for biotechnological applications for which native DNA cannot be used,"151 but this useful feature of isolated genes does not elevate them to patentable status.152 The court lauded the effort and ingenuity Myriad put into isolating the BRCA1 and BRCA2 genes, noting, however, that "the process and techniques used were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach."153 Thus, Myriad Genetics had done nothing new. They had not created a new form of DNA by isolating it from the surrounding cellular material, and they likewise did not create a new way to isolate such material.

The court focused on prior precedent to fortify its decision. While Chakrabarty instructs the court to interpret 35 U.S.C. § 101 broadly, the district court explained that the broad scope of § 101 is not without limits.154 One such limitation is the often-cited refrain of Chakrabarty and Diehr, both of which state that products of nature are not patentable subject matter and as such "fall outside the scope of § 101."155 Various courts have established the long history of this limitation beginning with General Electric Co. and ending with Laboratory Corp. of America Holdings v. Metabolite Labs, Inc. In defining the scope of § 101, Judge Sweet relied on In re Bergy and Diehr in concluding that novelty, subject matter, and utility are all appropriate considerations under § 101.156 Thus, Judge Sweet subjected the Myriad Genetics' patents to two tests: (1) "whether the claimed invention possesses utility"; and (2) "whether the claimed invention constitutes statutory subject matter."157 The court found that the gene patents possessed utility, leaving only the question of whether the genes "constitute statutory subject matter."158

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148 Id.
149 Plaintiffs' Statement of Material Facts, supra note 58, at 15.
150 Ass'n for Molecular Pathology, 2010 WL 1233416, at *43 (S.D.N.Y. Mar. 31, 2010).
151 Id. at *36.
152 Id. at *37.
153 Id. at *53.
154 Id. at *96.
155 Id. at *97.
156 Id. at *101.
157 Id. at *102.
158 Id.
The court then determined whether the patentable subject matter was "markedly different" from a product of nature. 159 Myriad argued that neither form of the isolated BRCA genes are found in nature, 160 and furthermore relied on Parke-Davis as the basis for the genes' patentability. 161 Relying on American Fruit Growers, Funk Brothers, and Chakrabarty the court declared that a product must be significantly different from its natural source in order to be patented. 162 The court then addressed American Wood-Paper Co., which stood for the proposition that the "purification" of a natural compound, without more, is insufficient to render a product of nature patentable. 163 Judge Sweet relied on Cochrane, General Electric, and Ex parte Latimer for the same proposition. 164 Based upon this precedent, Judge Sweet held that Myriad Genetics' argument that genes are patentable subject matter under relevant case law was incorrect. 165 He further noted that Parke-Davis (the case on which Myriad Genetics relies) does not hold that "the purification of a natural product necessarily renders it patentable" as claimed by Myriad Genetics. 166 Rather, Parke-Davis dealt with a § 102 novelty issue, whereas the current controversy hinges on a § 101 patentable subject matter theory. 167 Additionally the court noted that the portion of Parke-Davis upon which Myriad based its argument was simply dicta after the central novelty issue was decided, and is no longer good law after the Chakrabarty decision. 168 Judge Sweet also shot down Myriad Genetics' reliance on two other cases, which speak to novelty instead of patentable subject matter. 169 Summing up his argument, Judge Sweet concluded that "purification of a product of nature, without more, cannot transform it into patentable subject matter" and "the purified product must possess 'markedly different' characteristics in order to satisfy the requirements of § 101." 170 Using this 'test' the district court ruled that the isolated DNA for which Myriad Genetics holds patents is not patentable because it is not "markedly different" from its natural source. 171 The court did not agree with Myriad Genetics' contention that isolated DNA is a chemical compound and thus can be

159 Id. at *107.
160 Id. at *113.
161 Id. at *114.
162 Id. at *107–10.
163 Id. at *110.
164 Id. at *111.
165 Id. at *113–14.
166 Id. at *115.
167 Id. at *115.
168 Id. at *116.
169 Id. at *117–19 (showing Myriad Genetics' reliance on In re Bregstrom, 427 F.2d 1394 (C.C.P.A. 1970) and In re Kratz, 592 F.2d 1169 (C.C.P.A. 1979)).
170 Id. at *121.
171 Id. at *122.
The court differentiated DNA from other chemical compounds, arguing that while they are chemical compounds they are also “physical carriers of information.” Because of this unique characteristic, the court found that it “would be erroneous to view DNA as ‘no different’ than other chemicals previously the subject of patents.” The court differentiated this case from Parke-Davis stating that the information that DNA carries is not “its own molecular structure incidental to its biological function . . . . Rather, the information encoded by DNA reflects its primary biological function: directing the synthesis of other molecules in the body,” thus, DNA “serves as the physical embodiment of the laws of nature.” Because DNA is a law of nature under this theory, it is not ‘markedly different’ making it unpatentable.

The court did not rule on a few subjects that were part of the plaintiffs’ original complaint. Judge Sweet noted the plaintiff’s issue of whether gene patents “impact[ed] the testing for BRCA1/2 mutations favorably or unfavorably,” but did not make a final decision on the matter saying it was an “issue of factual dispute not resolvable in the context of the instant motions.” Judge Sweet also noted the inability to resolve “disputes of fact and policy” under the motion when he declined to rule on whether the gene patents at issue impeded the progression of research and scientific knowledge noting the “sharp dispute concerning the impact of patents directed to isolated DNA on genetic research and consequently the health of society . . . .” Additionally, Judge Sweet failed to address the plaintiffs’ constitutional claims, regarding them as irrelevant, considering Myriad Genetics’ patents were granted under the authority of 35 U.S.C. § 101.

A day after the decision was handed down Myriad vowed to appeal the decision, noting that “even in the worst case for them, [it] would take years [for the decision] to have a significant effect.” Myriad CEO, Peter Meldrum, said the company was “disappointed that Judge Sweet did not follow prior judicial precedent or Congress’s intent that the Patent Act be broadly construed and applied, [but Myriad is] very confident that the Court of Appeals for the Federal Circuit will reverse this decision and uphold the patent claims being challenged in this litigation.” Additionally, Myriad Genetics holds sixteen more patents on.
BRCA genetic tests that were not at issue in this case, leaving the company's revenue streams that are uninterrupted by this decision. Several lawyers expect the ruling to be overturned, or at the very least “an important Supreme Court showdown” to ensure. Despite Judge Sweet’s decision, the patentability of genes is still a very real issue and the District Court’s decision is nothing but a bandage for Myriad Genetics’ patent problems. Until other courts take similar measures, the reach of the current decision is severely limited. At this point in time the District Court’s decision does not affect gene patents that were not at issue in the current controversy (although should the decision be upheld on appeal other patents will likely be challenged), thus the decision’s precedential value for other courts at this time is limited. This decision is hardly the end to the battle over gene patentability, and as such other avenues for limiting gene patents’ breadth should be explored in the event that this initial decision is ultimately overturned.

b. Public Response to the Myriad Genetics Decision. Many organizations and commentators were unenthusiastic about the decision. Biotechnology Industry Organization (BIO) President and CEO Jim Greenwood released a statement after the decision criticizing the holding and reiterating the patentability of genes:

From the mass production of life-saving medicines by cell cultures to the screening of our blood supply for life-threatening viruses, patented DNA molecules have been put to countless uses that have benefited society. Preparations of isolated and purified DNA molecules, which alone can be put to use in these ways, are patentable because they are fundamentally different from anything that occurs in nature.

Likewise, IP attorney and blogger Eric Guttag finds fault with Judge Sweet’s interpretation of prior precedent and argues that the decision goes against earlier...
Supreme Court decisions. Guttag claims that Judge Sweet misinterpreted In re Bergy, which Guttag claims “actually supports the patent-eligibility of Myriad’s BRCA1 and BRCA2 gene sequence technology.”

Myriad attorney Brian Poissant argued to the court that “disallowing the patents would wreck the foundation of the biotechnology industry.” Judge Sweet attempted to quell the fears of many that the decision would destroy the biotechnology industry stating that the decision “concerning the subject matter patentability of isolated DNA ... [is] based on the unique properties of DNA that distinguish it from all other chemicals and biological molecules found in nature.” In line with Judge Sweet’s conclusion, the market for Myriad Genetics’ stock saw little effect from the decision, with analysts noting that the case may be years from a final conclusion due to appeals. Additionally, they note that while other companies may eventually compete with Myriad Genetics in the testing market, the competing products will likely not materialize for a while because Myriad Genetics still holds other patents and the decision may still be reversed on appeal. Some fear invalidating these patents will hinder biotechnology companies’ ability to retain financial backers and “diminish the incentives for genetic research.”

Kenneth Chahine, author of an amicus brief in support of Myriad Genetics, claims that should the District Court’s decision be upheld, the “industry is going to have to get more creative about how to retain exclusivity and attract capital in the face of potentially weaker patent protection.” This is not an issue that will cease in the near future. Biotechnology companies have much to gain by protecting their patents, and much to lose in the face of the changing landscape shaped by Judge Sweet’s decision.

Commentators in favor of the decision addressed the issues of access, quality, research, and cost in light of this decision. Noting the decision’s effect on cost and access, James Love, the American co-chair of the intellectual property committee of the TransAtlantic Consumer Dialogue and director of Knowledge

189 Id.
193 Id.
195 Id.
Ecology International, lauded the holding as "a very pro-consumer decision... [that is] going to make it much cheaper for people to get the tests they need." Addressing the issue of impeding research, President of the Association for Molecular Pathology, Dr. Karen Mann, released a statement claiming "this judgment removes numerous barriers and impediments to clinical research, testing, and innovation." Explaining the decision's effect on patient rights and quality, Michael S. Watson, Executive Director of the American College of Medical Genetics agreed "this is a huge, huge victory for better patient care" and that the "invalidation of gene patents will allow patients to get second opinions on test results, encourage quality improvement of current testing, allow researchers to develop new and better methods of testing and decrease costs of laboratory testing." Finally, the popular press, including the New York Times, noted the potentially broad scope of the decision, stating that if Judge Sweet's decision is upheld "the invalidation of genetic patents could hit diagnostics companies, agricultural biotechnology companies and perhaps even traditional drug makers." Because of the sharp division this case has caused, as evidenced by emotionally charged commentary following the holding by both camps, the war for and against gene patents will be fought for years to come.

C. IMPLICATIONS FOR ACCESS, QUALITY, AND RESEARCH

Even with the potential positive effects the interim decision in the Myriad Genetics case may have on access, quality, and research, evidenced by the positive commentary of industry professionals, there is still strong opposition to the interim decision. Should the appellate court overturn the ruling, access, quality, and research will all be directly affected by the validation of gene patents. Thus, it is important to discuss the substantial effect gene patentability has had on these areas in the past.

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199 Pollack, supra note 134.
1. **Issue of Access.** The issue of limited access is inherent whenever there is a sole provider of a service.\(^{200}\) The patent protection afforded to Myriad Genetics leaves no other option for patients whose health insurance is not accepted by Myriad Genetics.\(^{201}\) When proper testing is unavailable, these patients are left to make medical decisions for themselves, without adequate information and with little choice but to pay out-of-pocket for the test. One may argue that it is the insurance companies and social issues, such as poverty, that limit access to these tests, and patients’ limited access is not the fault of the patents granted to Myriad Genetics. However, if the patents remain void, other companies could enter the testing market allowing insurance carriers a broader choice. The more providers that are available, the more likely an individual’s insurance will cover at least one of these testing facilities, leading to broader access overall.

Patent protection also limits patients’ access to a second opinion. The ability of a patient to seek out an independent second opinion is an important part of the medical process.\(^{202}\) Should the test performed by Myriad Genetics come back inconclusive, a patient has no choice but to accept this finding at face value.\(^{203}\) While additional testing may be performed, the additional BART test is not covered by the initial fee, and some insurance providers may not cover the increased cost of testing.\(^{204}\) Even with additional testing, mutation identification based on Myriad Genetics’ data may not be available, considering the information contained in Myriad Genetics’ databank has been shown to be inconclusive in a small percentage of cases.\(^{205}\) Patients who receive inconclusive results have little free choice. Their options are limited to paying Myriad Genetics to perform the second test, which may not lead to additional information, or accepting the inconclusive results.\(^{206}\) Accepting inconclusive results, without the ability to further identify the issue, may be detrimental to a patient’s health. Without proper gene identification, medically uneducated patients are left to make life-altering medical decisions, such as whether or not to undergo preventative measures to

\(^{200}\) Complaint, *supra* note 2, at 10 (presenting the case of Lisbeth Ceriani, whose insurance was not accepted by Myriad and thus remains untested).

\(^{201}\) *Id.* at 27 (showing that two plaintiffs whose insurance was not accepted by Myriad are left to pay out-of-pocket for the test).


\(^{203}\) Complaint, *supra* note 2, at 11 (demonstrating the problem that two plaintiffs encountered when they received inconclusive results).

\(^{204}\) *Id.* at 27–28 (stating that additional BART testing costs approximately $650 when not covered by insurance).

\(^{205}\) *Id.* at 26.

\(^{206}\) *Id.* at 27 (describing the expanded BART test or the alternative of no additional testing).
avoid the development of cancer, based on little concrete information. The wrong choice may make the difference between life and death.

2. Issue of Quality. Quality concerns have also become a large part of the genetic testing debate. By several accounts, the test that Myriad Genetics provides could be improved significantly. One French study suggests that Myriad Genetics' testing procedure fails to find 10%-20% of mutations. Other tests that have been precluded from entering the market because of Myriad Genetics' patents may have the potential of providing more accurate results in certain circumstances.

3. Issue of Impeding Research. Most significantly, prior to Myriad securing the relevant patents, several scientists and researchers were conducting research on BRCA genes. However, when confronted with potential liability for their research activities, these researchers stopped their research. Because the actual genes and gene mutations are protected by the patents, researchers are unable to conduct research on the patented genes or any mutations thereof. This prohibition operates even if the actual test they are conducting is not the same type as the test conducted by Myriad Genetics. There is currently no workaround for researchers. The plaintiffs believe that research and testing will be stifled unless the appeals court upholds the District Court’s decision to void Myriad’s gene patents. While Myriad Genetics claims that it is not currently targeting researchers, many researchers are aware of instances where Myriad Genetics sought enforcement of the company’s patents. If researchers are not able to research the BRCA genes, the gene information available will remain woefully inadequate.

D. PATENT PROTECTION IN EUROPE AND THE EUROPEAN PATENT OFFICE’S TREATMENT OF MYRIAD GENETICS

The European Patent Office (EPO), a division of the European Patent Organisation, is a centralized body that grants patents for up to forty European countries. The requirements for EPO patents are similar to those of the

208 Plaintiffs' Statement of Materials Facts, supra note 58.
209 Id. at 3-5.
210 Id. at 34-35.
211 Id. (arguing that gene patents inhibit research because researchers are not able to conduct any testing on BRCA genes due to the patents).
212 Id. at 26-28.
USPTO. Under Article 52 of the European Patent Convention (EPC), a patentable invention is one that is (1) new, (2) "involve[s] an inventive step," and (3) has an "industrial application." Patented goods are granted up to twenty years of protection from the date in which they are granted.

Under the European Union Biotech Directive isolated biological material is patentable "even if it previously occurred in nature." Thus, a human gene sequence may be patentable "even if identical to the natural element." A human gene sequence that has been isolated from its natural surroundings, or isolated DNA, is included as patentable subject matter under the directive. Diagnostic tests, which use DNA, have also been held to be patentable.

After a patent has been granted by the EPO, third parties have the opportunity to oppose the patent in a formal opposition procedure if they believe that the patent should not have been granted. One reason that an opposition may be filed is if "the subject-matter of one or more of the claims is not new or inventive." The opposition division of the EPO will then investigate the basis for the opposition. Upon completion of this investigation, the opposition division may revoke the patent, maintain it, or maintain it in an amended form.

The EPO granted Myriad Genetics four patents in 2001. One of these patents covered the “method for diagnosing a predisposition for breast and ovarian cancer.” In particular, this patent covered mutations of the BRCA1 gene and the gene mutations’ use in determining whether an individual was at an increased risk of breast or ovarian cancer. This patent generated many critics.

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See Directive, supra note 216.

Yeats, supra note 217.


Id.

Id.

Id.


Id.


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In October of 2001, the Institut Curie filed an opposition with the EPO challenging European Patent No. 699 754.\textsuperscript{228} Five additional letters of opposition were also filed by other interested organizations.\textsuperscript{229} The Institut Curie claimed that the patent did not meet the novelty requirement under Article 52 of the EPC, lacked an inventive step, and contained an insufficient description.\textsuperscript{230} Additionally, the Institut argued that the patent at issue might "jeopardize the development of research, hinder access to testing, and furthermore go against [Europe's] approach to public health."\textsuperscript{231} Finally, Institut Curie claimed that the patent granted was too broad.\textsuperscript{232} The patent would prohibit labs that were already conducting research from continuing their research on these genes in Europe, regardless of the testing procedure used.\textsuperscript{233} The Institut further noted that Myriad's sequencing fails to detect 10% to 20% of all mutations, leaving room in the market for improvement using a different type of gene sequencing than Myriad uses.\textsuperscript{234} After the opposition hearing on May 18, 2004, the EPO revoked the opposed patent, European Patent No. 699 754.\textsuperscript{235} The opposition division found that the patent violated Article 56 of the EPC requiring an inventive step.\textsuperscript{236} Myriad Genetics challenged the revocation, and in a second hearing the patent was maintained in an amended form.\textsuperscript{237} The amended patent protects only certain diagnostic
methods. While overall a victory for those that opposed the patent, the amended form still includes about half of known mutations.

There was also a formal opposition process to two other Myriad Genetics patents granted in 2001. European Patent No. 705 902, which was related to the actual BRCA1 gene, was "maintained in a severely limited form." European Patent No. 705 903, which covered "[m]utations in the 17q-linked breast and ovarian cancer susceptibility gene," was also maintained in an amended form after being limited during its first opposition hearing in 2005.

E. SUGGESTIONS FOR CHANGE

1. National Institutes of Health. The National Institutes of Health (NIH), a subdivision of the Department of Health and Human Services, developed a series of recommendations that it released as its Best Practices for the Licensing of Genomic Inventions in 2005. NIH recommends several possible solutions, some of which conflict with each other. The NIH’s guidelines first suggest that gene patents be granted only "when it is clear that private sector investment will be necessary to develop and make the invention widely available." In contrast to the aforementioned recommendation, the NIH condemns the use of gene patents when "significant further research and development investment is not required." As a compromise to the above recommendations, the NIH suggests several licensing standards that borrow aspects from both. NIH’s best practice is to encourage the use of non-exclusive licenses whenever possible. If non-exclusive licensing is not feasible, then the NIH concedes that an exclusive license may be used but should be "tailored to ensure expeditious development of as many aspects of the technology as possible." NIH’s overall goal with respect to its best practices is to ensure continued access to new technologies for the public health. Restricting the use of gene patents would be ideal, however, ensuring

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238 Id.
239 Institut Curie Nov. 2008 Press Release, supra note 236.
241 Id.
242 Id.
244 Id. at 18,415.
245 Id.
246 Id. (allowing non-exclusive licensing would permit others to legally use patented material within the scope set forth in the licensing agreement).
247 Id.
248 Id.
the public availability of genes through licensing would be an acceptable compromise for the public as well as the biotechnology industry.

2. Secretary’s Advisory Committee on Genetics, Health, and Society. The Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS), an advisory committee to the Secretary of Health and Human Services, released a draft report for public comment in June 2009 outlining several issues regarding gene patents and presenting ways to improve the patenting of genes. SACGHS’s report described several concerns related to gene patents, finding some had merit while others lacked sufficient evidence upon which to form a solid conclusion at the time of publication. SACGHS first addressed access concerns, concluding that gene patents create several patient access problems. The access problems that arose were mainly due to the sole provider: (1) not providing the test, (2) not offering “complete testing of alleles and rare genes,” and (3) not contracting with certain payors (often third party insurers). SACGHS did note, however, that while patents “may limit clinical access to a test,” that does not directly correlate to “limited patient access to a test.”

SACGHS’s main concern was the effect of gene patents on continued research and development. From a research and development standpoint, SACGHS found that the “prospect of receiving a patent was not the major force motivating scientists.” SACGHS argues that many scientists in the genetic field will continue to carry on their research regardless of patent protection for a variety of other reasons, the most compelling of which is “clinical need.” However, the SACGHS did note the importance of patents to the eventual commercialization of a genetic test. SACGHS’s main concern within the research realm was the potential problem that could manifest itself in “multiplex genetic testing” and “whole genome analysis/sequencing,” where the use of several potentially patented genes would be required. SACGHS noted that the cost of purchasing several licenses to conduct testing may be cost-prohibitive for many researchers.

250 Id. at 109.
251 Id.
252 Id.
253 Id. at 99.
254 Id.
255 Id. at 111.
256 Id. at 100 (noting that although patents are not “uniformly a necessary incentive” to develop genetic tests, they may be necessary to encourage development of tests with “rare alleles”).
257 Id. at 106.
258 Id.
Furthermore, if the patent holder did not allow licensing at all, further testing with that gene would be impossible.

Taking the aforementioned findings into consideration, the SACGHS proposed several policy changes including: (1) increasing involvement of shareholders, (2) increasing transparency, (3) broadening licensing efforts, and (4) making statutory changes. SACGHS first recommends that stakeholders cooperate in order to "develop a code of conduct to encourage broad access." When there is a collaboration of stakeholders, such as private firms and university researchers working together on a product, these entities should plan in advance how issues such as patents and licenses will be addressed to avoid future conflict.

SACGHS then suggests increasing transparency in the patent and licensing process. One suggestion in this arena is to encourage patent holders to make information about their licensing standards public. SACGHS also suggests having the Food and Drug Administration and Medicare/Medicaid require genetic testing companies to display patent numbers on their product or website before the company could market the product. Based upon its recommendations, it appears that SACGHS’s focus is to make information on these patents easily accessible for others to find, leading to the possibility of increased communication and cooperation between the parties.

Third, SACGHS recommends having federal agencies promote broader licensing practices among patent holders to help ensure continued access of these tests to patients. SACGHS noted several organizations’ licensing guidelines as a starting point for federal agencies to abide by in pushing broader licensing practices but did not settle on one particular scheme. Suggestions include federal agencies promoting the use of exclusive licensing for genetic inventions and promoting licensing for "development and use" for "neglected patient populations." Additionally, SACGHS suggests that federal agencies look into new methods of dissemination of technologies including patent pooling and due diligence clauses in licensing agreements as potential answers to the access issue.

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259 Id. at 113–23.
260 Id. at 113.
261 Id. at 113–14.
262 Id. at 115.
263 Id.
264 Id.
265 Id. at 118.
266 Id. at 118–19 (looking at licensing schemes promulgated by the NIH, OECD, and AUTM).
267 Id.
268 Id. at 119.
Most importantly, SACGHS suggests statutory changes that could improve the current patenting of genes. \(^{269}\) Notably, SACGHS suggests limiting "patenting of diagnostic tests that rely on an association of a particular genotype with a disease/disorder," or, alternatively, only allowing these patents with conditions and scope limitations. \(^{270}\) Reaching beyond researchers, SACGHS also suggests limits on infringement liability for "medical practitioners who . . . perform diagnostic genetic tests in clinical care," and those who perform "diagnostic genetic tests in the pursuit of research." \(^{271}\) While other organizations recommend eradicating gene patents completely, SACGHS's recommendations target ways to improve the current gene patent system by focusing on the availability of licensing information and making exceptions for uses in the public interest.

3. Organisation for Economic Co-Operation and Development. In 2006, the Organisation for Economic Co-Operation and Development (OECD), an international forum, proposed new licensing guidelines for genetic inventions. \(^{272}\) The OECD presents a unique perspective on gene patenting, as it represents the interests of stakeholders from around the world. \(^{273}\) The interested parties agree that licensing may resolve many of the fears related to gene patents. \(^{274}\) The overall goal of the OECD's guidelines is to ensure availability of genetic testing by licensing inventions to assist in the "rapid dissemination of information," while still allowing the original patent holder to make a return on his investment. \(^{275}\) Specifically, the OECD recommends that rights holders "broadly license genetic inventions for research and investigation purposes" to ensure the widest public access to the inventions. \(^{276}\)

The OECD seeks to limit licensing, stating that "exclusive control over human genetic information" should not be maintained by the licensor and licensors should license their genetic invention as to maximize its utilization. \(^{277}\) To combat the possible impediment of research, the OECD focuses on continued development, ensuring that licensing agreements allow licensees to improve upon

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\(^{269}\) Id. at 122.

\(^{270}\) Id.

\(^{271}\) Id. at 123.


\(^{273}\) The OECD member countries are: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States. Id. at 2.

\(^{274}\) Id. at 3.

\(^{275}\) Id. at 7.

\(^{276}\) Id. at 9.

\(^{277}\) Id. at 8.
the invention. As additional protection, the databases that hold the information derived from continued research on the invention should not be restricted or solely controlled by the licensor, but widely disseminated. With a focus on balancing the commercial and research issues that arise with gene patents, the OECD suggests that the commercial value of the gene should not unduly affect the work of academic researchers. Should royalty payments be necessary, they should be reasonable. In addition to licenses, the OECD also suggests that "research deference" or a research exception be provided where allowed by the individual jurisdiction. Essentially, the OECD is concerned with producing the least restrictive licensing scheme possible to ensure the public's access to these important inventions while still keeping the patent holder's interests in mind.

III. ANALYSIS

Under the current gene patent standards, Myriad Genetics has the USPTO's Guidelines on its side, however the current law is not. While research suggests that gene patents may not be the sole cause of limited access or increased cost of genetic testing, it is still a relevant consideration. The actions taken in response to the Myriad case will likely change the face of gene patenting from this day forward. Thus, the legal community must be aware of the practical implications of the current controversy. This case extends far beyond the named plaintiffs; it extends to all people who have a family history of genetic disorders who wish to be tested, and to all of those who will be refused a second opinion when the sole provider of the test refuses to license it. To allow a company to profit off of nature at the expense of the public health should not be permitted by the USPTO, but that is exactly what the current Utility Examination Guidelines allow. The patents issued by the USPTO deprive women of the right to take control of their own health for the length of Myriad's patent protection, while protecting the company that is depriving these women of this right. Myriad Genetics has been hiding behind its patent while exploiting patients in their time of greatest need.

This is not simply the economics of allowing a company to recoup its research and development costs through patents. This case is about inserting humanity back into the patent process, and using the patent process to protect those who need it the most, the public. It would be ideal if the appellate court would uphold

278 Id.
279 Id. at 9, 16.
280 Id. at 10.
281 Id. at 11.
282 Id. at 18.
283 Id. at 11.
the decision of the District Court for the Southern District of New York, ensuring that Myriad Genetics' BRCA patents remain void. However, in the event the decision is overturned, a very real possibility, steps must be taken to protect the public to ensure continuing access, quality, and research for all. Additionally, there are still thousands of gene patents that were not subject to this suit, which are linked to numerous genetic diseases and disorders. Any final decision in the Myriad Genetics case, be it for or against gene patentability, will reverberate across the industry. Should the Myriad case be overturned and the relevant patents held valid, the policymakers' focus should shift toward limiting or narrowing the scope of gene patents. The suggestions made by various organizations and the example set by the countries of the EU should be viewed with an eye toward limiting gene patents. If gene patents are ultimately held valid, limitations should be put on patenting isolated and purified genes and the related gene mutations linked to specific diseases, or, alternatively, all current gene patents should be revoked. This is not to say that a company is completely left without reward for its discovery. The best option for all parties involved is to deny patents for genes, but to allow them for the testing process. Additionally, other yet undisclosed or undiscovered options for dealing with gene patents may be available through legislation and regulation.

This Part will discuss how the current USPTO Utility Examination Guidelines should be amended. It will then examine how to close the gap between the needs of these for-profit corporate entities and the needs of current and future patients should the Myriad decision be overruled. Next, this Part will take suggestions from recently released reports and evaluate the practicability of those suggestions. In conclusion, this Part will evaluate whether the actions taken by the EPO could work in the United States.

A. CHANGING THE USPTO'S UTILITY EXAMINATION GUIDELINES

The District Court noted the USPTO's Utility Examination Guidelines in its decision, and dismissed Myriad Genetics' reliance on them. The Court stated that it owed the USPTO's Guidelines "no deference," and as such the current Utility Examination Guidelines may be of little practical value. However, should the Myriad decision be overturned on appeal, the Guidelines will once again be in force. Thus, it is important to evaluate changes that could be made to the Guidelines to limit gene patents, despite the Guidelines' current status.

285 Id.
One option that may be implemented to protect the public health is to revise the current Utility Examination Guidelines. As they currently stand, any gene that is found, isolated, and purified can be patented. Thus, theoretically, the Guidelines would grant protection to any gene found in the human genome. What happens when research is halted because a patent holder refuses to allow researchers access to the gene? New discoveries that could help millions are at risk. Genes that are currently being patented are related to a number of debilitating diseases. In order to continue research on unpatented genes, access to patented genes may be necessary in order to establish how one gene reacts with another to produce a given ailment. Without reevaluating the Utility Examination Guidelines, the ability of researchers to continue their research on genetic diseases will continue to decline.

Because the Guidelines are in a state of limbo in light of the current controversy, it is difficult to determine exactly what type of changes would be most beneficial. If the District Court’s decision is upheld, the lack of deference afforded to the Guidelines by the courts will force the USPTO to redraft the Guidelines to comport with the appellate decision. However, if the case is overturned on appeal, the USPTO should implement a limiting principle into the current Guidelines to further narrow the scope of any gene patents that are granted. Either way the current broad scope of the Guidelines must be addressed, be it by judicial decision or the USPTO’s own pen.

B. HOW TO CLOSE THE GAP BETWEEN THE NEEDS OF THE CORPORATION AND THE PATIENT

One major objective in granting patents is to allow inventors to reap the financial benefits of their discovery. While public health must be protected, the courts and legislature must not forget about the need to incentivize innovation. Generally, without the prospect of commercialization, financial backers would not invest in genetic research. In fact, the owner of Myriad Genetics claims that without the promise of a patent, the research that led to the discovery of the

286 See supra note 92 and accompanying text.
287 See supra note 65 and accompanying text (describing patents for long QT Syndrome, nemochromatosis, and cystic fibrosis).
288 See supra notes 257–58 and accompanying text.
289 See U.S. CONST. art. I, § 8, cl. 8 (stating that patents are available to “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”).
290 See supra note 39 and accompanying text (showing how Myriad would not have had the resources to discover the BRCA genes without the prospect of commercialization).
BRCA genes would never have occurred. The question then remains, how can one close the gap between the needs of the public and the needs of the corporation? Several organizations have made suggestions in regards to fixing the current gene patent problem, should the Myriad decision be overturned.

1. Licensing Reform. One suggestion the NIH presented in its *Best Practices for the Licensing of Genomic Inventions* is non-exclusive or exclusive licensing for genetic materials. While the NIH noted the importance of prospective patents to the eventual commercialization of a product, and suggests that patents be available when necessary to ensure wide distribution of the product, it also noted the importance of licensing as a limitation on the patent. If non-exclusive licensing is not possible, then NIH suggests that exclusive licensing be used. Additionally SACGHS suggests that federal agencies promote broader licensing practices to ensure continued access to patients. Both of these suggestions would work to close the gap between what the company needs to commercialize its product, while protecting the public. Statutorily requiring compulsory licensing for genetic materials is one way to handle the current dilemma. The licensing of patented genetic inventions would take care of many issues that arguably face this industry, including lack of access, lack of quality, and impeded research. Even if a company is required by statute to license out its invention, it would still reap the financial benefits that come from the patent protection. Statutorily mandated compulsory licensing is also advantageous for the consumer, because it ensures access to the product. Additionally, because more than one company would be conducting the testing, the quality of the test could be verified, leading to more accurate results. Lastly, statutorily based compulsory licensing ensures that research on these genes continues. While the cost of procuring a license may still be prohibitive for some researchers, simply having the ability to work with a gene through a license is better than not having access to the gene at all. Statutorily required compulsory licensing would not alleviate all of the issues that are currently plaguing gene patents. However, it may help in securing the financial rewards that companies need while protecting access and quality for the public, and allowing continued research for all.

The OECD agrees that changes in licensing must occur, and detailed its findings in its *Guidelines for the Licensing of Genetic Inventions*. Unlike the broader statutorily based compulsory licensing scheme of the NIH, the OECD argues that

\[291\] See *supra* notes 37–39 and accompanying text.

\[292\] See *supra* Part II.E.1.

\[293\] See *supra* Part II.E.1.

\[294\] See *supra* note 247 and accompanying text.

\[295\] See *supra* Part II.E.2.

\[296\] See *supra* Part II.E.3.
the best way to ensure access to genetic testing, while keeping companies’ interests in mind, is to encourage biotechnology companies to license broadly for “research and investigation purposes.” OECD’s model recommends that any royalty payments made by researchers be reasonable, thus making it financially practical to conduct their research. In an ideal world, the OECD suggests that there be a research exception that would allow research to be conducted without charge. This would ensure that research continues while still allowing the patent holder to conduct the actual testing. This suggestion would benefit both the patent holder and the public. The patent holder would remain in control of his invention, while research could continue to benefit the public. However, the practicability of this recommendation is slim at best. If biotechnology firms are already refusing to license their invention, it is unlikely that the mere suggestion that they do so in the name of research would change their minds. In order for a biotechnology company to take the financial risk of licensing its invention to researchers with little or no royalty payments, there must be an incentive for the company. The company must be able to recoup its lost profits through alternate means, possibly in the form of tax breaks or grants for further research. Without such an incentive scheme in place, the likelihood that a company would be willing to part with the control and financial resources that come with being a sole provider is slim.

The OECD’s suggestion is not as favorable to the public as statutory compulsory licensing. Compulsory licensing lends itself well to quality control because other laboratories would also be conducting testing. Without compulsory licensing this quality control is not realized. Under OECD’s model, however, the license would allow licensees to improve upon the invention. While not directly related to the day-to-day quality control of the test, this proposal may help in increasing the quality of the test as a whole. It would allow others to build around the invention to create a better and more accurate test. The access and cost benefits of compulsory licensing are also not as apparent under this scheme. Because other laboratories would only be engaged in research and not public testing, there would not be an increased number of laboratories for consumers to choose from. As a consequence, the cost competition benefit of having several laboratories conducting public testing is not realized under this model. This theory, however, would address the concern the plaintiffs have about Myriad Genetics not sharing its database with the Breast Cancer Mutation Database.

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297 See supra note 276 and accompanying text.
298 See supra note 281 and accompanying text.
299 See supra note 282 and accompanying text.
300 See supra note 278 and accompanying text.
301 See supra notes 29–31 and accompanying text.
Under the OECD's model, informational databases should be shared and should not be under the sole control of the licensor. This model would be a good starting point for change. It allows research on genes to continue with little or no cost, thus protecting the consumer, while still allowing the company to reap the rewards of its invention.

2. Increasing Transparency. SACGHS suggests that patent holders be required to make information about their licensing standards public. This would ensure that those who wish to obtain a license to the patent holder's invention would not be unduly burdened in finding needed information about the patent holder's licensing standards. While Myriad Genetics claims that it did not wish to go after researchers, researchers stopped their research in fear of possible infringement lawsuits. Publicizing licensing information may help to increase the amount of research that takes place. There are several ways to make this type of information public. The biotechnology company could put the necessary licensing information on their official website. Arguably researchers would likely begin their quest for information at the company's website, making this a workable solution for both parties. SACGHS suggested that the FDA and Medicare/Medicaid require companies to make patent information available on the company's product. This recommendation is also an effective way to communicate information to researchers, while being a fairly simple fix for companies. Requiring that the patent information be displayed on both a company's website as well as on the product itself would be the best option. The only downside would be the actual administration of the program. While many companies would likely voluntarily display this information if requested, the FDA and Medicare/Medicaid may not have the resources to oversee such a program. It would be possible, however, to have a statutory penalty recoverable in a civil action for failure to provide the required information. Any increase in the degree of transparency should be encouraged. If adequate overhead for the program is not possible, then companies should be requested to comply with these transparency guidelines on a voluntary basis.

3. Additional Statutory Changes. SACGHS also suggests limiting "patenting of diagnostic tests that rely on an association of a particular genotype with a disease/disorder." If that is not possible, then it suggests allowing patents only with certain conditions and having limitations placed on their scope. Thus, the

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302 See supra note 279 and accompanying text.
303 See supra notes 262–64 and accompanying text.
304 See supra Part II.B.3.
305 See supra note 264 and accompanying text.
306 See supra note 270 and accompanying text.
307 See supra note 270 and accompanying text.
SACGHS provides two alternatives: if a strict prohibition of patents on these particular genes is not feasible, SACGHS recommends severely limiting their scope. These suggestions directly interfere with the USPTO’s Utility Examination Guidelines, however, which allows patenting of diagnostic tests and genes that have a known purpose. Limiting the ability to patent genes and tests that are directly related to known diseases would be a huge benefit for the public. However, these suggestions leave the companies that founded the test or isolated the gene without reward for their efforts and deprive them of the incentive to pursue further solutions. If these suggestions are implemented, companies would no longer be able to patent genes (and related tests) that have a known purpose. Thus, this suggestion in conjunction with the currently nullified USPTO Utility Examination Guidelines would lead to a near prohibition on the patenting of genetic inventions. While the idea is a good one, these suggestions may lean too far on the side of the public to survive passing through the legislature.

SACGHS alternatively suggests that if gene patents are once again granted, there should be limits on infringement liability for medical professionals and researchers. Unlike earlier suggestions, which would make licenses available to these researchers and medical professionals for reduced royalty fees, SACGHS suggests a blanket waiver of liability for these professionals. This would allow researchers to continue their research to the benefit of the public. Medical doctors would also be able to perform these tests for their patients. This suggestion, however, prevents the patent holder from reaping the financial benefits of its discovery. But, if the suggestion only included research activities and reinstated liability for medical professionals conducting their own testing, a better balance would be struck between the needs of the company and the needs of the public. Under this revised theory, the public would benefit from continued research, while the patent holder would continue to be the sole commercial source of the test.

C. LESSONS LEARNED FROM THE EUROPEAN UNION’S DEALINGS WITH MYRIAD

Taking into consideration the acts of the European Patent Office, several ideas for dealing with this international problem may be gleaned. The system that most closely resembles the United States’ patent process is that of the EPO. Much like its United States counterpart prior to the Myriad decision, the EPO allows isolated genes to be patented “even if identical to the natural element.” It also mirrors the USPTO’s stance on diagnostic tests, which have been held to be patentable

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308 See supra Part II.C.1.
309 See supra note 271 and accompanying text.
310 See supra note 217 and accompanying text.
under both regimes. The United States should utilize the EPO’s opposition procedure in the event that the Myriad decision is overturned on appeal. Through the EPO’s opposition process, individuals and organizations have the opportunity to oppose a patent application even after it has been granted. When this process was used by several organizations in Europe, the EPO was forced to reexamine the patents it had granted to Myriad Genetics. The effect of this opposition was the revocation and subsequent reinstatement of the patents in an amended form.

To ensure that patents granted by the USPTO undergo a high level of scrutiny, this type of public opposition procedure should be implemented if gene patents are reinstated. The opposition procedure should allow any party, whether an interested party or not, to submit a written challenge to the USPTO after a gene patent has been granted. A statute of limitations should be put in place to ensure a speedy resolution for all parties. After an opposition has been submitted, the USPTO should investigate the claims made in the written opposition and make a determination as to the product’s patentability. Like the EPO’s system, there should be three possible outcomes: the patent could be upheld, voided, or upheld in an amended form.

Had the United States implemented this type of opposition procedure earlier, lawsuits, including the current controversy, could be wholly avoided. The opposition to Myriad Genetics in Europe had many of the same concerns that the plaintiffs raised in the current lawsuit. The EPO’s opposition procedure is successful because it addresses many concerns and narrows the patents without costly litigation. In light of this small success, the United States should implement a similar opposition procedure for patents on genetic materials. The procedure appears to have worked in the European Union. While there may be an increased cost of reevaluation on the front end, eliminating the need for court proceedings, such as the current case, may be well worth the added expenditure. Additionally, those who will be most affected by the patenting of a product, such as researchers and patients, should have the ability to have their voices heard. Europe’s treatment of Myriad Genetics shows that a balance can be struck between the financial interests of the patent holder and the interest of the public. While Myriad Genetics got to keep its patents, the scope of these patents was significantly narrowed from the originals. Had the United States used a similar process when Myriad Genetics’ patents were granted, it is likely that the broad scope of the patents could have been sufficiently narrowed to protect the public.

\[^{311}\text{See supra notes 216-19 and accompanying text.}\]
\[^{312}\text{See supra notes 220-23 and accompanying text.}\]
\[^{313}\text{See supra notes 224-42 and accompanying text.}\]
\[^{314}\text{See supra notes 235-42 and accompanying text.}\]
interest. Additionally, the current case may not have been necessary, thus improving judicial economy.

IV. CONCLUSION

The battle over whether genetic material should be patented is significant for any person who has a loved one that may one day need to make a tough decision about her health. Myriad Genetics has locked down the market for BRCA1 and BRCA2 testing in the United States and abroad. This has stifled research, restricted patents’ access to care, increased costs, affected quality of care, and interfered with patient rights.

Gene patents have become a hotbed for international debate. Several countries have found that a full patent, like the United States once provided Myriad Genetics, goes too far. In regions where opposition to patents is encouraged, such as in the European Union, change has occurred: first with the revoking of such patents, and then with their subsequent reinstatement in limited form.

The current patent process for genetic material is in a state of flux. Even with the district court decision invalidating the BRCA patents, the unstable patent process for gene patents is insufficient to protect the rights of patients in the United States and around the world. The district court decision in the Myriad Genetics’ case is a good stepping-stone toward gene patent freedom. While the decision has been both praised and criticized, everyone can agree that the fight over gene patentability is far from being over. Though with the decision being appealed, the future of gene patents remains uncertain.

At this juncture, it is prudent to look at all of the available options. While the district court’s decision may be upheld and gene patenting as we know it may be a distant memory, there is a chance that the appellate court could side with Myriad and reinstate their gene patents. Thus, this Note has outlined alternatives in light of gene patents’ uncertain future.

If gene patents are held to be valid once again, changes will have to be made to the USPTO’s Utility Examination Guidelines as they existed before the Myriad decision and additional changes will have to be made by the legislature to ensure that patients are not stripped of their right to make informed medical decisions. A new system of opposition, based on the EPO’s model, may help decrease litigation costs while increasing awareness of gene patenting in the U.S. for interested parties. The USPTO should be required to hear and address the concerns of private companies, researchers, and others, in order to ensure that only narrow gene patents are granted. If gene patents are reinstated, research will once again be hampered because of the lack of a workaround for researchers. Lastly, the United States should adopt a system of compulsory licensing of genetics material to ensure wide dissemination of testing and research.
opportunities if the patents are upheld. This would show concern not only for the patent, but also for the original patent holder’s bottom line. Either way something must be done. The appellate court will either have to uphold the invalidity of gene patents, or the public and the legislature will have to step in and ensure that any gene patents that are allowed are as widely licensed and as narrow in scope as possible. Simply stated, the fight over gene patenting is far from over. The plaintiffs in the Myriad case may have won the battle, but Myriad has vowed to fight, and the war rages on.