I. Introduction

On March 29, 2010, in a surprisingly sweeping summary judgment order, Judge Robert W. Sweet of the United States District Court for the Southern District of New York invalidated 15 claims on seven gene patents associated with detection of breast cancer genetic mutations. The lawsuit was initiated on May 12, 2009, by the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PUBPAT) on behalf of medical researchers, medical research associations, women’s health organizations and individual women, challenging various patents on two human genes associated with breast and ovarian cancer. The lawsuit, Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al., seeks declaratory relief to invalidate various patents on these genes granted to Myriad Genetics (Myriad) and the University of Utah Research Foundation on Constitutional and statutory grounds. Basically, the lawsuit requests invalidation of the BRCA1 and BRCA2 gene patents in that the genes are “products of nature, laws of nature and/or natural phenomena” and thus not patentable under Article I section 8, clause 8 of the United States Constitution and the Patent Act. An additional and unique legal argument against gene patents was also presented in the lawsuit but not addressed by the District Court in its summary judgment ruling. The challenged patent claims granted to the defendants were alleged to be unconstitutional under the First and Fourteenth Amendments in that they restrict “abstract ideas or basic human knowledge of thought.”

The defendant-patent holders have indicated that an appeal to the Federal Circuit is forthcoming. The complexity of the legal and scientific issues surrounding the patentability of genes lead to speculation whether this case will be the vehicle through which gene patents will be considered by the U.S. Supreme Court. The specific question of the patentability of genes has not been addressed by the Supreme Court, and the issues as framed in this lawsuit could be considered as appropriate and timely for review.

Analysis of this lawsuit and the current state of U.S. law regarding gene patents highlights the intensity of issues being debated by scholars, researchers, the biotechnology industry, and patients. Critics of gene patents are alarmed that approximately 40,000 patents on human genes have been issued, relating to approximately 20% of the genes mapped in the human genome. The most essential question remains: are genes patentable? Yet the questions extend beyond this basic inquiry, to: What exactly is being patented in a gene patent? How broad should these patents be? Should there be additional legal, (i.e., legislative) protection beyond what exists, given the unique nature of our genetic material? The ACLU’s challenge refines these issues and seeks answers through this litigation.

This paper first explains, in general terms, the biology of our genes and the scientific importance of the BRCA1 and BRCA2 genes to the breast cancer research community and patients. The specific issues raised in the ACLU’s challenge are then discussed. Next, the law and recent commentary regarding gene patentability are summarized, specifically with regard to the BRCA patents at issue held by Myriad. Finally, the future of this lawsuit, as well as the challenges to gene patents in general, is forecast.

II. Basic Biology of Genes

A gene is “the basic physical unit of heredity; a linear sequence of nucleotides along a segment of DNA that provides the coded instructions for synthesis of RNA, which, when translated into protein, leads to the expression of hereditary character.” A large portion of the U.S. District Court’s opinion granting summary judgment, citing scientific treatises and
texts, explains the basic biology of genetics, beginning with Gregor Mendel’s experiments in the 19th century, Watson and Crick’s discovery of the “double helix”, and ending with the gene extraction and isolation processes involved with genetic testing. A discussion of the biology of genes for purposes of this paper may be summarized as follows:

Genes located within each and every cell direct the function and operation of the cell, and allow the cell to reproduce through a complicated process of exact replication of the genetic information. In 1952, discovery of the DNA “double helix” allowed understanding of how DNA information transfers. This double helix is structured as a long two-stranded ladder. The “rungs” are composed of four chemicals, called bases: adenine, cytosine, guanine, and thymine (abbreviated as A, C, G, and T). These bases can only pair up with one other base, referred to as “a complimentary pair.” The information contained in DNA is replicated through a process in which the base pairs “unzip” and an enzyme attaches to the gene sequence to create a template known as “messenger RNA.” This messenger RNA is a perfect copy, or mirror image, of the original DNA sequence of the cell protein, and is transported to the cell ribosome to create construction of the desired protein sequence in the original DNA.

Human DNA and genes are comprised of hundreds of thousands of these “nucleotides,” or bases. In scientific research, a gene is represented by its “genomic sequence,” which is the sequence of the A, T, C, and G bases of the gene. These sequences are important to researchers because our genes are not identical. Variations in an individual’s genomic sequence are referred to as “mutations” or “variants.” For example, someone may have a G where a C normally appears in a healthy sequence. Mutations may be inherited, or may be caused by environmental factors. Researchers examine the sequence of a certain gene or portion of a sequence of a gene, and compare it to a healthy sequence. Variations or mutations of gene sequences may indicate health issues or potential health issues in that the mutated sequence may prevent the body to create “proteins necessary for sound health.”

III. Significance of BRCA Genes to Breast and Ovarian Cancers

Every human, man or woman, has the BRCA (for BReast CAncer) genes, BRCA1 and BRCA2, located on chromosomes 13 and 17. BRCA genes function to keep breast cells growing normally and to prevent cancer cells from growing. It is the mutations in the sequencing of these genes which increase the likelihood of developing certain cancers during your lifetime. Although women with BRCA1 or BRCA2 abnormalities account for only 5-10% of diagnosed breast cancer cases, women who have a BRCA1 or BRCA2 abnormality have a 40-85% likelihood of developing breast cancer during their lifetimes (3 to 7 times greater than normal likelihood), and a 16-60% likelihood of developing ovarian cancer during their lifetimes (versus 2% for the general population). Men with genetic mutations of the BRCA2 genes may be at increased risk for developing breast cancer and prostate cancer. There also correlations between the types of breast cancer diagnosed in women with BRCA mutations. It is more likely to be “estrogen-receptor negative.” This means that the cancer’s growth is not hormonally fueled, and thus cannot be treated with anti-estrogen drug therapies such as Tamoxifen. Estrogen-receptor negative breast cancers are treated with chemotherapy, and tend to have “high-grade” (more aggressive) cell growth.

Since the majority of women who develop breast cancer have no family history, not all are tested for the BRCA1 and BRCA2 genes. If a strong family history (mothers, sisters) of breast/ovarian cancer exists, testing for a BRCA mutation is recommended. Close relatives of women diagnosed with breast cancer who have a BRCA mutation or women with a strong family history of breast cancer may also undergo genetic testing. Breast cancer specialists may recommend several preventive treatments for women with BRCA mutations, such as prophylactic mastectomy (which may reduce the risk of breast cancer in these high-risk women by 90%), prophylactic oophorectomy (surgical removal of ovaries), or the drug Tamoxifen, which blocks the effects of estrogen on breast tissue. Women in these high-risk categories may be urged to undergo cancer screenings such as mammograms, breast MRI (magnetic resonance imaging) more frequently and at an earlier age than the normally recommended age of 40.

IV. The Test for BRCA1 and BRCA2

The genetic test for BRCA mutations is performed on a blood sample drawn at a doctor’s office or medical facility and sent to a lab for analysis. In the United States, due to the patents which are the subject of this paper, Myriad Genetics is the only commercial laboratory performing the tests. A comprehensive test, examining hundreds of areas on both genes costs over $3,000.00. According to Myriad’s website, “most health insurance plans pay for BRAC Analysis.” More than 90% of tests receive coverage, and the average reimbursement is more than 90%.” Myriad provides several types of BRCA tests. The standard test, called “Comprehensive BRACAnalysis,” consists of full sequencing of the BRCA1 and 2 genes supplemented with a “large rearrangement panel” which detects five common mutations. A second more comprehensive
test, called “BRACAnalysis Rearrangement Test” (BART), detects almost all large rearrangement mutations in the BRCA genes. BART testing costs an additional fee over the original $3000 standard test, and is not covered by some insurers.  

Biologically, the isolated gene sequence examined by a laboratory conducting genetic testing is a “purified” copy of the original DNA, with some structural differences, such as removal of regions not necessary for examination. It is referred to as “cDNA” or “complimentary DNA. However, the structure of the lab specimen mirrors the RNA structure of the protein located in the body.

V. Myriad’s BRCA1 and BRCA2 Patents

Beginning around 1990, scientists became aware of a gene associated with an increased risk of breast and ovarian cancers located on the human chromosome 17. Shortly thereafter, research team, which later formed Myriad Genetics, was able to sequence the BRCA1 gene. Myriad applied for, and thereafter obtained several different patents on BRCA1. Eventually, Myriad isolated and sequenced and obtained a series of patents for BRCA2, another gene associated with increased risk of these cancers.

Due to the complex nature of genetic material, Myriad’s patents are numerous. The subject patents are numbers 5,693,473, 5,709,999, 5,747,282, 5,710,001, 5,735,441, 5,837,492, and 6,033,857. These disputed patent claims relate to natural, “unmutated” BRCA genes, mutated BRCA genes, methods for looking at mutations in BRCA genes, and patent claims over comparison of differences between gene sequences and the increased risk of breast or ovarian cancer. For example, the first patent listed above, No. 5,693,473, relates to “methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1), some mutant alleles of which cause susceptibility to cancer, in particular breast and ovarian cancer.” This patent covers the isolated DNA of various mutations in the base sequences. Patent No. 5,710,001 covers, among other things, various comparisons of genetic material between a tumor sample and a non-tumor sample to detect mutations. Thus, just looking at the isolated gene, and making comparisons, could be a violation of these patents. The plaintiffs contend that “what is patented is the abstract idea that nature has made two genes different in a manner that increases a person’s risk of breast cancer.”

In an organized fashion, the District Court divided the patents and associated claims into two categories: 1) “composition” patents; and 2) “method” patents. Composition patents pertain to the gene itself, method patents pertain to the processes for analysis and comparison of the specific mutation sequences.

It has been suggested that Myriad has a “fierce reputation” for enforcing these patents; its general counsel says that although a researcher would need Myriad’s permission to look at BRCA genes, Myriad “has never told someone they cannot do research on BRCA.” The District Court recites instances in which researchers involved with offering BRCA screening were notified with cease-and-desist letters. Myriad has offered several researchers licenses to conduct research on BRCA genes, but the research was to be limited in scope; for example, to study mutations in patients of Ashkenazi Jewish descent only.


A. History of the Case:

Plaintiffs, represented by attorneys from the ACLU and PUPAT, are: The Association for American Pathology, American College of Medical Genetics, American Society for Clinical Pathology, College of American Pathologists, Breast Cancer Action, Boston Women’s Health Collective, individual genetic researchers from universities such as the University of Pennsylvania and Emory University, and individuals affected or potentially affected by breast and/or ovarian cancer. Defendants named in the lawsuit are the United States Patent and Trademark Office (USPTO), Myriad Genetics, and the directors of the University of Utah Research Foundation (which is co-holder of some of the disputed patents).

The ACLU has posted the Plaintiff Statements on its website. Each plaintiff represents a different aspect of the challenges to the BRCA patents. The Plaintiff Statements and Expert Declarations also reflect the intensity of the debate over gene patents. Myriad American College of Medical Genetics expressed its concern that a due to the monopoly held by Myriad on BRCA testing, a woman is prevented from obtaining a second opinion or and independent confirmation through another laboratory before deciding to have a “radical surgical procedure” such as a prophylactic mastectomy.

Individual plaintiff Lisbeth Ceriani is a single mother diagnosed in 2008 at age 42 with bilateral stage IIA breast cancer. After undergoing chemotherapy, double mastectomy and radiation therapy, she was advised by her oncologist and genetic counselors to have Myriad’s BRAC Analysis® test. Ceriani’s health insurance, MassHealth (a form of Medicaid), would only pay half, or $1,599, of the $3,255 cost of Myriad’s test, because the lab is not a “contracted provider” of the insurance company. As of the date of the filing of the lawsuit, Ceriani has not had the BRCA test.
Individual plaintiff Runi Limari is a 32 year old Asian-American, who has joined the suit supporting the ACLU’s contention that the BRCA patents hinder research on BRCA genetic mutations appearing more commonly within specific ethnic groups. Limari was diagnosed with breast cancer at the early age of 28 and it was suggested that she undergo BRCA testing since women diagnosed at an early age are more likely to have aggressive forms of the disease, and more likely to have a BRCA mutation. Limari was tested for BRCA mutations by Myriad, and the results revealed that she had a mutation categorized as a “variant of uncertain significance.” This mutation has been seen in Asian women, but the significance is uncertain, because no research had been performed on this mutation. Limari contends that the BRCA patents inhibit research on unknown BRCA mutations such as hers.

Individual researcher Arupa Ganguly, Ph.D. states that the patents on BRCA genes have a “chilling effect on scientific research.” Ganguly, director of the Genetic Diagnostic Laboratory (GDL) at the University of Pennsylvania, set up a center for genetic testing until sued by Myriad in 1997 requesting GDL “cease and desist” testing for half of the rate Myriad charged.

The timeline of the case to date is as follows: After the complaint was filed on May 12, 2009, a Motion to Dismiss was filed on behalf of Defendants and denied by Judge Robert W. Sweet on November 1, 2009. Motions for Summary Judgment were then filed by both sides and argued before Judge Sweet in a packed courtroom on February 2, 2010. As stated previously, and as will be discussed in detail in the following section, plaintiffs’ Motion for Summary Judgment was partially granted on March 29, 2010, invalidating all of defendants’ patent claims.

The legal challenge to the patents, and to the USPTO’s grant of the BRCA patents, while complex, are essentially, that genes are a “product of nature” and therefore the patents violate Article I, section 8, clause 8 of the U.S. Constitution, the First Amendment to the U.S Constitution, and the patent statute, 35 U.S.C. § 101. Specifically, the USPTO has a “formal written policy” which provides that naturally occurring genes can be patented if they are “isolated from their natural state and purified.” Plaintiffs contend that the information contained in an “isolated and purified” gene is identical to a gene located inside the human body. In other words, “[R]emoving a product of nature from its natural location does not make it any less a product of nature.”

Plaintiffs’ unique First Amendment challenge is premised upon the argument that merely looking at the genes, comparing the sequences and thinking about this comparison is restriction by the government (through the USPTO) under the patents, thus limiting a researcher’s very thoughts about the genes. Plaintiffs compare the Myriad patents on making correlations between sequences and arriving at conclusions to the prohibition of copyrighting ideas, but allowing copyright of the expression of those ideas:

“The doctrine of patent law that abstract ideas are not patentable is statutory and has not been previously described as compelled by the First Amendment. 35 U.S.C. § 101. However, there can be little doubt that patenting of abstract ideas or thought or an entire body of knowledge would violate the First Amendment.”

Defendants claim that the BRCA genes are patentable under Section 101 of the patent statute for the reason that they fit within two of the categories of patentable things: processes and compositions of matter which are “new and useful.” It is the isolated nucleic acids, which do not exist in nature, which make the genes and the sequences eligible for patents. In other words, the “isolated and purified” genes are transformed into a new composition which achieves the required threshold for patentability. Defendants’ position is supported by current policy of the USPTO which has a practice of issuing gene patents.

B. Summary Judgment Granted, Declaring BRCA1/2 Patents Invalid

In a 152 page opinion, Judge Sweet tackled the complex scientific and legal issues presented in the lawsuit. The opinion systematically explains the biology of genes, the significance of the BRCA genes, and the process of gene isolation and purification. Each of the patents is discussed in detail. Precedents are either applied or distinguished, and finally, all seven BRCA1 and BRCA2 patents held by the defendants are declared invalid. The issues and court’s ruling are succinctly summarized early in the opinion:

“Plaintiffs' challenge to the validity of these claims, and the arguments presented by the parties and amici, have presented a unique and challenging question: Are isolated human genes and the comparison of their sequences patentable? Two complicated areas of science and law are involved: molecular
biology and patent law. The task is to seek the governing principles in each and to determine the essential elements of the claimed biological compositions and processes and their relationship to the laws of nature. The resolution of the issues presented to this 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…”

“The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA’s existence in an “isolated” form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to “isolated DNA” containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.”

After a detailed discussion of the intricate processes and descriptions of the disputed patent claims, the District Court concluded that neither the “composition” nor the “method” patents are valid. The court acknowledged the unique function of DNA and why genetic material is unpatentable: "DNA, and in particular the ordering of its nucleotides, therefore serves as the 'physical embodiment of laws of nature - those that define the construction of the human body.'" Thus, whether a gene is in our bodies or whether it is extracted, isolated, purified, or copied, its essence is the same and the information contained therein is the same. As will be discussed in the following section, the legal threshold of “markedly different characteristics” has not been reached in the mind of the court.

The District Court applied a second test to the disputed claims: the “machine-or-transformation” test of In Re: Bilski, 545 F.3d. 943 (Fed. Cir. 2008). Specifically, the Court concluded that acts of comparing and analyzing DNA sequences are "abstract mental processes" which are not physical transformations. Bilski is presently under appeal to the U.S. Supreme Court.

Since the District Court invalidated the patents under 35 U.S.C. § 101, it did not address the Plaintiffs’ constitutional arguments under the First and Fourteenth Amendments. Thus, the USPTO was granted dismissal as a defendant in the case.

VII. Law and Commentary on Gene Patents

Understanding complexity and variety of gene patents can be a challenge. Several legal scholars (some of whom have scientific training) have attempted to categorize the various types of gene patents currently in existence. These legal scholars have also attempted to make suggestions to limit gene patents using the existing legal framework, or by proposing new legislation which would both encourage the biotechnology industry without impeding the progress of pure research. Examination of some of these arguments and suggestions and applying them to the ACLU challenge against Myriad could assist in prediction of the ultimate outcome of the case. Reviewing precedent cited in the briefs in the BRCA challenge will aid in further understanding of gene patents.

A. Cases: Diamond v. Chakrabarty

The United States Supreme Court addressed the issue of the patentability of biological material under 35 U.S.C. § 101 in the case of Diamond v. Chakrabarty. Respondent Chakrabarty, a microbiologist, filed patent claims for genetically engineered bacteria able to break down crude oil. The USPTO denied the patent; Chakrabarty appealed to the U.S Court of Customs and Patent Appeals, and prevailed. The Supreme Court upheld the lower court’s recognition of the patentability of the bacteria created by Chakrabarty. The Court referred to 35 U.S.C. § 101, which provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter," and noted that broad construction should be employed when interpreting the language of the patent statute. Under this construction, it was held that Chakrabarty’s created micro-organism should not be excluded from patent protection: “Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity "having a distinctive name, character [and] use."
Myriad claims that its purified, isolated gene is protected by the holding of the Supreme Court in Chakrabarty. Plaintiffs in Association for Molecular Pathology contend that the organism in Chakrabarty was man-made, and thus distinguishable from the BRCA gene patents, which are products of nature, identical to the genes in our bodies. Additionally, plaintiffs assert that purification of these genes would not make a product of nature patentable, in that its essence remains the same—the sequence of DNA. The District Court, after analysis of Chakrabarty and cases cited by both sides, agreed with the plaintiffs. Purification alone of a substance does not make it patentable. In order to satisfy the requirements of §101, the substance must also possess “markedly different characteristics.”

Amgen, Inc. v. Chugai Pharmaceutical Co.

The disputed patents in Amgen, Inc. v. Chugai Pharmaceutical Co. involved a purified protein, Erythropoietin (EPO), used in the treatment of anemia and other blood disorders. The patent issue in the case involves whether or not the process was “obvious,” and not patentable. However, in the case the U.S. Court of Appeals for the Federal Circuit recognizes genes as patentable “chemical compounds:” “A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it.” The court in Amgen never actually held that genes are patentable; it assumes this.

Funk Bros. Seed Co. v. Kalo Inoculant Co.

In its opinion, the U.S. District Court also refers to the United States Supreme Court case of Funk Bros. Seed Co. V. Kalo Inoculant Co. The patent at issue in the case pertained to the mixing of several bacteria which were selected for their ability to extract nitrogen for plant usage. The Supreme Court found the product claims were not patentable because the combination of the bacteria, while new and useful, lacked the requirement of discovery:

“Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable.”

The bacteria patents at issue in Chakrabarty are distinguished from the bacteria in Funk Bros. by the District Court in its opinion in support of its summary judgment ruling. The Funk Bros. bacteria were a mixture of naturally occurring bacteria; the bacterium in Chakrabarty did not exist in nature, and was “markedly different characteristics from its natural counterpart.” This distinction is essential to the reasoning of the court in its summary judgment ruling in Association for Molecular Pathology. To the District Court, the isolated, purified gene is not markedly different biologically from the gene as it exists in its natural state in the human body.

Many additional cases are discussed within the opinion of the District Court in Association for Molecular Pathology, some relating to medical and biological patents. Each of the cases is either distinguished by the court or used to support its ruling declaring the BRCA gene patents invalid.

B. Categorizing gene patents

Applying the general term “gene patent” to the various claims of gene patent holders ignores the complexities which exist in these claims. Several commentators have attempted to categorize gene patents and attribute patent protection (or no patent protection) based on the type of gene patent sought. Bryan Nese, crediting Professor Jon Merz of the University of Pennsylvania School of Medicine, takes a utilitarian approach to gene patent sorting with three distinct categories: 1) diagnostic gene patents, which claim methods that diagnose particular illnesses (like one of the BRCA patents), 2) composition-of matter gene patents, or claims on the genes themselves, and 3) functional-use gene patents, or gene therapy-related patents. While the BRCA genes at issue in Association for Molecular Pathology were categorized by the court into the first two categories, it is arguable that one of the patent claims, claim 20 of the ‘282 patent, relates to therapeutic usage of the gene (category 3 in Nese’s analysis). This patent claim pertains to the comparison of the “growth rates of cells in the presence or absence of a cancer therapeutic.” While the court concedes that there are transformative steps involved with this claim as opposed to merely analyzing of comparing genetic sequences, it ultimately invalidates claim 20 for the reason that this patent also claims to patent a recognized scientific principle: the growth rates of cells.

Using these three categories, and examining the current state of patent law, Nese finds composition-of-matter genes to be problematic, since they are claims on the genes themselves rather than something new or innovative. Going a step further,
this type of gene patent impedes research since anyone isolating the gene “by any means” cannot do so without a license from the patent holder. Plaintiffs in Association for Molecular Pathology argue that the method for extraction of the DNA is an obvious, well-known process which is not patentable. The District Court in its summary judgment opinion agreed. “The techniques required for gene sequencing are well-known and understood by scientists skilled in molecular biology, and scientists and clinicians sequence and analyze genes literally every day.” Nese proposes a middle ground: allowing genetic tests to be patented but not the genes themselves. Under this analysis, the “composition” patents would likely be invalid, but the “method” patents would stand. Patents on diagnostic gene testing (a type of “method” patent) would be afforded patent protection because they encourage innovation.

The narrowing of the scope of gene patents through the courts or through additional legislation is a recurring theme of legal scholars analyzing gene patents. The concern with the current policy of patenting the gene itself is that a gene is unique and other inventors cannot invent “around” the patent. The gene is the gene, and a patent blocks all unlicensed research related to the gene in any manner.

Contrary to the middle ground analysis described above, the District Court in Association for Molecular Pathology chose not to distinguish gene patents as permissible and impermissible based upon the complexity of the processes. To Judge Sweet, the essence of all gene patents, whether composition, method, or therapeutic is that they involve products of nature and are thus unpatentable.

C. Argument for broad gene patents

From the standpoint of the biotechnology industry, the current legal framework granting broad patent protection to firms which isolate a specific gene encourages innovation through economic incentive. Without a monopoly on the gene and the resulting profits, there would be no reason to invest huge amounts of capital in a project. Many gene patent holders freely allow researchers to use the patented material and processes, as long as there is no competition with the patent holder or profit derived from the gene. It has been suggested that Myriad filed suit against plaintiff-researchers at the University of Pennsylvania because they were directly competing with Myriad by offering the BRCA testing and charging less. Holman, Pennsylvania, and denial of patients eliminates the exclusive profits the patent protection period provides. A court determining the validity of a patent should be focused upon patent law, and not the effect of the ruling on research or profit.

Broad patent claims on genes raise both moral and utilitarian objections. Conversely, the invalidation of gene patents has far-reaching implications due to the thousands of these patents granted by the USPTO. Morally, it may seem inconceivable that an entity may hold a patent on something as essentially human as our DNA. “The notion that anyone can obtain private property rights in such a fundamental aspect of our common human heritage strikes some as an affront to human dignity.” Utilitarian reasons are raised in the ACLU’s challenge to the BRCA patents. Research may be slowed, and patients could be denied access to treatment. Whether research may be hindered by gene patents or whether profits may be lost by the invalidation of these patents should not be a consideration under legal analysis. Patients do not limit competitors’ access to technology, and denial of patents eliminates the exclusive profits the patent protection period provides. A court determining the validity of a patent should be focused upon patent law, and not the effect of the ruling on research or profit.

Obviously, the District Court’s ruling in Association for Molecular Pathology is precedent-setting, and its sweeping invalidation of all patents held by the defendants may not be upheld on appeal. One possibility is a ruling distinguishing between “composition” patents and “method” gene patents, giving patent protection to the latter, but not to the former. If method patents are viewed as sufficiently transformative by an appellate court, they may be declared valid. Additionally, gene therapy patents may also be viewed as sufficiently different from the original gene and be granted patent protection. Ruling that certain gene processes are patentable, while the gene itself is not, makes sense in the scheme of patent law and the basic question of what is patentable.

There is also the possibility that at some future date Congress may amend the Patent Act to specifically permit or prohibit gene patents. Given its controversial nature, and the lobbying which will occur by interested parties on both sides of the debate, it may be difficult to achieve a political consensus on the patentability of genes. Gene patents are not strictly a liberal/conservative Republican/Democrat issue. The ACLU, traditionally considered a more liberal defender of personal freedoms, may be on the same side of this issue with conservatives who value the individual and his right to be free from outside interference with what is the essence of what makes us unique.

At a 2004 conference run by the organizations Living Beyond Breast Cancer and the Young Survivors’ Coalition, a researcher commented that breast cancer research is progressing at an exponential rate. Researchers are now doubling their
body of knowledge every few years, instead of every 10 years, as has occurred in the past. If medical research is progressing at a more rapid rate every year, do gene patents encourage or hinder the pace of research? Regardless of which side of the debate one supports, gene patents need to be scrutinized legally in a thorough manner. The case of Association for Molecular Pathology provides the opportunity for such legal scrutiny, and will hopefully provide definitive guidelines for those involved in gene research for profit or for scientific progress.

FOOTNOTES

1 Association for Molecular Pathology v. USPTO, et al., No. 09 Civ. 4515 (RWS), 2010 U.S. Dist. LEXIS 30629 (S.D.N.Y. March 29, 2010).
3 Complaint ¶ 102.
4 Compl. ¶ 103.
5 As of the writing of this article, defendants have not filed an appeal of the District Court’s ruling, although Myriad has indicated on its investor website that it will appeal the ruling. See Federal District Court Rules Isolated DNA Claims Are Not Patentable (March 30, 2010), http://investor.myriad.com/releasedetail.cfm?ReleaseID=455348.
8 See Association for Molecular Pathology, supra note 1, at 25-36.
10 Id.
11 Id.
12 Id., at 190.
13 Compl. ¶ 33.
14 Compl. ¶ 35.
15 Compl. ¶ 36.
16 Compl. ¶ 35.
17 Compl. ¶ 42.
20 Id.
21 This is mostly true of BRCA1 mutations. www.breastcancer.org, supra note 18.
22 Id.
23 Id.
24 Id.
25 Id.
26 There is also a more limited test available for around $300. Id.
28 Association for Molecular Pathology, supra note 1, at 57.
29 Id.
31 Compl. ¶ 42.
32 Compl. ¶ 43.
33 Compl. ¶ 45.
34 Brief for Amicus Curiae, March of Dimes, et al., In Support of Plaintiffs, 6; Compl. ¶ 30.
35 Compl. ¶ 32.
37 Id.
38 U. S. Patent No. 5,710,001 (filed June 7, 1995).
39 Compl. ¶ 75.
Association for Molecular Pathology, supra note 1, at 80.

41 Begley, supra note 6.

42 Id.

43 Association for Molecular Pathology, supra note 1, at 62-3.


45 Id.

46 Plaintiff Ceriani was interviewed for a segment of the television show “60 Minutes,” which aired on April 4, 2010.


47 BRCA-Plaintiff Statements supra note 44.

48 Id.

49 Id.

50 Id.

51 Id.

52 Id.

53 Id.

54 Association for Molecular Pathology, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).


56 The Patent Clause, which gives Congress the power “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;…” 35 U.S.C. § 101 et seq.

57 “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

58 Compl. ¶ 52.

59 Compl. ¶ 50.

60 Compl. ¶ 51.

61 Id.

62 Plaintiffs’ Memorandum of Law in Support of Motion for Summary Judgment, 33.

63 Id.

64 Powell & Elman, supra note 55.

65 The District Court in Association for Molecular Pathology notes that courts do not defer to the USPTO when evaluating the validity of a claim: “The Federal Circuit has previously held that it owes no deference to USPTO legal determinations… While Congress has created a presumption of validity for issued patents, approximately 40% of patents challenged in the courts have been found invalid, demonstrating that this presumption is far from absolute.” Supra note 1, at 110-11 (citations omitted).

66 Association for Molecular Pathology, supra note 1, at 3-4.

67 Id. at 135.

68 Association for Molecular Pathology, supra note 1, at 137-47.


70 “As determined above, the patents issued by the USPTO are directed to a law of nature and were therefore improperly granted. The doctrine of constitutional avoidance, which states that courts should not reach unnecessary constitutional questions, thereby becomes applicable.” Association for Molecular Pathology, supra note 1, at 161-2.


73 Id. at 309-10.

74 Plaintiffs’ Memorandum, supra note 62, at 22.

75 Id.
See Bryan Nese, Bilski on Biotech: Limiting the Negative Impact of Gene Patents, 46 CAL. W. L.R. 137 (2009), citing Amgen for the proposition that “[b]y 1991, the Federal Circuit regularly seemed to accept the notion that purified DNA sequences constitute patentable subject matter.” Id. at 151.

333 U. S. 127 (1948).

Additional cases cited by the parties and the District Court of significance its discussion of patent law are: The American Wood-Paper Co. v. The Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566 (1874); Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (S.D.N.Y. 1911); Am. Fruit Growers, Inc. v. Brodgex Co., 283 U.S. 1 (1931).

Nese, supra note 80, at 146-50.

Association for Molecular Pathology, supra note 1, at 159.

Id.

Nese, supra note 80, at 149.

Compl. ¶ 70.

Association for Molecular Pathology, supra note 1, at 48.

Nese, supra note 80, at 165-6.

See Hill, supra note 30; Liivak, supra note 9. This barrier to research innovation was noted by the District Court in Association for Molecular Pathology: “The proliferation of intellectual property rights directed to genetic material has also been postulated to contribute to a phenomenon dubbed “the tragedy of the anti-commons,” in which numerous competing patent rights held by independent parties prevents any one party from engaging in productive innovation.” Id. at 72-3 (citing Michael A. Heller & Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 SCIENCE 698 (1998)).

Hill, supra note 30, at 236-7.


Id.

Id.

Id. at 297.

Attended by the author.