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A Myriad of Misunderstanding Standing: Decoding Judicial Review for Gene Patents

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A MYRIAD OF MISUNDERSTANDING STANDING: DECODING JUDICIAL REVIEW FOR GENE PATENTS

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I. INTRODUCTION

Two small gene molecules may give rise to the end of the patenting process as we know it today. The BRCA1 and BRCA2 (BRCA1/2) genes are a mutated genetic sequence thought to indicate the predisposition for hereditary breast and/or ovarian cancer.¹ To date, the United States Patent and Trademark

¹ See *Detailed Guide: Breast Cancer: Do We Know What Causes Breast Cancer?*, AM. CANCER SOC'Y (Sept. 18, 2009), http://ww2.cancer.org/docroot/CRI/content/CRI_2_4_2X_Do_we_know_what_causes_breast_cancer_5.asp.

Office (USPTO) has issued patents covering twenty percent of genes which have been isolated and purified from their natural state found in the human body.² The issuance of gene patents has long been a hot-button issue both legally and ethically around the world, but it was a shock when the American Civil Liberties Union (ACLU) appeared with an unprecedented move in patent law: it raised a First Amendment violation of non-patent holder rights of researchers, doctors, and patients.³

Currently, the fate of gene patents—and potentially all patents—rests in the hands of the United States Court of Appeals for the Federal Circuit.⁴ This fate was improperly before the United States District Court Southern District of New York because of a misunderstanding of standing. This case Comment specifically reviews the first district court opinion in *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*⁵ involving the authority to have judicial review over the USPTO and of the BRCA1/2 gene patent holder, Myriad Genetics (Myriad).

Part II of this case Comment provides background information intended to help the reader learn about genes and gene patents, the parties involved in the litigation, the events leading up to the litigation, and finally the district court's opinion which held that the plaintiffs satisfy the standing requirements against both the USPTO and Myriad. Part III of this Comment reviews the district court's opinion. First, Part A analyzes the opinion regarding the USPTO. The court failed to distinguish reviewability from constitutional standing. Further, the plaintiffs were unable to establish an injury, prudential standing, and redressability. The only requirement that was possibly established by the plaintiffs was traceability; however, the same could apply to all plaintiffs challenging any patent. Finally, Part A closes with a discussion about how this decision affects gene patents, the patenting process, and the potential consequences to intellectual property. Part B analyzes the district court's opinion regarding Myriad. The court used a new standard provided by the Supreme Court and interpreted by the federal courts to support a declaratory judgment action. Despite the district court's analysis, the plaintiffs were unable to satisfy the requirements for an "actual controversy."⁶ Further, most of the plaintiffs do not qualify under the new standard set forth by the Supreme Court. Part B closes by illustrating how

² See Joe Mullin, *Patent Litigation Weekly: PubPat and ACLU Aim to Take Down Gene Patents*, THE PRIOR ART (May 14, 2009, 2:09 PM), http://thepriorart.typepad.com/the_prior_art/2009/05/association-for-molecular-pathology-v-uspto.html#more.

³ See *ACLU Challenges Patents On Breast Cancer Genes: BRCA*, ACLU (Dec. 10, 2010), <http://www.aclu.org/free-speech-womens-rights/aclu-challenges-patents-breast-cancer-genes-0>.

⁴ See Brief for Appellants, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406, 2010 WL 4600106 (Fed. Cir. Oct. 22, 2010).

⁵ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

⁶ See *infra* note 215.

the district court's broadening availability of declaratory judgment actions will diminish patent incentives and potentially destroy the patenting process. Finally, Part III recommends the legislative process as the appropriate method through which a system-wide change should be obtained.

II. A MACROSCOPIC OVERVIEW

In scientific terms, a macroscopic view is defined as a view "large enough to be observed by the naked eye."⁷ While deoxyribonucleic acid (DNA) and genes are just small molecules, they have become a large issue both legally and ethically in the public's eyes. Despite the numerous issues within this case, this overview will highlight intellectual property concepts and standing issues to be analyzed throughout this Comment. First, Part A describes the biological process of genetics. It is essential to know the biological make-up of the BRCA1/2 gene because different parts of the gene may affect what biotechnology is considered patentable subject matter. Next, Part B provides a brief summary describing the roles of the parties involved and their purpose for being joined in this litigation. Part C outlines the key events triggering the alleged First Amendment violation. Finally, Part D recapitulates the district court's opinion of the standing elements for two different scenarios. The court analyzed constitutional standing requirements in order to bring the USPTO to federal court and it analyzed the "*MedImmune* standard"⁸ in order to support a declaratory judgment action against Myriad.

A. DNA 101

Understanding the DNA process, genes, and the patented gene test is critical to understanding this dispute. Deoxyribonucleic acid (DNA) is a double-stranded molecule, which looks like a spiral staircase, located in the nuclei of all biological cells.⁹ The sides of the staircase are made of sugar-phosphates.¹⁰ Each step of the staircase has a left and a right side called a base.¹¹ Each base is a complex molecule termed adenine (A), thymine (T), guanine (G), or cytosine (C).¹² Certain pairings are required to connect the left and

⁷ *Macroscopic*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/macroscopic> (last visited Mar. 7, 2011).

⁸ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

⁹ See Lotta Fredholm, *The Discovery of the Molecular Structure of DNA – The Double Helix*, NOBELPRIZE.ORG (Sept. 30, 2003), http://nobelprize.org/educational_games/medicine/dna_double_helix/readmore.html.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

right bases to form the step.¹³ The pairings require A to form with T and require G to form with C for the DNA to function properly.¹⁴

“A gene is a stretch of DNA that codes for a protein. To encode a protein the gene is divided into groups of three bases.”¹⁵ These groups of three bases, called codons, provide genetic instructions for a two step process—transcription and translation—which produces an amino acid.¹⁶ A series of amino acids create a protein.¹⁷ This process can be analogized to building a wooden toy train. The instruction pamphlet to build the toy train is the gene. Each instruction step builds one boxcar of the train. Similarly, the codon is an instruction step to build one amino acid. Once several boxcars are made, they connect together to form the toy train. The toy train is the protein.

BRCA1/2 is the given name for a set of genes that are present in every human.¹⁸ The BRCA1/2 genes, when activated, create a protein using the process above.¹⁹ This resulting protein is used to repair damaged DNA.²⁰ Health risks occur when the BRCA1/2 genes mutate.²¹ Most of these mutations lead to an abnormally shortened version of the protein when the protein is created.²² Some mutations can prevent the protein from being created entirely.²³ Various mutations can even delete other BRCA1/2 gene segments from the DNA.²⁴ “Researchers believe that a defective or missing BRCA1 protein [prevents the] repair [of] damaged DNA or . . . mutations that occur in other genes. As these defects accumulate, they can allow cells to grow and divide uncontroll-

¹³ *Id.*

¹⁴ *Id.*

¹⁵ ROBERT P. MERGES, PETER S. MENELL, & MARK A. LEMLEY, INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGY AGE: 2008 CASE AND STATUTORY SUPPLEMENT 528 (Aspen Publishers 2008).

¹⁶ *See id.* at 529.

¹⁷ *Id.*

¹⁸ *See Definition of BRCA1*, MEDICINET.COM, <http://www.medterms.com/script/main/art.asp?articlekey=2522> (last visited Mar. 7, 2011).

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.* The National Cancer Institute defines gene mutation as

[a]ny change in the DNA of a cell. Mutations may be caused by mistakes during cell division, or they may be caused by exposure to DNA-damaging agents in the environment. Mutations can be harmful, beneficial, or have no effect. If they occur in cells that make eggs or sperm, they can be inherited; if mutations occur in other types of cells, they are not inherited. Certain mutations may lead to cancer or other diseases.

Definition of Mutation, NAT'L CANCER INST., <http://www.cancer.gov/dictionary?cdrid=46063> (last visited Mar. 7, 2011).

²² *See Definition of BRCA1*, *supra* note 18.

²³ *See BRCA1*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/gene=brca1> (last visited Mar. 7, 2011).

²⁴ *Id.*

ably and form a tumor.”²⁵ The BRCA1/2 gene has been identified in tumors found in breast tissue and the ovaries.²⁶ Therefore, by evaluating the presence of a mutated BRCA1/2 gene, a medical professional can assess an increased risk for breast and ovarian cancer.

Myriad, the patentee and one of the defendants, has created two medical tests for patients: “the Comprehensive BRACAnalysis Test and the BRACAnalysis Rearrangement Test (‘BART’). The Comprehensive BRACAnalysis Test costs over \$3000; BART costs approximately \$600, but Myriad will offer BART testing for free to some women who meet certain criteria.”²⁷ These tests calculate the patient’s genetic predisposition to breast cancer by extracting and purifying DNA from the patient’s blood or mouth-swab samples.²⁸ The isolated DNA sample is then compared to Myriad’s patented BRCA1/2 gene, which is the standard mutated BRCA1/2 gene in isolated form.²⁹ Using its patented methods, Myriad’s computer-based software reviews the comparisons to find abnormalities or deletions in the DNA sample. BART is highly recommended for those patients with a strong family history of breast or ovarian cancer; it is estimated that one percent of patients will have a mutation detected by the test.³⁰ Subsequently, if a patient receives a positive match for the mutated BRCA1/2 gene, the patient may choose how to act next. For example, the patient can undergo a bilateral mastectomy (the removal of all breast tissue), bilateral oophorectomy (the removal of ovaries), or can increase the frequency of preventative screenings and act promptly at the first signs of cancer.³¹ However, BRCA1/2 is not the only gene known to be correlated with breast cancer;³² therefore, Myriad’s analysis may not be a conclusive indication of a patient’s potential risk.

Presently, Myriad is the only company offering this testing analysis on the BRCA1/2 gene because it is the only company with exclusive patent rights to do so. Consequently, the following legal action has ensued.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 380 (S.D.N.Y. 2009).

²⁸ MYRIAD GENETIC LABORATORIES, INC., BRACANALYSIS TECHNICAL SPECIFICATIONS (Feb. 2009), available at <http://www.myriadtests.com/provider/doc/BRACAnalysis-Technical-Specifications.pdf>.

²⁹ *Id.*

³⁰ See Mary Beattie, *Updated Test Improves Detection for Breast and Ovarian Cancer Gene*, UCSF MED. CENTER (June 2008), http://www.ucsfhealth.org/newsletters/primary_care_connections/june_2008/cancer_genes/.

³¹ See *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#11> (last visited Mar. 7, 2011).

³² See *generally Mutated Genes and Abnormal Protein Expression*, CANCER GENETICS WEB, <http://www.cancerindex.org/geneweb/X0401.htm#genes> (last visited Mar. 7, 2011).

B. Facts: Who's in the Gene Pool?

At the heart of this action are seven patents issued by the USPTO.³³ In order to obtain a patent in the United States, a patent applicant must show to the USPTO a useful, new, and nonobvious discovery.³⁴ To be useful, the applicant must be able to specifically detail how the item works and that it is beneficial to the public rather than only helpful for further research.³⁵ To be new, the discovery could not exist prior to the filing of the application (also known as prior art), and could not be currently known or used by others.³⁶ To be nonobvious, a person having ordinary skill in the art (PHOSITA) must believe the discovery is not obvious to try, conceive, combine, reduce to practice, or result from prior art.³⁷ Finally, the invention or discovery must be of patentable subject matter.³⁸ A patent applicant cannot attempt to patent laws of nature, physical phenomena, or abstract ideas.³⁹ Although genes are found in nature, common law established that a gene is patentable subject matter only if the gene has been "isolated and purified" from its natural state.⁴⁰ Once the patent is issued, the patent owner has exclusive rights over the patented discovery for seventeen years from the date of filing if filed before June 8, 1995 or twenty years if filed after.⁴¹

The patents at issue cover the isolated unaffected BRCA1/2 genes, some isolated mutated BRCA1/2 genes, methods for comparing patient BRCA1/2 genes with the isolated unaffected and mutated BRCA1/2 genes, and a method for examining the growth of cells containing the BRCA1/2 genes.⁴²

The driving force behind this matter is the ACLU; it named the Association for Molecular Pathology (AMP) as the lead plaintiff among other large

³³ See generally U.S. Patent No. 5,747,282 (filed June 7, 1995), U.S. Patent No. 5,837,492 (filed April 29, 1996), U.S. Patent No. 5,693,473 (filed June 7, 1995), U.S. Patent No. 5,709,999 (filed June 7, 1995), U.S. Patent No. 5,710,001 (filed June 7, 1995), U.S. Patent No. 5,753,441 (filed June 5, 1996), & U.S. Patent No. 6,033,857 (filed Mar. 20, 1998), available at <http://assignments.uspto.gov/assignments/q?db=pat> [hereinafter Myriad's patents].

³⁴ 35 U.S.C. §§ 101–103 (2006).

³⁵ 35 U.S.C. § 101 (2006); See also *In re Fisher*, 421 F.3d 1365, 1376 (Fed. Cir. 2005) (holding the patent invalid because the tools were used to search for practical utility and no other use was specifically defined or for the benefit of the public to satisfy the utility requirement).

³⁶ 35 U.S.C. § 102(a), (e), (g) (2006).

³⁷ 35 U.S.C. § 103 (2006).

³⁸ 35 U.S.C. § 101 (2006); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that nature, physical phenomena, and abstract ideas as unpatentable subject matter).

³⁹ 35 U.S.C. § 101.

⁴⁰ *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 109 (C.C.S.D.N.Y. 1911).

⁴¹ U.S. CONST. art. I, § 8, cl. 8; U.S. Patent & Trademark Office, Changes to Implement 20-Year Patent Term and Provisional Applications, 60 Fed. Reg. 20195 (Apr. 25, 1995), 1174 Off. Gaz. Pat. Office 15 (May 2, 1995) (final rule).

⁴² *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 380 (S.D.N.Y. 2009).

organizations⁴³ wanting to perform research and clinical practice involving the BRCA1/2 genes if the Myriad patents are invalidated. Additionally, several doctors and professors,⁴⁴ non-medical organizations, and women diagnosed with breast cancer are also plaintiffs named in the complaint.⁴⁵ The plaintiffs argue that the established policy permitting gene patents is unconstitutional because it violates First Amendment rights.⁴⁶ Therefore, the plaintiffs brought this joint action against the USPTO for abiding by the established policy and issuing a gene patent, and against Myriad for enforcing its exclusive rights authorized by the issued gene patent.⁴⁷

The first defendant in this matter is the USPTO. The USPTO is a government agency under the Commerce Department of the United States.⁴⁸ The USPTO's defendant status in this matter is seemingly for the sole purpose of creating a constitutional argument in order for the ACLU to obtain standing.⁴⁹

Myriad Genetics⁵⁰ is a for-profit corporation recognized for its worldwide leadership in the molecular diagnostic field.⁵¹ Prior to the formation of Myriad, several research teams looked into the possibility of the correlation between genetics and an increased risk of cancer.⁵² One of these research teams, eventually associated with Myriad, isolated the precise gene thought to be related to breast cancer susceptibility and named it BRCA1.⁵³ Once this gene was discovered and its precise structure determined, the researchers explored for additional relevant genes and subsequently found BRCA2.⁵⁴

Presently, Myriad has ownership or exclusive license in both Europe and the United States for the human version of and methods relating to the BRCA1/2 genes. The European Patent Office (EPO) granted Myriad four pa-

⁴³ These organizations include the American College of Medical Genetics (ACMG), the American Society for Clinical Pathology (ASCP), and the College of American Pathologists (CAP) [hereinafter the plaintiffs]. See Complaint at 3–5, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

⁴⁴ Robert Hubbard, Ph.D., Jeffrey Kant, M.D., Ph.D., Haig Kazazian, Jr., M.D. (Dr. Kazazian), Wendy Chung, M.D., Ph.D., Harry Ostrer, M.D. (Dr. Ostrer), David Ledbetter, Ph.D., Stephen T. Warren, Ph.D., Ellen Matloff, M.S., and Elsa W. Reich, M.S. [hereinafter the plaintiffs]. *Id.* at 5–13.

⁴⁵ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 374–76 (S.D.N.Y. 2009).

⁴⁶ *Id.* at 369–70.

⁴⁷ *Id.* at 380–81.

⁴⁸ *Id.* at 376.

⁴⁹ *Id.*

⁵⁰ See generally MYRIAD, <http://www.myriad.com/about/> (last visited Mar. 7, 2011).

⁵¹ *Id.*

⁵² *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 377–78 (S.D.N.Y. 2009).

⁵³ *Id.*

⁵⁴ *Id.*

tents on the BRCA1/2 genes.⁵⁵ These patents cover “all methods of diagnosis (EP0699754), specific mutations (EP0705903), and diagnostic kits (EP0705902 and EP0785216).”⁵⁶ Myriad obtained exclusive rights over diagnostic breast and ovarian cancer testing using these genes in all European countries because of its patents’ broad claim construction.⁵⁷ The United States patents were first filed in 1995 and 1996, which means Myriad’s exclusive rights over the patented items will expire in about five years.⁵⁸

C. *Sequence of Events*

Based on declarations made by the plaintiffs, the district court found the following. In the late 1990s, Dr. Kazazian, while working at the University of Pennsylvania, provided BRCA1 genetic testing services to women.⁵⁹ In May of 1998, Myriad sent Dr. Kazazian and the university an offer to buy a license allowing them to continue commercial work, but neither responded to the offer.⁶⁰ In August of 1998, Myriad sent Dr. Kazazian and his assistants a cease-and-desist letter warning that his commercial testing was infringing upon Myriad’s patents.⁶¹ About a year later, Myriad sent another letter reiterating the warning to counsel from the university and the counsel requested Dr. Kazazian to stop his activities shortly thereafter.⁶² At that time, Dr. Kazazian discontinued his BRCA1 screening tests.⁶³ Around the same time, Dr. Ostrer provided patient samples to Dr. Kazazian for screening and received a cease-and-desist letter.⁶⁴ Dr. Ostrer’s letter contained an offer for a license which he declined.⁶⁵ Yale DNA Diagnostics Laboratory (YDL) performed BRCA1/2 genetic testing and received a cease-and-desist letter.⁶⁶ Later, a director from YDL called Myriad to see if certain testing would infringe to which Myriad responded in the affir-

⁵⁵ Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 136 (2004).

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ See generally Myriad’s patents, *supra* note 33; see also U.S. Patent & Trademark Office, *supra* note 41.

⁵⁹ Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 378 (S.D.N.Y. 2009).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.* at 378–79.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office, 669 F. Supp. 2d 365, 379–80 (S.D.N.Y. 2009).

⁶⁶ *Id.* at 379.

mative.⁶⁷ In 1997–1998, Myriad brought *Oncormed*, a company offering competing BRCA1/2 genetic testing, to court for an alleged infringement; however, the case ended in a settlement.⁶⁸ In the midst of protecting its patents from commercial infringement, Myriad sent a letter to the National Cancer Institute (NCI) to reassure NCI that it would not take any legal action for research on the patented discoveries.⁶⁹

Approximately ten years later, on May 12, 2009, the ACLU filed its complaint on behalf of the plaintiffs in the Southern District Court of New York (S.D.N.Y.).⁷⁰ The complaint alleged that the defendants' BRCA1/2 gene patents were unconstitutional and invalid.⁷¹ The complaint created four types of categories and divided each patent and its corresponding claims into those categories.⁷² The plaintiffs argued that these claims should be invalidated because they violate Article I, Section 8, Clause 8 of the United States Constitution,⁷³ the First Amendment,⁷⁴ the Fourteenth Amendment,⁷⁵ and 35 U.S.C. § 101⁷⁶ on the

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.* at 379–80.

⁷¹ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 379–80 (S.D.N.Y. 2009).

⁷² *Id.* at 380.

[Category One:] claims 1, 2, 5, and 6 of the '282 patent and claim 1 of the '492 patent, cover isolated, non-mutated forms of *BRCA1* and *BRCA2* as well as fragments of *BRCA1* of 15 nucleotides or more. [Category Two:] claim 1 of the '473 patent, claim 7 of the '282 patent and claims 6 and 7 of the '492 patent, cover isolated forms of *BRCA1* and *BRCA2* that contain mutations that may or may not have any correlation with an increased risk of breast and ovarian cancer. [Category Three:] claim 1 of the '999 patent, covers any method of analyzing an individual's *BRCA1* gene to determine whether the individual's gene contains an inherited mutation. [Category Four:] claim 1 of the '001 patent, claim 1 of the '441 patent, and claims 1 and 2 of the '857 patent, covers comparison of a patients' *BRCA1* and *BRCA2* gene sequences with the normal *BRCA1* and *BRCA2* gene sequences to determine whether there are differences that would indicate a genetic predisposition to breast cancer. Claim 20 of the '282 patent, which the Plaintiffs include in this fourth category of claims, covers a method of examining the growth of cells containing a mutated form of *BRCA1* following their treatment with a potential therapeutic compound.

Id.

⁷³ “Congress shall have the power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. CONST. art. I, § 8, cl. 8.

⁷⁴ “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.” U.S. CONST. amend. I.

⁷⁵ U.S. CONST. amend. XIV, § 1.

basis that the BRCA1/2 genes are “products of nature, laws of nature, and/or natural phenomena, and abstract ideas or basic human knowledge or thought.”⁷⁷ The plaintiffs’ request for relief asked the court to declare the patents invalid and/or unenforceable and to enjoin the defendants from enforcing its patent holder’s rights.⁷⁸ On July 13, 2009, the defendants filed a motion to dismiss based on lack of subject matter jurisdiction and lack of standing pursuant to the Fed. R. Civ. P. 12(b)(1), lack of personal jurisdiction pursuant to Fed. R. Civ. P. 12(b)(2), and failure to state a claim for which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6).⁷⁹

On August 26, 2009, the plaintiffs made a motion for summary judgment to argue that the case did not turn on factual findings but on legal questions regarding the ability to patent genes.⁸⁰ On November 2, 2009, Judge Robert W. Sweet issued the court’s opinion, denying all motions to dismiss for each of the defendants.⁸¹ Quickly, patent attorneys and science gurus everywhere began feverishly blogging about the revival of the great policy debate: Can and should genes be patented?

After the issued opinion, the defendants continued their struggle to get out of court. On December 23, 2009, Myriad submitted its own motion for summary judgment and, on December 24, 2009, USPTO followed suit with its own motion for summary judgment.⁸² On February 2, 2010, oral arguments

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Id.

⁷⁶ “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.” 35 U.S.C. § 101.

⁷⁷ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 380 (S.D.N.Y. 2009).

⁷⁸ See generally Plaintiff’s Memorandum of Law in Support of Motion for Summary Judgment, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

⁷⁹ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 381.

⁸⁰ See generally Plaintiff’s Memorandum of Law in Support of Motion for Summary Judgment, *Ass’n for Molecular Pathology*, 669 F. Supp. 2d 365.

⁸¹ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 370.

⁸² See John Conley, *Myriad Genetics, USPTO File Summary Judgment Motions in Gene Patent Case*, GENOMICS LAW REPORT (Jan. 13, 2010), <http://www.genomicslawreport.com/index.php/2010/01/13/myriad-genetics-uspto-file-summary-judgment-motions-in-gene-patent-case/>.

were made to the court.⁸³ Judge Sweet's final order came down on March 29, 2010, finding in favor of the plaintiffs by declaring gene patents invalid.⁸⁴ Presently, the bloggers, patent attorneys, scientists, and researchers await the response of the United States Court of Appeals for the Federal Circuit.

Once the November 2, 2009 opinion on standing was released, the district court continued with the matter and ruled that the patents were invalid and issued prospective orders to the USPTO regarding the issuance of future genetic patents. The rest of this Comment will summarize, analyze, and critique the opinion on standing because without this determination the substantive issues would not have been reviewed.

D. *The Court's Conclusive Results*

The court broke the standing question into two sections. The court first evaluated standing to bring the USPTO to federal court for constitutional violations and then the standing to have a declaratory judgment action on Myriad's patents.⁸⁵ This section will summarize the court's argument as to how the plaintiffs obtained standing to reach each of the defendants.

1. Standing Against USPTO Tests Positive

The district court began by outlining the requirements for constitutional standing and prudential standing. Summarizing the rule from *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*⁸⁶ the court wrote:

Art. III requires the party who invokes the court's authority to show (1) that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, that (2) the injury fairly can be traced to the challenged action, and (3) is likely to be redressed by a favorable decision.⁸⁷

⁸³ See *Judge Hears Arguments in Challenge to Patents on Genes Tied to Breast, Ovarian Cancer*, MED. NEWS TODAY (Feb. 5, 2010), <http://www.medicalnewstoday.com/articles/178289.php>.

⁸⁴ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

⁸⁵ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 383-92 (S.D.N.Y. 2009).

⁸⁶ 454 U.S. 464 (1982).

⁸⁷ *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 384 (quoting *Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State*, 454 U.S. 464, 472 (1982) (internal citations omitted)).

Additionally, the court addressed the prudential requirements, which must be satisfied beyond the constitutional requirements. It stated:

[T]he judiciary should “avoid deciding questions of broad social import where no individual rights would be vindicated.” Prudential standing requires, inter alia, that a party “assert his own legal interests rather than those of third parties,” and that a claim must not be a “generalized grievance” shared in by all or a large class of citizens. Prudential standing also addresses whether “the constitutional or statutory provision on which [a plaintiff’s] claim rests properly can be understood as granting persons in the plaintiff’s position a right to judicial relief.” Thus, the litigant’s complaint must fall within the “zone of interests to be protected or regulated by the statute or constitutional guarantee in question.”⁸⁸

First, the court reused an earlier section of its opinion in favor of subject matter jurisdiction in order to satisfy the injury requirement. In this section, the court stated, “[The USPTO] cites to no comparable statutory scheme providing a remedy for persons who complain about the constitutionality of patents issued by the USPTO and/or the policies and practices of the USPTO.”⁸⁹ For this reason alone, the court determined that the plaintiffs should have standing to allege a constitutional claim if there is no other remedy provided.⁹⁰ And, although the court does not specifically address the issue, the opinion seems to conclude that this lack of remedy is the injury the plaintiffs sought to redress.

Second, the court agreed with the USPTO that “Myriad’s refusal to license its patent broadly contributes to [p]laintiffs’ alleged injuries.”⁹¹ However, the court continued the analysis and stated that “the patents were issued by the USPTO, in accordance with its policies and practices. It is those policies and practices that the [p]laintiffs allege are unconstitutional. The injury alleged is therefore ‘fairly traceable’ to the USPTO.”⁹²

Finally, the court analyzed the redressability requirement and concluded that the injuries would be redressed if the court “declare[s] unconstitutional the USPTO’s policies and practices with respect to the challenged claims and similar classes of claims . . . [it] would serve to render the claims-at-issue definitionally invalid.”⁹³ The court further reasoned that “[a]s a result, the [p]laintiffs

⁸⁸ *Id.* (internal citations omitted).

⁸⁹ *Id.* at 382–83.

⁹⁰ *Id.* at 384–85.

⁹¹ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 385 (S.D.N.Y. 2009).

⁹² *Id.*

⁹³ *Id.*

would be allowed to engage in conduct currently prohibited by Myriad's patents."⁹⁴

Thus, the court concluded that the plaintiffs had standing to sue the USPTO.⁹⁵

2. Standing Against Myriad Tests Positive

In the standing section of the opinion, the district court acknowledged that this was a declaratory judgment action between the plaintiffs and Myriad and stated that the purpose "is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights."⁹⁶ Therefore, there are different requirements set forth to determine standing. The Declaratory Judgment Act⁹⁷ requires a constitutional case or controversy in order to have standing in a federal court.⁹⁸ However, the court rested heavily on a recent case,⁹⁹ which provided that declaratory judgment cases involving patents must be examined with regard to "all the circumstances."¹⁰⁰ Under this approach, the court stated that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."¹⁰¹ Unsure of the "all circumstances" boundaries, the court determined there was enough guidance provided by federal courts to declare a two part test: there must be some "affirmative act" taken by the patent holder to enforce the patent and there must be "meaningful preparation" to infringe the patent by the plaintiffs.¹⁰²

First, the court found that the defendants had taken affirmative acts to enforce their patent rights.¹⁰³ The court arrived at this conclusion by referencing the cease-and-desist letters to Dr. Kazazian, the University of Pennsylvania, Dr.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.* (quoting *Goodyear Tire & Rubber Co. v. Relesomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987)).

⁹⁷ 28 U.S.C. § 2201 (2006).

⁹⁸ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 385–86 (S.D.N.Y. 2009).

⁹⁹ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (holding a licensee had standing for a declaratory judgment action even though the licensee continued to pay royalty fees and there was no infringement yet).

¹⁰⁰ *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 386.

¹⁰¹ *MedImmune*, 549 U.S. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)); see also *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 386.

¹⁰² *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 386–87.

¹⁰³ *Id.* at 387–90.

Ostrer, and YDL, as well as the lawsuit against Oncormed.¹⁰⁴ The court determined that the combined weight of all the previous actions was enough to give the presumption that the defendants would take action to enforce its patent rights, despite the fact that the action was not taken against all of the named plaintiffs and the attempted infringement action had been against a party outside of the action.¹⁰⁵

Second, the court found that the plaintiffs had taken meaningful preparation to infringe the patent.¹⁰⁶ After reviewing the plaintiffs' declarations, the court found:

The [p]laintiffs have demonstrated that the researcher [p]laintiffs are poised to begin *BRCA1/2* testing and that the patents-in-suit present the only obstruction to doing so. Moreover, Drs. Kazazian, Ganguly, and Ostrer had previously engaged in *BRCA1/2* testing prior to Myriad's assertion of its patent rights against them. Consequently, the researcher [p]laintiffs are meaningfully prepared to begin 'BRCA testing to advance research and/or to offer . . . an important service to the public' and 'could do so within a matter of weeks.' Plaintiffs' affidavits similarly establish that members of the various medical organizations, represented by the organizations under the 'doctrine of associational standing,' are, like the researcher [p]laintiffs, also meaningfully prepared and possess the desire to engage in *BRCA1/2* testing were the patents-in-suit invalidated.¹⁰⁷

The court also addressed potential contributory infringers who are named plaintiffs by stating:

[T]he non-researcher [p]laintiffs, may very well understand the precise nature of, and be prepared to take advantage of, the services of a potential infringer were the latter not prevented from offering those services by a third party's assertion of its patent rights. Here, it is alleged that the researcher [p]laintiffs would offer infringing *BRCA1/2* genetic testing services of the type the non-researcher [p]laintiffs would solicit or encourage others to solicit.¹⁰⁸

¹⁰⁴ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 387–90 (S.D.N.Y. 2009).

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 390–92.

¹⁰⁷ *Id.* at 391–92 (internal citations omitted).

¹⁰⁸ *Id.* at 392.

Finally, the court held that the plaintiffs had satisfied the “all circumstances” test in order to establish declaratory judgment standing.¹⁰⁹

III. WHERE DO WE STAND ON STANDING?

Part III of this Comment will provide an analysis of why the district court should have decided the standing issue differently. By analyzing precedent and reviewing the court’s application of the law, Part III will review the standing requirements against the USPTO and then the declaratory judgment standing requirements against Myriad.

A. *Standing Up for USPTO*

Like the district court, this section begins with the conditions required for the plaintiffs to have standing against the USPTO. First, the court misused the reviewability requirement in order to establish an injury. Therefore, this Comment analyzes the reviewability requirement separately from the standing requirements. Next, the Comment guides the reader through each hurdle required to establish standing in a federal court when applying a First Amendment violation claim. The hurdles demand that plaintiffs establish injury, prudential standing, traceability, and redressability.

1. Reviewing Reviewability

The Administrative Procedures Act (APA) provides a presumption of judicial review if the agency has made a final decision or there is no other remedy in court, unless the agency’s statute precludes judicial review or the agency action is committed to agency discretion by law.¹¹⁰ Currently, one opportunity for a third party to claim a patent’s invalidity is by using invalidation as a defense in federal court against an infringement charge.¹¹¹ Additionally, a third party can ask the USPTO for *inter partes* reexamination.¹¹² An *inter partes* reexamination requests the USPTO to reexamine the patent under the provisions of 35 U.S.C. § 301.¹¹³ Finally, the third party can petition the USPTO for an *ex parte* reexamination.¹¹⁴ Once the petition is filed, the director may determine if there is a substantial new question of patentability affecting any claim of the patent.¹¹⁵ The plaintiffs did not use invalidation as a defense prior to bringing

¹⁰⁹ *Id.* at 390–92.

¹¹⁰ 5 U.S.C. §§ 701–706 (2006).

¹¹¹ 35 U.S.C. § 282 (2006).

¹¹² 35 U.S.C. § 311 (2006).

¹¹³ 35 U.S.C. §§ 311–312 (2006).

¹¹⁴ 35 U.S.C. § 303 (2006).

¹¹⁵ *Id.*

the USPTO to court, did not request an *inter partes* reexamination to consider the possibilities of prior art for the BRCA1/2 gene, and did not petition for an *ex parte* reexamination allowing the director to determine a substantial new question. Therefore, the plaintiffs appear to be precluded from having the presumption of judicial review for not exhausting all administrative remedies.¹¹⁶

However, the court decided that these remedial schemes actually prevented the plaintiffs from raising the First Amendment argument and no other avenue was available to review this particular issue.¹¹⁷ Although the Supreme Court has not decided whether Congress *may* preclude judicial review of constitutional challenges,¹¹⁸ the Supreme Court has determined that unless Congress is clear, constitutional claims can be reviewed.¹¹⁹ Throughout the patent statutes, Congress did not clearly state whether constitutional claims could be reviewed.¹²⁰ Therefore, it is possible that the plaintiffs' First Amendment claim would have a presumption of judicial review.

On the other hand, by reviewing the USPTO's history and patterns, there is evidence that another remedial scheme is provided to allow the plaintiffs to bring a First Amendment claim prior to reviewing agency action. The USPTO has consistently abided by federal court and Supreme Court precedent to establish examination procedures and to properly issue a valid patent.¹²¹ This remedial scheme would allow the plaintiffs to bring a valid action—like a declaratory judgment action—to attempt to invalidate a patent against the patent holder. Then, whatever the court holds would determine how the USPTO acts. Therefore, if the court finds the USPTO policy to be wrong and it violates the First Amendment, then the USPTO will no longer follow that policy and the First Amendment would no longer be infringed. Thus, the plaintiffs would be precluded from reviewing agency action because the plaintiffs did not use this remedial scheme first.

Nonetheless, reviewability under the APA and the requirements to obtain standing are two different hurdles. “[A] plaintiff who brings a statutory enforcement action under the [APA] must meet its statutory requirements for

¹¹⁶ 5 U.S.C. §§ 701–706 (2006).

¹¹⁷ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 385 (S.D.N.Y. 2009).

¹¹⁸ *But cf. Webster v. Doe*, 486 U.S. 592, 611–15 (1988) (Scalia, J., dissenting) (arguing that Congress does have the power to preclude judicial review of circuit courts under the United States Constitution, Article 3, Section 1).

¹¹⁹ *Id.* at 603 (“We emphasized . . . that where Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear.” (citations omitted)).

¹²⁰ 35 U.S.C. §§ 282, 311–312 (2006).

¹²¹ *See generally* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (MPEP) (8th ed. Rev. 7, Sept. 2008), available at <http://www.uspto.gov/web/offices/pac/mpep/index.htm>.

standing.”¹²² Therefore, a plaintiff must separately illustrate “that there has been final agency action adversely affecting the plaintiff, and . . . as a result, it suffers legal wrong or that its injury falls within the ‘zone of interests’ of the statutory provision the plaintiff claims was violated.”¹²³ For these reasons, the court, although finding a possible presumption of reviewability, failed to distinguish reviewability and standing. Therefore, the court’s opinion insufficiently satisfied the requirements for standing discussed below.

2. (Under)Standing

As mentioned by the court, Article III provides three requirements for standing: injury, traceability, and redressability.¹²⁴ Furthermore, the court acknowledged the prudential standing requirement, which provides an additional threshold to prevent “generalized grievances.”¹²⁵ This segment will provide a critique of the court’s reasoning for each of these elements and the outcome at which the court should have arrived.

a. Injury

Article III requires the plaintiff to show an injury-in-fact, which generally may be the hardest to establish out of the three standing requirements. The Supreme Court has explained that the plaintiff “must be able to show not only that the statute is invalid but that he has sustained or is immediately in danger of sustaining some *direct injury* as the result of its enforcement, and *not* merely that he suffers in *some indefinite way* in common with people *generally*.”¹²⁶ Unfortunately, the district court did not provide in its opinion an analysis of the injury requirement. Instead, the court narrowly focused on the facts in the case law provided by the USPTO’s motion to dismiss and reasoned that an injury existed.¹²⁷ The complaint brought by the plaintiffs is a First Amendment challenge, not the complaint of an improper remedial scheme as the court analyzed.¹²⁸ Had the court properly analyzed the injury requirement, it would have arrived at the following conclusions.

¹²² *Churchill Cnty. v. Babbitt*, 150 F.3d 1072, 1078 (9th Cir. 1998) (internal citations omitted); see also *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 882–883 (1990).

¹²³ *Churchill Cnty.*, 150 F.3d at 1078 (citing 5 U.S.C. § 702).

¹²⁴ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 384 (S.D.N.Y. 2009).

¹²⁵ *Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State*, 454 U.S. 464, 475 (1982).

¹²⁶ *Id.* at 478 (quoting *Frothingham v. Mellon*, 262 U.S. 447, 488 (1923) (emphasis added)).

¹²⁷ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 384–85; see also Defendant’s Memorandum of Law in Support of Motion to Dismiss, *Ass’n for Molecular Pathology v. U.S. Patent & Trade Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

¹²⁸ See Complaint, *supra* note 43, at 19–20 (claims 50, 52, and 54).

First, there is no direct injury. The USPTO patent policies only directly affect patent applicants because those policies determine whether or not a patent will be issued. If anything, the plaintiffs have an indirect injury based on USPTO policies because an issued patent is a consequence of those policies. Nevertheless, the USPTO policy in question provides that “DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.”¹²⁹ This policy was provided after the courts consistently upheld the validity of gene patents.¹³⁰ The Utility Examination Guidelines are set forth by the USPTO so examiners can evaluate pending applications and either reject or deny them.¹³¹ Therefore, the only parties *directly* affected are patent applicants who have their applications approved or denied by this written policy. However, the “written policy” complained of was not even in effect during the examination period of the patents in question.¹³² Thus, the “written policy” could not directly affect these patents or the patent holders, nor indirectly affect any other third party.¹³³

Second, the injury claimed is indefinite. The plaintiff must show that he has suffered some injury “actual or imminent, not conjectural or hypothetical.”¹³⁴ Had the written policy been in effect, the policy would still not infringe on the plaintiffs’ First Amendment rights. The supposed “illegal conduct” occurs if the patent application satisfies the written policy and all other requirements under 35 U.S.C. § 101 et seq., and a patent is then issued. “Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive[,] and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other

¹²⁹ U.S. PATENT & TRADEMARK OFFICE, UTILITY EXAMINATION GUIDELINES, 66 Fed. Reg. 4, 1092, 1093 (Jan. 5, 2001) *available at* <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf> (last visited Mar. 7, 2011) [hereinafter Utility Examination Guidelines].

¹³⁰ *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (holding compounds isolated from nature are patentable); *In re Bergstrom*, 427 F.2d 1394, 1397 (C.C.P.A. 1970) (holding “these compounds do not exist in nature and appellants have not merely discovered nor claimed sufficiently broadly to encompass what was previously in nature”); *See also* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“nonnaturally occurring manufacture or composition of matter—a product of human ingenuity” as patentable subject matter).

¹³¹ *See generally* U.S. PATENT & TRADEMARK OFFICE, PATENT EXAMINATION POLICY, <http://www.uspto.gov/patents/law/exam/index.jsp> (last visited Mar. 7, 2011).

¹³² Utility Examination Guidelines, *supra* note 129 (stating the effective date for the policy as Jan. 5, 2001); *see also* *Myriad’s* patent, *supra* note 33 (showing the patent validation dates to be as follows: ‘282 patent on May 5, 1998, ‘492 patent on Nov. 17, 1998, ‘473 patent on Dec. 2, 1997, ‘999 patent on Jan. 20, 1998, ‘001 patent on Jan. 20, 1998, ‘441 patent on May 19, 1998, and ‘857 patent on March 7, 2000.).

¹³³ *See* Complaint, *supra* note 128 (Claim 50 argues that *Myriad* obtained its patents from the USPTO “pursuant to a formal written policy by the Patent Office.”).

¹³⁴ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (alteration in original) (citations omitted).

media of his choice.”¹³⁵ Neither the contested policy, governing statute, Intellectual Property Clause nor the issued patents prohibit the plaintiffs from printing, thinking, speaking, or discussing with others the patented product or the methods patented.¹³⁶ In fact, anyone can look up an issued patent or patent application and all of the information contained therein through a simple search on the USPTO’s website.¹³⁷

For example, the Supreme Court has discussed what others can do with patented subject matter without infringement. In *Microsoft Corp. v. AT & T Corp.*,¹³⁸ the Court compared a patented software code to a blueprint containing instructions, where the code is an idea not actually patented until it becomes a computer-readable hard copy.¹³⁹ The Court further explained, “[a] blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component” of that device.¹⁴⁰ “Blueprints too, or any design information for that matter, can be independently developed, bought, and sold.”¹⁴¹ Similarly, the patents and patent claims are “blueprints” describing the BRCA1/2 gene as well as the methods for testing patients.¹⁴² Therefore, the plaintiffs have the capability to use the blueprint in any way to freely express the information without infringing, as long as the end product described by the blueprint is not constructed and used.

Furthermore, the plaintiffs have the freedom to perform research and experiments on patented products and also had the opportunity to do both for commercial purposes.¹⁴³ Myriad illustrated this freedom by notifying NCI that it could continue and that Myriad would not interfere with the NCI’s research at all.¹⁴⁴ Additionally, Myriad had offered to sell licenses to laboratories so those labs could continue commercial testing without infringing.¹⁴⁵ Finally, Myriad backed up this claim when it offered Dr. Ostrer, Dr. Kazazian, and the University of Pennsylvania licenses to use the patented discoveries, but those plaintiffs

¹³⁵ *The United Nations International Covenant on Civil and Political Rights*, CECC.GOV, <http://www.cecc.gov/pages/general/unCivilPolitical.php?mode=print&PHPSESSID=2b043edcff5e7a9649dbc40e05447e19> (last visited Mar. 7, 2011).

¹³⁶ See U.S. CONST. art. 1, § 8, cl. 8; 35 U.S.C. § 101 (2006).

¹³⁷ See generally U.S. PATENT & TRADEMARK OFFICE, Search Page, <http://patft.uspto.gov/> (last visited Mar. 7, 2011).

¹³⁸ 550 U.S. 437, 449 (2007) (holding that the abstract part of the software are instructions and was not a component; therefore, there is no infringement until the next step is taken to render the components useful).

¹³⁹ *Id.* at 449.

¹⁴⁰ *Id.* at 438.

¹⁴¹ *Id.* at 450–51.

¹⁴² See Myriad’s patents, *supra* note 33.

¹⁴³ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

¹⁴⁴ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 379 (S.D.N.Y. 2009).

¹⁴⁵ *Id.*

either turned down or ignored the offer.¹⁴⁶ The plaintiffs' freedoms were not hindered and no actual injury or imminent injury occurred. Third and finally, the injury is common with people generally. As mentioned earlier, the injury resulting from the illegal conduct is that a patent is issued, which, arguendo, infringes the plaintiffs' First Amendment rights. Specifically, the complaint went as far as stating that the injury was caused by the "monopoly" that Myriad held over the genetic testing of BRCA1/2 genes.¹⁴⁷ Following this logic, every policy followed by the USPTO that results in an issued patent would violate the First Amendment rights of any researcher, inventor, innovator, or average Joe who may have wanted to use the patented product for any of the aforementioned freedoms of expression, but are unable to do so because of the monopoly provided to the patent holder. The plaintiffs' real qualm is not truly the freedom to seek, receive, or impart information; the actual injury is that the plaintiffs do not wish to pay to practice the patent, a limitation that applies to any patent of any type. If the plaintiffs' claim was cognizable, patent and copyright protection would cease to exist.

Standing is not satisfied because it is an "abstract injury in nonobservance of the Constitution asserted by . . . citizens." Such claims amount to little more than attempts 'to employ a federal court as a forum in which to air . . . generalized grievances about the conduct of government.'¹⁴⁸ Allowing the plaintiffs to implicitly claim a direct injury on the basis that the monopoly provided by the issuance of patents inhibits others' First Amendment rights does not satisfy the standing requirement; rather it serves as a generalized grievance of the entire patenting process. Consequently, this argument takes us to the next section: prudential standing.

b. Prudential Standing

Although the district court outlined the rules for prudential standing, it did not analyze the effect of those rules as applied to this case. Again, the court narrowly applied the facts from the authority cited by the USPTO and glossed over the clumsy efforts by the plaintiffs to establish prudential standing.¹⁴⁹ Prudential standing requirements are narrower than the constitutional requirements. The court can find an injury-in-fact, which is "an invasion of a legally protected interest."¹⁵⁰ "[T]he interest sought to be protected by the complainant [must be] arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question."¹⁵¹ Further, the protected claim cannot

¹⁴⁶ *Id.*

¹⁴⁷ See Complaint, *supra* note 43 at 25–26 (claims 84 and 85).

¹⁴⁸ Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State, 454 U.S. 464, 482–83 (1982) (citations omitted).

¹⁴⁹ *Ass'n for Molecular Pathology*, 669 F. Supp. 2d at 384–85.

¹⁵⁰ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

¹⁵¹ *Ass'n of Data Processing Serv. Orgs., Inc., v. Camp*, 397 U.S. 150, 153 (1970).

be a “generalized grievance,”¹⁵² but can be overcome if there is a “chilling effect” caused by the direct prohibition of First Amendment rights.¹⁵³ By appropriately evaluating the additional requirements for agency review, the court should have arrived at the conclusions stated below.

To begin, the plaintiffs are not in the zone of interests. There must be a “legally protected interest,”¹⁵⁴ which was violated causing the injury and that injury must be “‘within the meaning of the relevant statute’- *i.e.*, [meet] the ‘zone of interests’ test. The relevant statute, of course, is the statute whose violation is the gravamen of the complaint”¹⁵⁵ The legally protected interest sought is the plaintiffs’ First Amendment rights. Based on causes of action 102 and 103, the plaintiffs try to establish First Amendment rights within the Intellectual Property Clause and 35 U.S.C. § 101 as providing the legally protected interest.¹⁵⁶

The plaintiffs are not in the zone of interests under the Intellectual Property Clause. Specifically, the Clause states that Congress shall secure “for limited Times to Authors and *Inventors* the *exclusive Right* to their respective Writings and *Discoveries*.”¹⁵⁷ The interests sought to be protected by the Framers are those of the patent holder. Moreover, there is no language that evidences intent for the protection of the public or to elicit First Amendment rights from patent holders. Previously, the Intellectual Property Clause has been reviewed subject to First Amendment analysis, but under the realm of Copyright Infringement. The Supreme Court held:

The Copyright Clause [also known as the Intellectual Property Clause] and First Amendment were adopted close in time. This proximity indicates that, in the Framers’ view, copyright’s limited monopolies are compatible with free speech principles. Indeed, copyright’s purpose is to *promote* the creation and publication of free expression. As *Harper & Row* observed: “The Framers intended copyright itself to be the engine of free expression. By establishing a marketable right to the use of one’s expression, copyright supplies the economic incentive to create and disseminate ideas.”¹⁵⁸

¹⁵² Warth v. Seldin, 422 U.S. 490, 499 (1975).

¹⁵³ Laird v. Tatum, 408 U.S. 1, 11 (1972).

¹⁵⁴ *Defenders of Wildlife*, 504 U.S. at 560.

¹⁵⁵ Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 886 (1990).

¹⁵⁶ See Complaint, *supra* note 43 at 29.

¹⁵⁷ U.S. CONST. art. 1, § 8, cl. 8 (emphasis added).

¹⁵⁸ *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003) (citing *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 558 (1985)).

Since it is the same clause, this same concept would hold true to patent law. Nonetheless, Congress has provided for a balance between the Intellectual Property Clause and the First Amendment over time through administrative regulations.

To assist in the dissemination of information, issued patents and patent applications are published, viewable, and printable.¹⁵⁹ Further, Congress has not extended the reach of “exclusive right” to prohibit speech, thought, or the conveyance of information provided in issued patents or patent applications. Although Congress has avoided challenges to non-patent holders’ First Amendment rights, the Intellectual Property Clause “empowers Congress to determine the intellectual property regimes that, overall, in that body’s judgment, will serve the ends of the Clause,”¹⁶⁰ and Congress has yet to change the intended protected interest of patent holders.

The plaintiffs are not in the zone of interest under 35 U.S.C. § 101. This statute states, “[w]hoever invents or discovers . . . composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, *subject to the conditions and requirements of this title.*”¹⁶¹ Based on the conditions and requirements of the statute, these plaintiffs are not an intended protected interest because they were not patent applicants and were an outside party to the patent application process. Again, there is no express language within this statute or the rest of the title illustrating the intent for First Amendment rights.¹⁶² Nevertheless, the Supreme Court has extracted from the conditions and requirements of this statute the patentability of “laws of nature, physical phenomena, and abstract ideas.”¹⁶³ The plaintiffs have relied on this precedent to attach First Amendment rights to the intended protected interest of 35 U.S.C. § 101. Ironically, this same Supreme Court decision also said in discussing the patentability of genetic research, this subject “should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.”¹⁶⁴ Therefore, it would seem that the plaintiffs’ interest would not be protected here.

Finally, the plaintiffs have not been “chilled” in a way that makes their generalized grievance actionable.¹⁶⁵ “In recent years this Court has found in a number of cases that constitutional violations may arise from the deterrent, or ‘chilling,’ effect of governmental regulations that fall short of a direct prohibi-

¹⁵⁹ See U.S. CONST. art. 1, § 8, cl. 8; 35 U.S.C. § 101 (2006); 35 U.S.C. § 122 (2006).

¹⁶⁰ *Eldred*, 537 U.S. at 222.

¹⁶¹ 35 U.S.C. § 101 (emphasis added).

¹⁶² See generally *id.*

¹⁶³ *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980).

¹⁶⁴ *Id.* at 317.

¹⁶⁵ See generally Complaint, *supra* note 43 at 25–26 (claims 84 and 85); *Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State*, 454 U.S. 464, 482–83 (1982) (citations omitted).

tion against the exercise of First Amendment rights.”¹⁶⁶ The plaintiffs claim that (1) there is a chilling effect because the patent holder can enforce its patent and that enforcement prevents the plaintiffs from establishing new tests; and (2) there is a chilling effect for researchers for fear of enforcement if they perform research.¹⁶⁷ First of all, neither of these “chilling effects” is caused by the USPTO’s “written policy;” rather the claims relate to the Intellectual Property Clause’s and Patent Act’s grant of exclusive rights. Moreover, Myriad has allowed for research use, negating any chilling effect and demonstrating that the proper party is the patentee and not the patent granting agency.¹⁶⁸

A chilling effect only exists because of the limited exclusive right the patent holder has obtained. However, this chilling effect applies to *all* patents. This deterrent described by the plaintiffs was an intention of the Intellectual Property Clause. Previously discussed, the Supreme Court held that the proximity in adoption of the Intellectual Property Clause and the First Amendment signifies that the limited exclusive right is attuned with the freedom of expression.¹⁶⁹ By bringing the USPTO into the litigation, the plaintiffs will continuously have a generalized grievance because any policy the USPTO enforces results in a patent and this end result is what leads to “a chill factor.” This leads to the absurd result that the USPTO can be sued every time it issues a patent, let alone an invalid one.

Instead, as discussed above, the USPTO implements federal court decisions and statutes when examining patents.¹⁷⁰ Therefore, there are two ways to provoke a system-wide change without being faced with a generalized grievance issue. First, the plaintiffs could directly challenge the validity of the isolated BRCA1/2 gene claims and the result may change, narrow, or omit entirely the “isolated and purified” rule. This is what the potential infringers have done by suing Myriad for declaratory relief. A change by the federal courts would change the USPTO’s examination policy. Alternatively, the plaintiffs could create a system-wide change through legislation, discussed in Part IV, for which the courts exhibited their preference in the past concerning biotechnology.¹⁷¹

The court appears to have misinterpreted the injury and prudential standing requirements. The injury was an indirect and indefinite injury which could not apply generally. Although there was a generalized grievance, the plaintiffs failed to overcome this limitation because the plaintiffs were not in the zone of interests and did not suffer from a chilling effect under the First Amendment. Nonetheless, the court established that an injury did occur; there-

¹⁶⁶ *Laird v. Tatum*, 408 U.S. 1, 11 (1972).

¹⁶⁷ *See* Complaint, *supra* note 43 at 26–27 (claims 88 and 89).

¹⁶⁸ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 381 (S.D.N.Y. 2009).

¹⁶⁹ *See generally* *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003).

¹⁷⁰ *See generally* the cases cited *supra* note 130.

¹⁷¹ *See, e.g.,* *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

fore, the following sections continue evaluating the court's reasoning for traceability and redressability.

c. Traceability

Another concept required by Article III standing is traceability. Traceability "examines the causal connection between the assertedly unlawful conduct and the alleged injury."¹⁷² The Supreme Court has contradictorily applied this requirement throughout the years.¹⁷³ Therefore, the Court could reasonably rule either way on this point. In this instance, the court found that the plaintiffs' First Amendment injury was based on the USPTO's written policy, and because the USPTO follows that written policy a patent is issued;¹⁷⁴ hence, the injury is fairly traceable to the USPTO.

The Supreme Court held that to satisfy this element "the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'"¹⁷⁵ At first glance, it appears that the Court is correct in its analysis because the alleged injury does stem from the USPTO's act of issuing the patent. However, the Court is correct for the wrong reason. Under 35 U.S.C. § 282, an issued patent is presumed to be valid despite whether or not the USPTO was correct in issuing it.¹⁷⁶ Further, the burden is shifted to the challenger (here the plaintiffs) to prove that the patent or an individual claim within the patent is invalid.¹⁷⁷ It is not uncommon for the USPTO to issue invalid patents, whether it be for prior art, public use, or obviousness, but the patent is still enforceable until proven otherwise. Therefore, it would not matter whether the written policy is or is not unconstitutional because the patent could have been issued and the plaintiffs

¹⁷² *Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984).

¹⁷³ *See* *Northeastern Fla. Chapter of Ass'n of Gen. Contractors v. Jacksonville*, 508 U.S. 656 (1993) (holding that white contractors did have an injury because they lacked the ability to compete, and that injury was fairly traceable to a program assisting minorities in the same industry); *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669 (1973) (holding increased litter in parks was fairly traceable to a freight rate increase causing prices to increase for shipment of trash for recycling). *But see* *Simon v. E. Ky. Welfare Rights Org., Inc.*, 426 U.S. 26 (1976) (holding that enforcement of charitable status for hospitals was not fairly traceable to free medical care availability); *Warth v. Seldin*, 422 U.S. 490 (1975) (holding potential builders' and residents' future injury was not fairly traceable to zoning laws preventing building of low-income housing).

¹⁷⁴ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

¹⁷⁵ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quoting *Simon*, 426 U.S. at 41–42).

¹⁷⁶ "A patent shall be presumed valid. Each claim of a patent . . . shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim." 35 U.S.C. § 282 (2006).

¹⁷⁷ "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.*

would have the same alleged injury. Granted, the USPTO was more likely to issue the patent because of the written policy, but the driving force is the presumption of validity. Since every patent issued is automatically valid and can be enforced by the patent holder until a challenger can prove the patent invalid, every person has a traceable injury to the USPTO. As mentioned before, this injury is unlikely to be supported because it is a generalized grievance attacking the foundations of the patent process.

d. Redressability

Redressability is the last standing requirement set forth in Article III. “[W]hen a plaintiff’s standing is brought into issue the relevant inquiry is whether, assuming justiciability of the claim, the plaintiff has shown an injury to himself that is likely to be redressed by a favorable decision.”¹⁷⁸ This standard can be broken into two subsections: first, whether declaring the USPTO’s acts unconstitutional would provide the remedy sought, and second, whether it is likely that the court will find in favor of the plaintiffs.

First, finding the USPTO policy unconstitutional would provide some of the remedy sought. The court claims that if the USPTO’s written policy was found unconstitutional, then the issued patents under this policy would be definitionally invalid.¹⁷⁹ Again, assuming there is a First Amendment violation, then the policy would be found unconstitutional, but this is not the entire relief sought by the plaintiffs. To invalidate the gene patent claims, the plaintiffs would still have to take the patent holders to court to have the claims invalidated. The plaintiffs have simultaneously done this action by joining Myriad in a declaratory judgment action. Then, if the court declares the gene patent claims invalid, the isolated unaffected and isolated mutated BRCA1/2 genes become usable by the public. However, this only partially fulfills the plaintiffs’ prayer for relief. The plaintiffs also want the patent claims regarding methods using the BRCA1/2 genes to be invalidated. Unfortunately, this would not occur by declaring the written policy unconstitutional because methods are patentable through other USPTO policies. Therefore, the plaintiffs can only receive a partial remedy at most.

Moreover, the plaintiffs are unlikely to receive a favorable judgment in order to remedy the injury. “[I]t must be ‘likely,’ as opposed to merely ‘speculative,’ that the injury will be ‘redressed by a favorable decision.’”¹⁸⁰ Based on the court’s opinion, it must have assumed that the plaintiffs were likely to win. Because this opinion strongly favors the plaintiffs, it is likely that the Court may also favor the plaintiffs when it reviews the substantive issues of the case.

¹⁷⁸ *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26 (1976).

¹⁷⁹ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 385 (S.D.N.Y. 2009).

¹⁸⁰ *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (citing *Simon*, 426 U.S. at 38, 43).

Although the Supreme Court has not had many opportunities to clarify,¹⁸¹ in *Diamond v. Chakrabarty*, the Court held that patent protection extended to “anything under the sun that is made by man.”¹⁸² This left the door wide open to gene patentability. The Federal Circuit has laid a clear foundation about the validity of gene patents and touched on each of the requirements to obtain a patent: utility, novelty, and obviousness. Regarding utility, *In re Fisher* established that genes were patentable as long as the applicant could provide a “specific and substantial utility,” practical utility, and its use would benefit the public.¹⁸³ Gene patents also satisfied the novelty requirement of 35 U.S.C. § 102. “If the holdings in *In re Bergstrom* are strictly followed, virtually any recombinant protein should be deemed novel over its extracted counterpart, since invariably obtained under a purer form”¹⁸⁴

One of the more difficult hurdles in gene patentability is the obviousness requirement under 35 U.S.C. § 103. “*In re Bell* and *In re Deuel* make clear that prior art disclosures of genes that are similar to a newly discovered gene do not render obvious the particular sequence of the newly discovered gene, even if the methods of discovering [it] . . . are obvious.”¹⁸⁵ Finally, the Federal Circuit has even illustrated how the gene sequences should be characterized in the description claims for a gene patent.¹⁸⁶

Assuming the Federal Circuit is correct and gene patents can be valid, then the district court should have seen the lines of precedent set by the Supreme Court regarding Copyright and First Amendment violations.¹⁸⁷ For example, the Copyright Act grants the author the exclusive rights to publish, copy,

¹⁸¹ “The Supreme Court has not recently considered the patentability of products derived from nature. The Court had the opportunity to consider one such patent in *In re Bergy*, a companion case to *Chakrabarty*. However, Bergy withdrew his application prior to the ruling, and the Court dismissed the appeal as moot.” Michael Risch, *Everything is Patentable*, 75 TENN. L. REV. 591, 612–13 (2008) (citations omitted).

¹⁸² *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1953); H.R. REP. NO. 1923, 82d Cong., 2d Sess., 6 (1952)).

¹⁸³ *In re Fisher*, 421 F.3d at 1377 (found nucleic acid sequences encoding proteins for maize plants unpatentable only because the applicant did not know what the proteins did and did not benefit the public).

¹⁸⁴ PHILIPPE G. DUCOR, PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES 14 (Kluwer Law Int’l Ltd. 1998) (citing *In re Bergstrom*, 427 F.2d 1394 (C.C.P.A. 1970)).

¹⁸⁵ Edward T. Lentz, *Are Real Business People so Easily Thwarted*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 441, 443 (F. Scott Kieff ed., 2003) (citing *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993); *In re Deuel*, 51 F.3d 1552, 1558 (Fed. Cir. 1995)).

¹⁸⁶ *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (“An adequate written description of a DNA . . . ‘requires a precise definition, such as by structure, formula, chemical name, or physical properties,’ not a mere wish or plan for obtaining the claimed chemical invention. . . . ‘[W]hat is required is a description of the DNA itself.’” *Id.* at 1566–67 (citing *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)).

¹⁸⁷ Risch, *supra* note 181 (“For example, copyright law limits speech by barring the distribution of copyrighted works, but arguments that such a bar is unconstitutional *per se* are unpersuasive.”).

and distribute the author's work starting from the time of creation,¹⁸⁸ this completely stifles the freedom to impart information, but it is constitutional. Issued patents are published online and can be printed, copied, distributed, and discussed. Moreover, the Copyright Act allows an identified author exclusive rights to his work from the time of creation until seventy years after his death¹⁸⁹ and unidentified authors' works are protected for ninety-five years from publication or 120 years from creation, whichever expires first.¹⁹⁰ If this exclusive right is considered constitutional, then a mere twenty-year patent protection period should be constitutional.

Lastly, the Supreme Court has recognized the dichotomy between the First Amendment and the Intellectual Property Clause,¹⁹¹ and has held "[d]ue to this distinction, every idea, theory, and fact in a copyrighted work becomes instantly available for public exploitation at the moment of publication."¹⁹² The Supreme Court reaffirmed this concept for patent law regarding ideas by holding, "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."¹⁹³ Lower courts have also created a strong precedent distinguishing gene subject matter from these categories. Judge Learned Hand opined in *Parke-Davis* long ago that a gene was not a product of nature if it had been isolated and purified from its state of nature.¹⁹⁴ Further in *In re Myer*¹⁹⁵ and *In re Grams*,¹⁹⁶ the Federal Circuit determined that DNA qualified as patentable subject matter because it fell within the definition of "composition of matter" under 35 U.S.C. § 101. The district court should have concluded that the plaintiffs would be unlikely to receive a favorable judgment to remedy their injury.

The court should not have found standing. All three elements of constitutional standing were not present. There was no definite, direct injury that would not apply generally. Furthermore, the plaintiffs could not overcome the generalized grievance limitations provided under prudential standing. Although the injury may be traceable, the court should have determined that the plaintiffs were unlikely to receive a favorable judgment because the Federal Circuit has already found genes to be patentable and the Supreme Court has established that

¹⁸⁸ *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 546–47 (1985).

¹⁸⁹ *Eldred v. Ashcroft*, 537 U.S. 186, 195–96 (2003).

¹⁹⁰ *Id.* at 196.

¹⁹¹ *Id.* at 219.

¹⁹² *Id.* (referencing *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340 (1991)).

¹⁹³ *In re Bilski*, 545 F.3d 943, 960 (Fed. Cir. 2008) (this concept was recently reaffirmed by the Federal Circuit); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

¹⁹⁴ See generally *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 109 (C.C.S.D.N.Y. 1911) (the patent on adrenaline was found valid because no one had purified it to that form before).

¹⁹⁵ *In re Meyer*, 688 F.2d 789 (C.C.P.A. 1982).

¹⁹⁶ *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989).

the Intellectual Property Clause's exclusive rights do not violate the First Amendment. Even if this precedent is ignored, the plaintiffs would still not receive the relief sought. For these reasons, a court reviewing this decision, should reverse the district court's standing conclusion.

Of course, alleged patent infringers are free to continue to challenge the validity of DNA patents, even in the face of unlikely victory; perhaps the Federal Circuit or the Supreme Court will reverse course. However, generalized grievances that are unlikely to win under current law mean that the USPTO is not the proper party to suit.

3. Dissecting the Consequences of the Court's Opinion

Due to the court's final decision, the lengths used to justify justiciability in order to review this major issue will likely cause other intellectual property problems. This section will provide a brief overview of procedural and policy outcomes that could result from this decision.

The Supreme Court has stated:

The "standing" requirement serves other purposes. Because it assures an actual factual setting in which the litigant asserts a claim of injury in fact, a court may decide the case with some confidence that its decision will not pave the way for lawsuits which have some, but not all, of the facts of the case actually decided by the court.¹⁹⁷

Unfortunately, the district court's opinion has set a precedent that will likely open the floodgates to review *any* of the USPTO's policies that lead to an issued patent. This decision seems to ignore the Supreme Court's stance declaring, "suits challenging, not specifically identifiable Government violations of law, but the particular programs agencies establish to carry out their legal obligations . . . [are], even when premised on allegations of several instances of violations of law, . . . rarely if ever appropriate for federal-court adjudication."¹⁹⁸ Based on the plaintiffs' reasoning, the written policy should be unconstitutional because it allows the USPTO to issue a patent and wrongly provide exclusive rights to patent holders. When the patent holders enforce those exclusive rights, then the plaintiffs lose their freedom of expression. If the court upholds this analysis, then it would be easy for *any* party to invalidate *any* of the USPTO's policies that allow a patent to be issued and provides the patent holder the ability to enforce exclusive rights.

¹⁹⁷ Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State, 454 U.S. 464, 472 (1982).

¹⁹⁸ Lujan v. Defenders of Wildlife, 504 U.S. 555, 568 (1992) (citing Allen v. Wright, 468 U.S. 737, 759–60 (1984)).

There are strong policy reasons for permitting exclusive rights, despite the fact that the plaintiffs may be discouraged to act. The Supreme Court has held that the exclusive right provided by patent protection affords the incentive to research and create ideas.¹⁹⁹ Further, if that protection is not made available then it is more likely for that incentive to diminish. If anything, the effect provided by patent protection is necessary to prevent others from usurping patent protection and diminishing that incentive to propagate information.

Alternatively, if only the written policy granting the USPTO authority to issue gene patents is found unconstitutional, then undiscovered genes and gene testing will likely be hidden; this will prevent the free flow of information as well as wasting time, energy, and resources as the plaintiffs and others attempt to reinvent what one company may have already secretly discovered. Particularly, the public will see an increase in trade secret use.²⁰⁰ The Uniform Trade Secrets Act defines a trade secret as “any information, including formulas, patterns, compilations, techniques, etc., that derive an actual or potential economic value from not being generally known or ascertainable in the market place . . . subject to reasonable efforts to maintain secrecy.”²⁰¹ For example, the discovery of a new gene may not be protected by trade secret, but what it can be used for and the results of its use may be hidden. Thus, elaborate gene testing software or machines to treat new diseases will be monopolized by those who can keep it a secret until the information becomes generally well known.

This scare of secrecy and stalling innovation has been acknowledged before. The Framers wanted to “*promote the Progress of Science and useful Arts, by securing for a limited time . . . exclusive Right[s]. . .*”²⁰² Analyzing the plain meaning acknowledges the fact that progress would be hindered if there was no security for going public with discoveries. Similarly, issues regarding decreased incentives arose during debates on expressed sequence tags (ESTs) patents relating to pharmaceutical companies.²⁰³

Reid Adler, the director of NIH’s Office of Technology Transfer, countered critics by contending that patenting ESTs would offer the protection needed to persuade drug makers to license the inventions and develop new medicines. He said that if the

¹⁹⁹ *Allen*, 468 U.S. at 753 n.19.

²⁰⁰

Trade Secrets generally are state law rights recognizing that some inventions are not suitable for patent or copyright protection, either because of the nature of the invention or because the inventor may wish to avoid public disclosure of the details so that it might extend the secrecy of the invention.

HUGH B. WELLONS ET AL., *BIOTECHNOLOGY AND THE LAW* 147 (2007).

²⁰¹ *Id.* at 148.

²⁰² U.S. CONST. art. 1, § 8, cl. 8 (emphasis added).

²⁰³ See generally GARY ZWEIGER, *TRANSDUCING THE GENOME: INFORMATION, ANARCHY, AND REVOLUTION IN THE BIOMEDICAL SCIENCE*, 61–76 (2001).

NIH put the sequences in the public domain and did not patent them, then they would be rendered unpatentable and drug makers would have less of an incentive to work with them.²⁰⁴

The EST debates coincided with congressional acts during the 1980s “to ensure that federally funded laboratory scientists and engineers supported technology transfer and commercialization through patent protection and licensing.”²⁰⁵ The acts also were to “lead to commercial products that were previously unavailable, and licensing revenue generated . . . [to] help fund further research.”²⁰⁶

Over time, the Supreme Court has acknowledged patent protection and its incentives. During the 1940s and 1950s, Justices Black and Douglas controlled the power of patents by narrowly reading claims in favor of permitting others to enter the market to compete with the patent holder.²⁰⁷ It was not until the 1970s when patent law was correlated with anti-trust law and trade secrets usage causing the Supreme Court to reconsider the benefits of patent protection.²⁰⁸

Then again, some believe that leaving the USPTO in the case allows an opportunity for the government to raise a defense to halt this debate once and for all.²⁰⁹

B. *Standing Up for Myriad*

The requirements for declaratory judgment have become more lenient over time; especially in the patent realm after the decision in *MedImmune, Inc. v. Genentech, Inc.*²¹⁰ Nonetheless, this section critiques the district court’s ruling finding standing against Myriad.

1. The Declaratory Relief Mutation

Declaratory Judgment has been codified by Congress to allow a court to hear a case of “actual controversy,” declare “rights and other legal relations” for

²⁰⁴ *Id.* at 64.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ Gerald Sobel, Esq., *Competition Policy in Patent Cases and Antitrust*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 23, 42–48 (F. Scott Kieff ed., 2003).

²⁰⁸ *Id.* at 48–56; *See Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 54–55 (1977) (the Supreme Court recognized the negative effects of “free riding” and held that a restriction on competition was justified because it had a pro-competitive effect); *Kewanee Oil Co. v. Bicon Corp.*, 416 U.S. 470, 480–81 (1974) (observing that the patent system stimulates invention and commercialization by providing a 17-year exclusive right to the inventor).

²⁰⁹ *See generally* Kevin E. Noonan, *BRCA Patent Suit to Continue in Southern District of New York*, PATENT DOCS: BIOTECH & PHARMA PATENT LAW & NEWS BLOG (Nov. 2, 2009), <http://www.patentdocs.org/2009/11/patent-suit-to-continue-in-southern-district-of-new-york.html>.

²¹⁰ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

parties who bring this action, declare a final judgment on the action, and permit further relief based on the judgment if necessary.²¹¹ Prior to the *MedImmune* holding, the federal courts had consistently used a two prong analysis to find standing in a declaratory judgment action.

There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.²¹²

However, in *MedImmune* the Supreme Court altered the “reasonable apprehension” prong and replaced it with a more lenient standard called the “all the circumstances” test.²¹³ By applying recent court interpretations of *MedImmune*, the court determined the new test to include an evaluation of affirmative acts by the defendants and meaningful preparation by the plaintiffs.²¹⁴ Although this standard has opened up declaratory judgment actions in patent law, other recent authority has distinguished *MedImmune*, rebutting the court’s conclusions.

a. Actual Controversy

There is no actual controversy between most of these plaintiffs and these defendants. For an actual controversy to exist under the Article III, there must be “a real and substantial dispute affecting the legal rights and obligations of parties having adverse interests.”²¹⁵ Not all of the plaintiffs have a real and substantial dispute. For example, ACMG, ASCP, and CAP did not infringe, did not receive cease-and-desist letters and were not contacted by Myriad in order to expect to have a real and substantial dispute.²¹⁶ None of the breast cancer victims and most of the named doctors have not infringed directly or secondarily, did not receive cease-and-desist letters, and were not contacted by Myriad to expect to have a real and substantial dispute.²¹⁷ The only plaintiffs who have received cease-and-desist letters were Dr. Kazazian and Dr. Ostrer. The others

²¹¹ 28 U.S.C. §§ 2201–2202 (2006).

²¹² *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

²¹³ *MedImmune*, 549 U.S. at 127.

²¹⁴ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 387 (S.D.N.Y. 2009).

²¹⁵ *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879 (Fed. Cir. 1983); *See also* 60 AM. JUR. 2D. PATENTS § 870 (2010) (“[A]ctual controversy exists only when the plaintiff has been threatened with an infringement suit, charged with infringement, inducement of infringement, or contributory infringement; the plaintiff has actually produced the infringing article, or has immediate intention and ability to do so . . .”).

²¹⁶ *See supra* note 43 and accompanying text.

²¹⁷ *See supra* note 44 and accompanying text.

who were contacted by Myriad are not named as plaintiffs in this action. Thus, the only possible parties who could move forward would be Dr. Kazazian and Dr. Ostrer because the cease-and-desist letters create an actual controversy. Alternatively, all the other plaintiffs have adverse interests because all of them want the patent invalidated, but is that interest enough to establish an actual controversy?

In the patent realm, typically the actual controversy is found when the parties are adverse, such as using declaratory judgment as a defense during an infringement suit²¹⁸ or for licensees who will be sued for infringement as for its present or future failure to pay royalties.²¹⁹ Further, the Supreme Court has held that real and substantial controversies shall be “distinguished from an opinion advising what the law would be upon a hypothetical state of facts.”²²⁰ Myriad has not brought suit against the plaintiffs for infringement which would allow the plaintiffs to use declaratory action as a defense.²²¹ What the court considered were alleged facts describing a potential infringement that results in a hypothetical situation attempting to cross the judicial threshold. Regrettably, the court seemed to be looking forward to applying *MedImmune* rather than applying Article III of the Constitution.

There seems to be no actual controversy between most of the plaintiffs and Myriad. However, in 2007, *MedImmune* created a significant change to the standing requirements for declaratory judgments, especially for patent cases, which overshadowed the Article III issues for declaratory judgment. “[T]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”²²² The court analyzed this test based on guidelines set forth by the Federal Circuit establishing a two part test which evaluated the affirmative acts of the defendants and the meaningful preparations of the plaintiffs.²²³

b. Affirmative Acts

The acts taken by Myriad are not enough to find standing. The first test is the affirmative acts test. The Federal Circuit interpreted the *MedImmune* case: “Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing

²¹⁸ Hofstadter v. Ruderman, 118 F. Supp. 477 (S.D.N.Y. 1953).

²¹⁹ See generally *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

²²⁰ *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 241 (1937).

²²¹ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 378–80 (S.D.N.Y. 2009).

²²² *MedImmune*, 549 U.S. at 127.

²²³ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d 365.

arguably illegal behavior or abandoning that which he claims a right to do.”²²⁴ Despite the court’s statement that it follows Federal Circuit guidelines, it loosely cites a handful of Federal Circuit authorities and it justifies a low standard by its own previous interpretations and a few surrounding district courts having less influence on the matter.²²⁵ Had the court strictly applied the Federal Circuit guidelines,²²⁶ it should have found the following.

First, Myriad did not take affirmative acts toward most of these plaintiffs. In *SanDisk Corp. v. STMicroelectronics, Inc.*, the Federal Circuit held that declaratory judgment “will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee.”²²⁷ Out of several associations of researchers, eight doctors, and six breast cancer patients, only Dr. Kazazian and Dr. Ostrer received affirmative acts from Myriad. At most, the rest of the plaintiffs only can perceive that Myriad’s patent will pose a risk of infringement.

Conversely, the Federal Circuit has also held that not only will the court look at prior litigation between the parties, but also the “behavioral observations” of “an aggressive litigation strategy.”²²⁸ To begin, no prior litigation between Myriad and any of the named plaintiffs occurred. However, “[p]rior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy.”²²⁹ Myriad has filed two infringement complaints against non-plaintiffs, but Oncormed and Myriad settled, and Myriad dropped the suit against the University of Pennsylvania when it stopped infringing.²³⁰ Additionally, “substantial controversy has also been found where patentees made direct accusations of infringement or demanded licensing fees.”²³¹ Myriad had sent cease-and-desist letters to Dr. Kazazian, Dr. Ostrer, the University of Pennsylvania, and YDL and two of the letters offered licenses. Looking at “all of the circumstances” it could seem that Myriad took affirmative acts sufficient to support declaratory judgment *with* respect to those

²²⁴ *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

²²⁵ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 387–88.

²²⁶ See *infra* Part III.B.2.

²²⁷ 480 F.3d at 1380–81.

²²⁸ *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 901 (Fed. Cir. 2008).

²²⁹ *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed. Cir. 2008) (but held that one prior suit concerning different products and different patents should be given minimal weight).

²³⁰ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009).

²³¹ *Geospan Corp. v. Pictometry Int’l Corp.*, 598 F. Supp. 2d 968, 971 (D. Minn. 2008) (paraphrasing *SanDisk*, 480 F.3d at 1382) (but *Geospan* found no declaratory judgment because the two letters sent to *Geospan* were only for information gathering purposes for potential infringement, which does not create an adverse interest).

parties. But, it also seems that these acts do not support a showing of “an aggressive litigation strategy” with respect to all the other parties.

c. Meaningful Preparation

“[T]he ‘meaningful preparation’ inquiry properly focuses on whether the Plaintiffs are meaningfully prepared to engage in the infringing act such that the court’s decision would serve as more than an ‘advisory opinion.’”²³² For example, *MedImmune* was already producing the patented product as a licensee and that license was the only thing shielding the company from an infringement suit.²³³ The only step away from infringement it had was by failing to pay its royalties.²³⁴

The plaintiffs’ key showing is that they are “ready, willing, and able” to use the patented product if the patent is invalidated.²³⁵ Similarly, the same terms have been used for declaratory actions in antitrust law for those who knowingly enforce invalid patents to maintain a monopoly.²³⁶ The terms have come to mean that the plaintiffs must establish that a desire to enter the relevant market, the ability to enter the market, and but for the fear of infringement would have entered the market.²³⁷ It is possible to establish the desire to enter and the causation elements for each of the plaintiffs, but it is difficult to ascertain the ability of the plaintiffs to do so. For example, the researcher plaintiffs all say that they are ready, willing, and able, but do not discuss any further how the researchers are actually able. The court assumes they meet the ability requirement because they have the equipment and expertise to begin.²³⁸ This assumption would definitely ring true for Dr. Kazazian, Dr. Ganguly, and Dr. Ostrer who had all performed the work prior to receiving cease-and-desist orders. Even the court could reasonably assume this ability, “to allow such a scant showing to provoke a declaratory judgment suit would be to allow nearly anyone who so desired to challenge a patent.”²³⁹

Nevertheless, the rest of the plaintiffs do not seem “able” to enter the market at all, and therefore, should not have standing to support a declaratory judgment action. Both the Breast Cancer Action group and the Boston Women’s Health Book Collective assert that they are ready, willing, and able to pro-

²³² *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 390 (citing *Cat Tech LLC v. TubMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008)).

²³³ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 121–25 (2007).

²³⁴ *Id.*

²³⁵ *Ass’n for Molecular Pathology*, 669 F. Supp. 2d at 390.

²³⁶ Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 167 (Nov. 2006).

²³⁷ *Id.* at 167–70.

²³⁸ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365, 373 (S.D.N.Y. 2009).

²³⁹ *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1349 (Fed. Cir. 2007).

vide information and data.²⁴⁰ These organizations do not have the equipment or the expertise to actually extract BRCA1/2 genes and perform the patented methods because these are not the activities in which these organizations engage. Further, it is understandable to put a face with the disease, but the breast cancer patients should not qualify for standing. They have the desire to *use* the market not to enter it and, but-for the risk of infringement, are unable to seek testing more convenient for them because *others* cannot enter the market. Moreover, the breast cancer patients, as far as alleged in the complaint, do not have the equipment or expertise to achieve the ability to use and perform the patented products and methods. For these reasons, at least some of the plaintiffs should have been dropped for lack of standing.

In summary, most of the plaintiffs do not achieve standing for a declaratory judgment action. First, there is no actual controversy as defined by Article III because the parties who did not receive cease-and-desist letters do not have a real or substantial suit. Even though *MedImmune* applies a more lenient standard, under the totality of the circumstances most of the plaintiffs would not have satisfied the elements to obtain standing. Either there were no acts taken directly to the plaintiffs or the affirmative acts may not be enough to show an aggressive pattern of litigation. Finally, at least the non-researcher plaintiffs are not meaningfully prepared to use the patented product in a way that would infringe. The court should have reached a different outcome. Therefore, any reviewing court should reverse this decision.

2. Procedural and Patent Policy

The district court's analysis of the standing requirements for declaratory judgment action may lead to procedural and patent law issues in the future. With this precedent, potential infringers have a greater opportunity to challenge patent validity. Moreover, shifting the power to the potential infringers will reduce the incentives for patent holders and will cause changes in intellectual property as well as technological advancement benefits to the public.

In *MedImmune*,²⁴¹ the Supreme Court began its standing discussion by reviewing criminal precedent and upheld that no one should have to carry out a criminal act before having the opportunity to challenge the validity of the law.²⁴² By reviewing criminal violations, the Supreme Court exhibited the severity of the consequences needed to obtain standing. Additionally, the Supreme Court emphasized that the plaintiffs should not have to "bet the farm" or lose everything they have, which also illustrates the severity of the consequences to be shown by the licensee.²⁴³ Nevertheless, interpretations by the district court al-

²⁴⁰ See Complaint, *supra* note 43.

²⁴¹ *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 127 (2007).

²⁴² *Id.* at 129.

²⁴³ *Id.*

lows it to open its courtroom doors to almost anyone who may be unhappy with the exclusive rights of any patent holder whether or not there really is a controversy. This is not the result the Supreme Court intended.

To obtain declaratory judgment following the court's opinion, any person would have to allege that they are ready, willing, and able, and that some affirmative action was previously taken by the patent holder against *anyone* at some point, *even in the distant past*. Thus, any challenger of any patent holder can allege a First Amendment violation, meet these standing requirements, and attempt to invalidate any patent. This precedent extinguishes the exclusive rights granted by the Intellectual Property Clause if a patent holder acts to use those rights.

This change in power removes the incentives provided by the Intellectual Property Clause. Historically, patent incentives have enhanced research activity. Patents "have fostered research by providing a niche of exclusivity by forcing would-be copyists to invent around or to pursue alternative avenues of research."²⁴⁴ Thus, researchers may stumble upon an even better method or discovery because they had to come up with a way to avoid infringement. Additionally, discoveries are produced more quickly. Researchers and inventors want to be the first to file at the patent office in order to evade a rejection by others who beat the applicant to it. In addition, the public receives high-end medical technologies and better quality inventions because companies are willing to spend more money in order to see a guaranteed return on their investment during their limited hold on the invention. As discussed earlier, patents require information to be disclosed to the public in return for the incentive of limited exclusivity preventing what may otherwise be kept as trade secrets.²⁴⁵ These incentives and benefits will be diminished if the availability of patent challenges continues to increase because patent holders will not want the hassles and costs of litigation or the risk of patent invalidation to interfere with their investment.

IV. IF YOU CAN'T CREATE . . . LEGISLATE

Legislation is the most appropriate method for the plaintiffs to achieve a legitimate pronouncement that gene patents are valid and that the USPTO written policy should be enforced. In *Chakrabarty*, the Supreme Court declared that genetic research "should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts."²⁴⁶ Unlike the right to a speedy trial where complex subject such as biotechnology may not receive the scrutiny it deserves, the slow and deliberative nature of the legislative process was intended by our forefathers to prevent irrational change and upset of the status quo. It has been found that district court judges improperly con-

²⁴⁴ Lentz, *supra* note 185, at 442.

²⁴⁵ See *supra* Part III.A.3.

²⁴⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

strue patent claims in thirty-three percent of the cases appealed to federal court; this should be compared with the less than ten percent reversal rate on all other criminal and civil cases.²⁴⁷ Congress is more likely to have experience on biotechnology matters than the judicial system because Congress has the opportunity to call in experts, listen to public testimony, and order the Secretary of Commerce to engage in thorough research and report back to Congress about the necessity and economic impact of gene patents. It is difficult for the judicial branch to ascertain the same level of expertise in such a short period of time and with limited resources.

Furthermore, the Intellectual Property Clause “empowers Congress to determine the intellectual property regimes that, overall, *in that body’s judgment*, will serve the ends of the Clause.”²⁴⁸ Thus, Congress is the more appropriate venue for a system-wide change regarding gene patents. Correspondingly, the European Union (EU) and the European Patent Convention (EPC) have implemented restrictive patentability standards involving biotechnology. For example, simple discoveries of a sequence or partial sequence of a gene and some methods used to treat the human body are not patentable subject matter.²⁴⁹ Although isolated forms of the sequence or partial sequence of a gene is still patentable in the EU, patent protection can still be refused based on a determination of morality.²⁵⁰ Specifically, the policy prohibits inventions contradictory to public morality from patent protection.²⁵¹

Likewise, the plaintiffs could have gone through Congress to encourage restrictions on patentable subject matter. It appears that the plaintiffs already have a strong foundation for lobbying efforts. For example, the ACLU, American Medical Association (AMA), March of Dimes, and other organizations that are very influential in Congress support the invalidation of gene patenting.²⁵² Further, the plaintiffs could rally support from medical professionals and breast cancer patients to contact their local representatives on the issue. For example, in the early 1980s, Congress adopted two acts limiting the scope of some medical technology.²⁵³ The Bayh-Dole Act of 1980 “enables the government to seize control over certain patents if health care is thought to be impeded by either the actions or inaction of those holding rights to patents.”²⁵⁴ Furthermore, the

²⁴⁷ See Kimberly Moore, *Are District Court Judges Equipped to Handle Patent Law Cases?* 15 HARV. J. L. & TECH. 1 (Fall 2001).

²⁴⁸ *Eldred v. Ashcroft*, 537 U.S. 186, 222 (2003) (emphasis added).

²⁴⁹ *Paradise*, *supra* note 55, at 140.

²⁵⁰ *Id.* at 140–41.

²⁵¹ *Id.*

²⁵² See Daniel B. Ravicher, *AMA, March of Dimes and Others Support PUBPAT/ACLU challenges to breast cancer genes: Briefs Filed in Support of PUBPAT/ACLU Motion to Declare Patents Unconstitutional*, PUB. PATENT FOUND.: REPRESENTING THE PUB.’S INTEREST IN THE PATENT SYS. (Aug. 27, 2009), <http://www.pubpat.org/brcaSJfiled.htm>.

²⁵³ See generally Zweiger, *supra* note 203, at 61–76.

²⁵⁴ *Id.* at 67.

Waxman-Hatch Act of 1984 “enables patent infringement litigation to be halted while drug products are in clinical trials.”²⁵⁵

On the contrary, gene patent invalidation may not be what the general public wants and this view can be reflected by Congress’s inaction. The United States government has yet to use the rights established through the 1980s Acts, which implies an overarching statement that “business and patent issues will not stand in the way of new medicine.”²⁵⁶ Moreover, on February 9, 2007, Representative Xavier Becerra introduced H.R. 977, the Genomic Research and Accessibility Act.²⁵⁷ If it had been enacted, this legislation would have prohibited genes from being patented.²⁵⁸ Nevertheless, H.R. 977 died at the end of the 110th Congressional Session awaiting action in the House Judiciary Committee and has yet to be reintroduced during the 111th Congressional Session.²⁵⁹ More recently, four representatives from both sides of the aisle sent a letter to the entire House leadership urging it to acknowledge the importance of patent protection during economic hardship because patents increase job growth and support American businesses.²⁶⁰

Despite the current hesitation, using the legislative branch is the most appropriate venue for the plaintiffs. Congressional action will provide a clear determination for both the USPTO, researchers, patent holders, and the public as to whether gene patents are or are not valid.

V. CONCLUSION

This one district court opinion has caused an analysis covering the interrelation of patent law, constitutional law, administrative law, federal courts law, First Amendment law, intellectual property law, and the legislative process. In summary, the patentability of the BRCA1/2 gene can either cause the law to stand firm or to alter and expand the laws as we know them to be. Any appellate court should be able to perform this analysis and determine that the district court misunderstood standing.

The district court should not have found standing to support a First Amendment action against the USPTO. The court wrongfully applied the reviewability standards to support an injury. Due to that analysis, the plaintiffs were unable to establish a direct and definite injury. Further, the plaintiffs generalized grievance could not meet the prudential limitations in order to qualify as

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ See *H.R. 977: Genomic Research and Accessibility Act*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h110-977> (last visited Mar. 7, 2011).

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ See Donald Zuhn, *New False Marking Bill Introduced in the House*, PATENT DOCS: BIOTECH & PHARMA PATENT L. & NEWS BLOG (Oct. 14, 2010), http://www.patentdocs.org/patent_legislation/.

an injury. This generalized grievance also caused a false positive of the traceability standard. Finally, the plaintiffs would not be able to meet a full remedy because they are unlikely to receive a favorable judgment. Consequently, this decision has the ability to majorly affect gene patents because researchers will lose the incentive to patent and revert to using trade secrets. The increase in trade secret use will result in higher informational and fiscal costs to the general public.

The court should not have found standing to support a declaratory judgment action against Myriad as to *all* the plaintiffs, and maybe not as to any of them. The court failed to acknowledge the constitutional requirement of an actual controversy. Therefore, the court did not dismiss the complaint for lack of adversity. Furthermore, the court did not properly interpret the *MedImmune* standard, which has led to broadening of the patent challenger's ability to invalidate a patent. Subsequently, the court's decision has the potential to diminish the incentives for all patents.

Finally, Congress has the power to limit patentable subject matter. The plaintiffs seem to have a strong lobbying foundation and their efforts to make a system-wide change may have been more fruitful by urging congressional action against the patentability of biotechnology. For these reasons, any reviewing court should reverse the district court's decision.

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