SEEING THE FOREST THROUGH THE TREES: GENE PATENTS & THE REALITY OF THE COMMONS

Tina Saladino[†]

Patents prevent anyone but the patent-holder from manufacturing, using, or distributing discoveries and inventions for twenty years from the date of filing.[1] In order to be patentable, an invention needs to be useful, non-obvious, and represent an original design or process rather than an abstract concept or item commonly found in nature.[2]

Patents related to genetics received their first legal test in 1980, when the U.S. Patent and Trademark Office (USPTO) granted protection to a genetically engineered bacterium that consumed oil and was useful in cleaning oil spills.[3] The legality of this patent was affirmed in *Diamond v. Chakrabarty*, where the Supreme Court observed that although "[t]he laws of nature, physical phenomena, and abstract ideas" were not patentable subject matter under § 101, the claimed invention in the case was distinguished from nature as "a product of human ingenuity having a distinctive name, character and use."[4] The Court held that although the invention comprised a living thing, the patentee had produced a new bacterium with "markedly different characteristics" from the original. The bacterium was, therefore, "not nature's handiwork but [the patentee's] own."[5]

Although *Chakrabarty* settled the question of whether manufactured genes can receive patent protection, it did not address the patentability of naturally occurring genes.[6] In the absence of such definitive legal guidance, the USPTO routinely issues patents on human deoxyribonucleic acid (DNA) sequences, reasoning that the material has been purified from its natural form through human intervention and is thus sufficiently "touched by man" to be

† J.D. Candidate, 2012, University of California, Berkeley School of Law.

1. 35 U.S.C. § 154(a)(2) (2006).
2. *Id.* §§ 101–103.
3. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
4. *Id.* at 309.
5. *Id.* at 310.
6. Robert Field, *New Court Ruling May Alter the Legal Landscape for Gene Patents*, 35 PHARMACY & THERAPEUTICS 322–23 (2010).

beyond the scope of nature.[7] From 1980 to 2009, the USPTO issued between 3,000 and 5,000 patents on human genes, encompassing nearly 20% of the human genome.[8] In addition, the USPTO has issued nearly 50,000 patents involving human genetic material, yet the fundamental validity of such patents has never been reviewed until now.

In March 2010, a district court decision in New York brought attention to the role of gene patents in the advancement of biomedical research. In *Association for Molecular Pathology v. United States Patent and Trademark Office* ("*AMP*"),[9] the Southern District of New York enforced a strict standard for subject matter patentability by invalidating seven patents relating to the human breast cancer genes BRCA1[10] and BRCA2[11] (collectively "BRCA").[12] The court reasoned that not only were the coding sequences and mutations of BRCA results of natural phenomena, but that the purified forms of BRCA maintain essentially the same structures and functions as their natural forms and therefore fall outside the scope of patent law protection.[13]

Although the decision primarily addressed the patent's subject matter, the court also noted the possible social implications resulting from how patents affect access and innovation in biomedical research.[14] Contrary to concerns raised by the plaintiffs in *AMP*, empirical studies indicate that gene patents do not impede access to biomedical research data or play a significant role in

7. Parke Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) ("[B]y removing it [adrenaline] from the other gland-tissue in which it was found . . . it became for every practical purpose a new thing commercially and therapeutically."); *see also* Kuehmsted v. Farbenfabriken, 179 F. 701 (7th Cir. 1910) (holding that aspirin, purified from a previously known compound, constituted a new invention as the beneficial and therapeutic effects of aspirin were unavailable in the known compound); Union Carbide v. Am. Carbide, 181 F. 104 (2d Cir. 1910) (holding crystalline carbide novel and not anticipated by amorphous carbide); *In re* Bergstrom, 427 F.2d 1394 (S.D.N.Y. 1970) (product did not occur in purified form).

8. The accuracy of this percentage is questioned. Some argue that only 2% of the human genome is patented.

9. 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

10. BRCA1 is a human gene expressed in the cells of breast and other tissues to repair damaged DNA and suppress tumor growth.

11. BRCA2 is a human gene that binds to and regulates a protein which fixes breaks in DNA. Although structurally different from BRCA1, BRCA2 serves a similar function and the two genes are often referred to collectively as "BRCA".

12. *Id.*

13. *Id.* at 227, 231–32.

14. *Id.* at 207–11. (noting the deep divide between the parties with regard to the implications of patents on the furtherance of research and health of society. The court did not come to their own opinion on the social implications of the patent).

influencing the topics of research that scientists choose to pursue.[15] These results suggest that while gene patents do not impede innovation, they may not be necessary for it either, at least at the foundational level. Some scholars still maintain, however, that patent protection is necessary to ensure adequate funding for further research, development, and marketing of their innovations.[16]

This Note focuses on the role of patent law in encouraging or discouraging innovation in the field of biomedical research. Specifically, this Note analyzes the policy justifications underlying gene patents and explores whether these justifications validly apply to the patenting of the BRCA gene. Part I establishes a basic understanding of patents, genes, and gene patents. Part II provides greater detail regarding the arguments and holding in the *AMP* case. Part III introduces the traditional rationales for patent protection and applies them to gene patents. Part IV considers the concerns surrounding gene patents and whether these concerns are realistic given the results of empirical studies on the relationship between patents and biomedical research. Part IV also examines whether the district court's holding in *AMP* is consistent with the policy goals behind intellectual

15. *See* John P. Walsh et al., *Effects of* R*esearch Tool Patenting and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285–341 (Nat'l Academies Press 2003) (Wesley M. Cohen and Stephen A. Merrill eds.); *see also* Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, GENETICS IN MED., S15, S23 (April 2010 Supp.); Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, *in* 8 INNOVATION POLICY AND THE ECONOMY 1 (Adam B. Jaffe, Josh Lerner, & Scott Stern eds. 2008), *available at* http://www.nber.org/~marschke/mice/Papers/cohenwalsh.pdf; Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 12 ANN. REV. GENOMICS & HUM. GENETICS 383 (2010); Dianne Nicol & Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (Centre for Law & Genetics Occasional Paper No. 6, 2003), *available at* http://www.ipria.org/publications/reports/BiotechReportFinal.pdf; Sadao Nagaoka, An Empirical Analysis of Patenting and Licensing Practices of Research Tools From Three Perspectives, Presentation at the Conference on "Research Use of Patented Inventions" Organized by the Spanish National Research Council, the Spanish Patent and Trademark Office, and the OECD (May, 18–19 2006), *available at* http://www.oecd.org/dataoecd/20/54/36816178.pdf; Joseph Straus, Genetic Inventions and Patents: A German Empirical Study, Presentation at Genetic Inventions, Intellectual Property Rights and Licensing Practices (Jan. 24–25 2002), *available at* http://www.oecd.org/dataoecd/36/22/1817995.pdf.

16. *See BIO Speakers See IP Spurring Innovation in Life Sciences Despite Its Legal Battles*, 80 PATENT TRADEMARK & COPYRIGHT JOURNAL 47 (Mar. 14, 2010) (quoting Robert Armitage, senior VP and general counsel for Eli Lilly, who said that "the ability to cure rests largely on IP"); *see also* Lee Bendekgey & Diana Hamlet-Cox, *Gene Patents and Innovation*, 17 ACAD. MED. 1373, 1375–76 (2002).

property rights and the reality of the industry. Finally, this Note concludes that, in general, patents do not impede upon innovation. However, the broad issuance of composition claims, such as those held by Myriad in *AMP*, may block research in areas of study that the patent holder is not pursuing (such as therapeutics). This Note suggests that this issue could be resolved by narrowing the focus of the patent claim to the application of the gene composition, rather than the composition on its own.

I. BACKGROUND

The primary fact at issue in the *AMP* case was whether isolated DNA is patentable within Section 101 of the Patent Act.[17] In order to understand the arguments as well as the district court's holding, this part provides background on patents and genes.

A. WHAT IS A PATENT?

A patent is a social contract between the government and an inventor in which the inventor is granted a state-sanctioned monopoly over their invention for a fixed term in exchange for making their discoveries public.[18] These contracts are intended to stimulate innovation by providing investors with an opportunity to temporarily dominate the market to recoup their investment and continue to invest in new ideas.[19] To be eligible for patent protection, the invention must be useful, novel, and non-obvious.[20]

Patent protection does not automatically afford the holder the right to do anything, but patent rights do exclude everyone, except the patentee and its licensees, from making, using, selling, offering for sale, or importing the invention for twenty years from the date of filing.[21] If patent infringement

17. 35 U.S.C. § 101 (2006).

18. 35 U.S.C. § 101 ("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 therefore, subject to the conditions and requirements of this title."); *see* Alan R. Williamson, *Gene Patents: Socially Acceptable Monopolies or an Unnecessary Hindrance to Research?*, 17 TRENDS GENETICS 670 (Nov. 2001); *see also* Eli Lilly & Co. v. Barr Labs. Inc., 251 F.3d 955, 963 (Fed. Cir. 2001) ("[A patent] creates a statutory bargained-for-exchange by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention"); Cook-Deegan & Heaney, *supra* note 15, at 386.

19. Cook-Deegan & Heaney, *supra* note 15, at 394, 395; *see also* Williamson, *supra* note 18, at 671.

20. 35 U.S.C. §§ 101–103 (2006); *see also* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

21. 35 U.S.C. § 154 (a)(2) (2006).

occurs, a patent holder can seek a court-issued injunction against the infringer to cease their infringing activity (and seek monetary damages) or demand that the infringer take a license under the threat of legal action.[22] But patent protection never guarantees permanent protection from competition, improvements, or alternative means of achieving the same effect.[23]

Patent law has a statutory disclosure requirement. The USPTO requires a patent applicant to describe their invention in sufficient detail such that a "person having ordinary skill in the art" will be able to make and use the claimed invention without "undue experimentation."[24] Each patent application is then published eighteen months from the earliest filing date.[25] Researchers and potential competitors can use this published data to pursue further innovation and improvements once the patent expires or through licensing agreements with the patent holder.

The claims in the patent application also establish the "metes and bounds" of the patent holders' rights, giving notice of the intellectual property rights claimed as well as those left to the public.[26] This includes the "best mode" known by the inventor to carry out the invention.[27] This requirement serves as a safeguard to prevent inventors from obtaining patent protection without making full disclosure as required by the statute.[28] By requiring that the best mode of a patent be disclosed, the USPTO encourages further improvements upon the most advanced, available technology.

Section 101 of the Patent Act specifies the general subject matter that can be patented. The language of the statute explains that any person who "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."[29] Interpretations by the Supreme Court have further defined the limits of the field of subject matter that can be patented, and have excluded from protection the laws of nature,[30] physical phenomena, and

22. Brandon L. Pierce et al., *The Impact of Patents on the Development of Genome-Based Clinical Diagnostics: An Analysis of Case Studies*, GENETICS MED., at 2 (Mar. 2009).

23. Cook-Deegan et al., *supra* note 15, at S30.

24. 35 U.S.C. § 112 (2006).

25. *Id.* § 122.

26. *Id.* § 112(b).

27. *Id.* § 112.

28. *Id.*; *see also In re* Nelson, 280 F.2d 172 (C.C.P.A.1960).

29. 35 U.S.C. § 101 (2006).

30. Funk Bros. Seed Co. v. Kalo Innoculant Co., 333 U.S. 127, 132 (1948) (holding that the combination of seeds to produce a more reproductively capable plant was new and useful, but lacked the requirement of invention and discovery). Once nature's secret of the

abstract ideas.[31] The exclusion by the Court of the laws of nature, however, does not preclude the patenting of certain works that are sufficiently "touched by man."[32] The USPTO has interpreted this exclusion to include isolated gene sequences.[33]

B. WHAT IS A GENE?

A "gene" commonly refers to a fundamental unit of inheritance.[34] A gene resides on a stretch of DNA that can code for a type of protein or for an RNA molecule that has a function in the person.[35] The genetic code stored within a gene is produced through the pairing and sequence of four specific nucleotides (adenine, thymine, cytosine, and guanine).[36] Similar to the order of words in a sentence, the sequence of these nucleotide pairings provides information in the form of the genetic code.[37] At its simplest, a gene includes these coding regions, but as knowledge in the field of genetic research expands so does the definition of a "gene", creating an increasing complex dialogue for such a small chemical composition.

The notion of a "gene" is evolving alongside the science of genetics. As a result, reaching a consensus over a modern definition has become increasingly challenging.[38] For instance, Karen Eilbeck, the coordinator of the Sequence Ontology Consortium (SOC)[39] at the University of California at Berkeley, said that it took twenty-five SOC scientists the better part of two days to reach a consensus on a loose, working definition of a gene.[40] They finally settled on defining a gene as "[a] locatable region of genomic

non-inhibitive quality of certain strands of the species was discovered the state of the art made respondent's production of a mixed inoculants a simple step. *Id.*

31. Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972) (holding that a certain use of a computer program related to processing data was not patentable because the claim was so abstract and sweeping that it covered a mere idea).

32. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (holding that a micro-organism produced by genetic engineering was not excluded from patentable subject matter since it avoided the category of law of nature by being sufficiently "touched by the hand of man").

33. Util. Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Dep't of Commerce Jan. 5, 2001) (notice).

34. *What is a Gene?—Genetics Home Reference*, U.S. NAT'L LIBRARY OF MED. (Feb. 27, 2011), http://ghr.nlm.nih.gov/handbook/basics/gene.

35. *Genome.gov—A Brief Guide to Genomics*, NAT'L HUMAN GENOME RESEARCH INST. (Aug. 24, 2010), http://www.genome.gov/18016863.

36. *Id.*

37. *Id.*

38. *See* Helen Pearson, *Genetics: What is a Gene?*, 441 NATURE 399 (May 2006).

39. SOC defines labels for landmarks within genetic sequence databases, so that research can be more easily collected and compared.

40. Pearson, *supra* note 38, at 401.

sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions, and/or other functional sequence regions."[41]

For scientists working in different disciplines, the term "gene" is used in a variety of contexts and often has dramatically different meanings.[42] Rather than striving to reach a single definition, most geneticists instead incorporate less ambiguous words into their vocabulary such as "transcript" or "exon" and then attach an adjective describing its function.[43] As a result, today a "gene" has begun to increasingly encompass not only the protein-encoding sequences as well as other functional regions of the genome itself.[44]

People have different physical characteristics because each person has a unique genetic code.[45] Each unique structure or version of a gene is called an allele.[46] Mutations (random changes) in genes create new alleles, which can produce new traits, for example through a change in cellular function.[47] These mutations can be helpful for the purposes of evolution, but they can also pose problems such increasing the risk of certain diseases, such as cancer.[48]

In order to study genes (e.g., to identify mutations), researchers use a process called genetic sequencing.[49] This process begins with the purification

41. *Id.* The scientists decided that the definition of a gene should include its nucleic sequences and the purposes these sequences serve. For example, sequences which regulate other bodily functions, copy and send the information within the DNA, and/or other functions. *Id.*

42. *Id.* (Explaining that the term varied depending on the researcher's use of the gene).

43. *Id.* "Transcripts" assist in the copying of genetic information stored in DNA. "Exons" are coding portions of a gene (the nucleic sequence) that produces a functional gene product.

44. *Id.* (quoting Francis Collins, director of the National Human Genome Research Institute at the National Institutes of Health in Bethesda, Maryland, who stated that when describing genes, "[w]e almost have to add an adjective every time we use that noun."). Although not discussed, an example of a functional region of a gene would include BRCA's nucleic sequences which suppress tumor growth in breast tissue.

45. *Genome.gov—Deoxyribonucleic Acid (DNA) Fact Sheet*, NAT'L HUMAN GENOME RESEARCH INST. (Nov. 26, 2010) http://www.genome.gov/25520880 (explaining animal characteristics and heredity).

46. *Allele—Glossary Entry—Genetics Home Reference Guide*, U.S. NAT'L LIBRARY OF MED. (Feb. 27, 2011), http://ghr.nlm.nih.gov/glossary=allele.

47. *What is a Gene Mutation and How Do Mutations Occur?—Genetics Home Reference Guide*, U.S. NAT'L LIBRARY OF MED. (Feb. 27, 2011), http://ghr.nlm.nih.gov/handbook/mutationsanddisorders/genemutation.

48. *Id.*; *see Genome.gov—A Brief Guide to Genomics*, *supra* note 35.

49. *Genome.gov—A Brief Guide to Genomics*, *supra* note 35.

of the gene from its natural state.[50] Purification occurs when a particular gene is "removed from the body and separated from the surrounding cellular material."[51] Once the gene is separated from the surrounding cellular material, it can be isolated into a concentrated form. Similar to removing a thread from a sweater, the isolated gene may maintain a similar structure and purpose[52] as it possessed in its original state but now a researcher can examine it to identify particular coding regions, make copies of it, and manipulate it more easily. Isolated genes are also extremely useful to researchers who may want to examine their therapeutic values and functions.[53]

C. GENE PATENTS

Much of the concern surrounding gene patents arises out of the erroneous perception that patent protection of a genetic sequence is equivalent to ownership of that gene.[54] The rights conferred by a patent, however, are distinct from those provided via ordinary personal property rights. In particular, ordinary property rights generally include a positive "right to use."[55]

A gene patent grant is limited to the right to exclude others from the use, sale, distribution, or production of the patented gene.[56] The patent owner's right to exclude is limited to the patented subject matter defined by the claims of the patent.[57] Some patent claims are broadly drafted in an attempt to encompass all possible variants of a gene, including those yet to be discovered. Such drafting comes close to a patent claiming a gene per se,

50. Util. Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Dep't of Commerce Jan. 5, 2001) (notice).

51. Brief for The Biotechnolgoy Indus. Org. as Amici Curiae in support of defendants opposition to plaintiffs motions for summary judgment, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010)(09 Civ. 4515)(2009 U.S. Dist. Ct. Briefs LEXIS 918); *see also DNA Extraction Virtual Lab*, UNIV. OF UTAH GENETIC SCI. LEARNING CTR., http://learn.genetics.utah.edu/content/labs/extraction/ (explaining how to isolate DNA from a human mouth)(last visited Mar. 30, 2011).

52. It is argued by Myriad and others that isolated genes are structurally and functionally different due to the fact that they are no longer in their chemical environment and their chemical links have been broken.

53. Util. Examination Guidelines, 66 Fed. Reg. 1092, at 1093 (Dep't of Commerce Jan. 5, 2001).

54. Christopher Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Litigation*, 76 UMKC L. REV. 295, 302 (2007).

55. *Id.*

56. 35 U.S.C. § 154(a)(2) (2006).

57. *Id.* § 112.

since they appear to include any biotechnological product, or process of making or using the claimed sequence. These broad claims to gene sequences, however, are more likely to result in litigation and are not the norm.[58] Most gene patents only claim some narrowly defined product or process involving the use of a genetic sequence. These patents do not impede the use of the gene in other contexts.

In sum, a "gene patent" is a patent on "specific sequences of genes, their usage, and their chemical composition[59]."[60] Some interpretations might say that genes are not patentable as elements of nature that are merely discovered.[61] However, there is no explicit rule that genes are unpatentable. Longstanding judicial precedent has held that the isolation of a natural product from its native environment can confer patentability by virtue of the application of human intervention.[62] This precedent was not directed to DNA,[63] yet in 1992, the USPTO granted the first DNA patent and continues to issue such patents today.

58. Holman, *supra* note 54, at 313.

59. "Chemical composition" refers to the amount of carbon, hydrogen, nitrogen, and phosphorous found in a nucleotide sequence.

60. *Id.* at 310.

61. For instance, the court in *Amgen* stated:

> [A] gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it [in order to acquire patent protection].

Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir.1991).

62. The court in *Park Davis* held "even if it were merely an extracted product without change, there is no rule that such products are not patentable. [B]y removing it from the other gland tissue . . . [adrenaline] became for every practical purpose a new thing commercially and therapeutically. That was good ground for a patent." Parke Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911); *see also Amgen Inc.*, 927 F.2d 1200; *In re* Bergstrom, 427 F.2d 1394, 1397 (C.C.P.A. 1970).

63. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980). This holding was in reference to a bacterium and was meant to encompass human-altered living things, not necessarily DNA, which arguably is not within the scope of the Court's intention. *See id.*

II. *AMP V. USPTO*

We have now arrived at *Association for Molecular Pathology v. the United States Patent and Trademark Office*. This part will begin with an analysis of the facts of the case and then detail the decision.

A. THE FACTS

In 1995, Myriad Genetics, in conjunction with the University of Utah and several other research laboratories identified the nucleotide sequences for BRCA and discovered links between mutations in those sequences and the development of breast and ovarian cancer.[64] Myriad also developed a diagnostic test to identify these mutations within women.[65] Subsequent to these findings, Myriad filed for patent rights in the United States and Europe.[66] Myriad's claims in their patent applications included the rights to the mutations of the genes, the mental act of comparing forms of the BRCA genes, and the correlation between certain genetic mutations and an increased risk of breast and ovarian cancer.[67]

On May 12, 2009, various non-profit agencies, led by the Association for Molecular Pathology ("AMP"), filed suit to challenge the validity of the BRCA patents held by Myriad Genetics and the University of Utah Research Foundation (collectively "Myriad").[68] The plaintiffs claimed that Myriad's patents were invalid under § 101 of the patent code because DNA is a product of nature and therefore not patentable subject matter.[69]

The BRCA genes encode proteins that assist in the repair of damaged DNA and the suppression of tumors.[70] Mutations in these genes are associated with a 40–85% increased risk of breast cancer and a 15–40% increased risk of ovarian cancer compared to a 1.4% risk in the general female population.[71] Between 5 and 10% of all women who will develop breast cancer have a BRCA gene mutation.[72] Through genetic testing, a

64. Ass'n of Molecular Pathology v. U.S.P.T.O., 702 F. Supp. 2d 181, 201–03 (S.D.N.Y. 2010).

65. *Id.*

66. *Id.* at 202.

67. *Id.* at 211–14.

68. *Id.* at 186.

69. *Id.* at 206–11.

70. *Id.* at 203.

71. Marisa Noelle Pins, *Impeding Access to Quality Patient Rights: How Myriad Genetics' Gene Patents are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 384 (2010).

72. *Id.*

patient not only learns of her risk but also obtains valuable information which may determine prevention and treatment options since BRCA mutations are an important factor in determining appropriate course of care[73; 74]

Myriad offers multiple forms of their patented BRCA testing to the public at a cost of $3,000 per test.[75] For low income patients who meet certain economic and clinical requirements, Myriad offers financial assistance programs and the opportunity for free testing at certain non-profit agencies.[76]

B. THE ARGUMENTS

AMP argued that Myriad's economic and clinical requirements are extremely steep and leave many at-risk patients without access to testing.[77] Many times, those who are tested at non-profit research agencies are denied access to the results of their tests due to the scope of Myriad's patents. [78] Because of the patents' scope these agencies are entitled to conduct the BRCA test for research purposes only while Myriad maintains the rights to diagnostic testing (i.e. the right to reveal results).[79] Women who do have access to the tests and wish to seek a second opinion are often denied since only Myriad-approved testing agencies are allowed to conduct the test and those agencies do not accept Medicaid or many other insurance programs.[80]

AMP also alleged that Myriad's patents hindered improvements in the screening of BRCA by refusing to issue licensing agreements to universities and non-profits who want to test the validity of Myriad's results or to conduct further genetic screening for clinical purposes.[81]

Myriad argued that DNA should be treated like any other chemical compound and that its purification from the body renders it patentable by transforming it into something distinctly different in character thereby complying with 35 U.S.C. § 101.[82] Myriad relied extensively on Judge Learned Hand's opinion in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y.

73. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 203.
74. *Id.* For example, certain chemotherapies depending on whether the mutation is on the BRCA 1 or BRCA2 gene.
75. *Id.*
76. *Id.*
77. *Id.* at 203, 206.
78. *Id.* at 203.
79. *Id.*
80. *Id.* at 188–89, 204.
81. *Id.* at 206–09.
82. *Id.* at 228.

1911).[83] In *Parke-Davis,* the court held that although adrenaline was a naturally occurring substance within the body, the process the patent protected was "for every practical purpose a new thing commercially and therapeutically" due to the fact that the adrenaline was separated and purified from the adrenal glands.[84]

On March 29, 2010, the Federal Circuit granted summary judgment, in part, to AMP, holding that Myriad's patents on BRCA were invalid. [85] Although the Court recognized that Myriad had identified and isolated the BRCA genes, Judge Sweet held that purified natural substances, without more, do not constitute § 101 subject matter. [86]

Judge Sweet held that manufacture, under § 101, implies a change that is transformative, distinct of character and use, and therefore requires markedly different characteristics from the original. [87] Mere purification of known materials, the court held, does not result in a patentable product. [88] Even in their isolated and purified forms, the BRCA genes were not markedly different from those that exist in nature. [89] Judge Sweet emphasized in his argument the importance of DNA as representing the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. [90] Judge Sweet reasoned that "DNA's existence in an 'isolated form' alters neither the fundamental quality of DNA as it exists in the body, nor the information it encodes." [91] Myriad's patents directed at "isolated DNA" were, therefore, "unsustainable as a matter of law."[92] The court also held that the method claims for identifying BRCA mutations and comparing cell growth were unpatentable mental processes.[93]

C. ANALYZING THE MYRIAD PATENTS

One of the chief issues surrounding the patents at issue in *AMP* was their breadth. Unlike most patents, the BRCA patents are neither narrowly defined nor limited by a particular usage. To illustrate, claim six of Myriad's 5,837,492

83. *See id.* at 224.
84. Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911).
85. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 181.
86. *Id.* at 227.
87. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 227–32.
88. *Id.* at 227.
89. *Id.*
90. *Id.* at 227–32.
91. *Id.* at 185.
92. *Id.*
93. *Id.*

patent, a composition claim,[94] is one of the broader claims asserted and is directed to a DNA nucleotide encoding any mutant BRCA2 protein that is associated with a predisposition to breast cancer.[95] Claim six reads: "[a]n isolated DNA molecule coding for a mutated form of the BRCA polypeptide set forth in SEQ ID NO:2, wherein said mutated form of the BRCA2 polypeptide is associated with susceptibility to cancer."[96]

As a result of the breadth of Myriad's composition claims, the patents foreclose researchers from the use of isolated BRCA obtained from any human being. Similarly, claim one of the 5,709,999 patent,[97] a method claim, forecloses researchers from the use of the process of identifying the existence of certain specific mutations in the BRCA1 gene by "analyzing" the sequence of the BRCA1 DNA, RNA, or cDNA obtained from any human being. Most of the remaining method claims are directed to the comparison of gene sequences.[98]

As written, Myriad's composition claims for isolated BRCA preclude anyone from isolating the genetic sequence for any purpose, even if the purpose is not within the scope of the claimed language of the patents. One fear is that patents with broad coverage will hamper research further downstream in areas including therapeutics. One way to avoid this type of monopolization is to limit gene patents only to particular usages. For example, the Myriad patent claims could be limited to using the isolation and comparison processes for the identification of the mutation for diagnostic purposes. Such a limitation would leave room for other researchers to utilize the sequence for therapeutic research purposes.

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94. A composition claim is a claim asserted over a composition of matter or a mixture of chemicals that produces a particular composition.

95. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 212–13.

96. *Id.* at 213 n.30.

97. Claim one states:

> A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from a group consisting of the alterations set forth in Table 12, 14, 18, or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base number 4184-4187 of SEQ ID No:1.

U.S. Patent No. 5,709,999 (filed June 7, 1995) (issued Jan. 20, 1998); *see also Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 213.

98. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 213 (referring to claim 1 of the '001 patent, claim 1 of the '441 patent, claim 2 of the '857 patent).

III. TRADITIONAL RATIONALES FOR PATENT PROTECTION

Patent protection confers to the patent holder the exclusive right to exclude others from the use of the patented product or process for a limited time period. This right has been traditionally justified as necessary to promote progress in science and the arts.

A. PATENT LAW AS PROMOTING INNOVATION AND PREVENTING UNAUTHORIZED FREE-RIDING

Patent protection supports the level of investment and risk necessary to develop and commercialize important research ventures.[99] Patents ensure that companies have a monopoly for a limited time frame over the products they develop. These companies can then recoup their initial investments and pass along the profits to investors. Such protections encourage future investment, and further research and development in other scientific ventures.[100] Absent the guaranteed protections of patents, companies will be forced to rely more heavily on trade secret[101] protections. Trade secret protections preclude the publication and disclosure of knowledge, counter to the goals of the U.S. Constitution in "promoting progress in Science and the Useful Arts."[102] By keeping secret the most advanced or efficient modes of a particular industry, trade secret precludes others from improving upon their methods and delays progress and advancement that would otherwise be made within the protected industry.

Patent protection discourages unauthorized free-riding by giving inventors a temporary monopoly to recoup their initial expenses in research and development. Concerns about free-riders are most acute in situations where the innovation is expensive to develop but easy to copy.[103] For example, in gene-based research, the cost of isolating and identifying a gene

99. *Economic Report of the President*, 1 PUB. PAPERS 1134 (Feb. 5, 2002) *available at* http://www.gpoaccess.gov/usbudget/fy03/pdf/2002_erp.pdf; *see also* Fabio Pammolli & Maria Alesandra Rossi, *Intellectual Property, Technological Regimes and Market Dynamics* 13 (Economia e Politica Industriale Paper No. 2/2005, 2005), *available at* http://www.who.int/intellectualproperty/submissions/IP-tech-reg-final.pdf.

100. Pammolli & Rossi, *supra* note 99, at 13.

101. A trade secret is information that is not reasonably ascertainable whereby a business can acquire an economic advantage. The secret is protected under state intellectual property or misappropriation laws as long as it continues to be a secret.

102. U.S. CONST. art. 1 § 8 cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . .").

103. Bendekgey & Hamlet-Cox, *supra* note 16, at 1375.

and transforming it into a commercially viable product is expensive, but once complete the gene is easily duplicated.[104] If the government did not provide patent protection for isolated gene sequences, laboratories would have little incentive to invest in the cost of pursuing such research knowing that others could take from their findings and profit with little investment.[105] Therefore, by providing a limited monopoly in the use of a gene sequence, the government encourages research labs to continue isolation and identification research, promoting further knowledge in the field while at the same time discouraging free-riding for the length of the patent term.[106]

B. PATENT LAW AS PROMOTING DISCLOSURE

As previously discussed, patent applicants must disclose their invention to receive a patent and provide sufficient information to enable a person skilled in the art to reproduce the invention.[107] The disclosure of technical information is the quid pro quo of legal protection in a balance of rights between the inventor and society.[108] Patents thus encourage the free dissemination of innovative knowledge in exchange for a limited monopoly.[109] Protection begins at the time of filing, and thus may encourage researchers who have filed a patent application to share their research findings at conferences and meetings.[110]

Due to the high cost of isolation and identification of genes and the low cost of duplication of that research, disclosure of the discovery of a particular sequence and the method of identification might otherwise be kept secret if patent protection were not guaranteed.[111] As such, the requirement of disclosure for gene patents encourages the dissemination of knowledge in this field.

C. PATENT LAW AS A SIGNALING FUNCTION

Through the requirement of disclosure, patents provide a unique "signaling" function.[112] First, through disclosure of claims, patent applications clearly define the boundaries of the object of the invention and

104. *Id.*
105. *Id.*
106. *Id.*
107. 35 U.S.C. § 112 (2006).
108. Pammolli & Rossi, *supra* note 99, at 4.
109. *Id.*
110. Wesley M. Cohen et al., *R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States*, 31 RES. POL'Y 1349, 1364 (2002).
111. *See supra* text accompanying note 101.
112. Pammolli & Rossi, *supra* note 99, at 4, 13.

thereby signal to scientists which areas of technology may require more research and development.[113] Second, possession of patents serves the purpose of signaling a firm's innovative capabilities and, as a result, increases its ability to raise the necessary capital for further research and development.[114]

1. Signaling Legal Title

Patent protection of gene sequences signals to others in the field the metes and bounds of the knowledge claimed. By defining the particular sequence and application of that sequence, gene patents signal to others in the industry which fields are still open to discovery and research.

A patent's limited time period also encourages innovation. This short-term of protection encourages competitors to improve and "invent around" existing patents. By publicly releasing the details of all patented inventions, the patent system provides researchers with an extensive database of relevant information to aid in focusing their own pursuits.[115]

2. Signaling Innovative Capabilities

In research fields characterized by significant levels of uncertainty, such as genetics, patent databases prove useful for the furtherance of innovation.[116] By signaling a researcher's competencies and capabilities, patents assist industries that might otherwise be crippled by uncertainty in attracting funding.[117] Patents influence investors' confidence in risky and uncertain innovative research where profitability is initially low.[118] Thus, patents encourage the adequate flow of funds toward innovative activities that would otherwise face challenges in exploiting other sources of financing.[119]

As discussed, in genetics, the initial costs of isolating and identifying a gene sequence can be high. The isolation of the sequences does not guarantee a profit if the protections of monopoly are not granted since others can enter the field, benefit, and even take credit for the research that

113. *Id.*

114. *Id.*

115. Ian R. Walpole et al., *Human Gene Patents: The Possible Impacts on Genetic Services Healthcare*, 179 MED. J. AUSTL. 203, 204 (2003).

116. *Id.* at 13.

117. *Id.*

118. *Id.*

119. *Id.* at 13; *see also* Paul Gompers & Josh Lerner, *The Venture Capital Revolution*, 15 J. ECON. PERSP. 145 (2001).

has already been done. Through the elements of publication and disclosure, gene patents signal to investors which researchers were the first to isolate and identify the gene sequence. Thus, those laboratories who invest the initial time and expense of the isolation and identification of the sequences are rewarded for their labor.

D. ARGUING AGAINST PATENTS: THE TRAGEDY OF THE ANTI-COMMONS

Numerous scholars have expressed concern regarding the recent proliferation of intellectual property rights in biomedical research.[120] These scholars are concerned that the fragmentation of rights will result in what Heller and Eisenberg coined "the Tragedy of the Anti-Commons."[121] This "tragedy" refers to a coordination breakdown where the existence of numerous rights holders obstructs the achievement of a socially desirable outcome.[122] This breakdown more readily occurs in the patent setting due to the exclusivity of rights that patent protection confers. For example, if the creation of a single product involves many techniques and components patented by different individuals, it can be challenging to effectively negotiate with all the necessary rights holders. The resulting licensing fees may be too expensive for a researcher attempting to create the desired product. Thus, socially desirable products may not be produced because the transaction and licensing fees associated with them, as a result of patents, are too high.

Applied to genetics, an excessive fragmentation of patent rights may prevent coherent aggregation of rights that are essential for future biomedical research.[123] For example, if one gene has three important alleles and the gene, as well as all three individual alleles, are covered by patents held by separate individuals; locating, negotiating, and paying the licensing fees in order to study the specific function of that gene in various organisms may be too expensive. This is of considerable importance to research when the patentee claims an entire sequence yet utilizes the sequence for only one isolated purpose. For example, in *AMP*, although they were not pursuing research in

120. Michael A. Heller & Rebecca S. Eisenberg. *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (postulating that the accumulation of intellectual property rights in medicine will hamper future research since scientists will be unable to pay all of the individual licensing fees); *see also* Walpole et al., *supra* note 115, at 203–05. *See generally* Pins, *supra* note 71 (arguing that Myriad's patents and others like it are hampering the advancement of necessary therapeutics and putting patients at risk.).

121. Heller & Eisenberg, *supra* note 120, at 698.

122. *Id.*

123. Pammolli & Rossi, *supra* note 100, at 26.

developing a therapeutic treatment for BRCA-linked cancers, Myriad maintained control over *all* uses of the BRCA mutation.[124] This precluded research and development into necessary therapies and was a significant source of frustration with the patents.

Because academic research is facilitated by the freedom to operate, granting monopolies could slow down and even prevent the advancement of genomic medicine.[125] Granting patents at such early stages of research as purification and isolation may be too early since it precludes any use of the isolated sequence outside that of the patent holder. Conversely, if gene patents were limited to a specific application of an isolated segment, this would serve both the goal of awarding research and encouraging future innovation.

IV. SEEING THE FOREST THROUGH THE TREES: THE REALITIES OF SCIENTIFIC RESEARCH

A patent holder maintains the right to exclude anyone from the use of his invention. This exclusionary right lies at the heart of the controversy in biomedical research. Some argue that in biomedical research, this right to exclude precludes individuals from access to necessary diagnostic testing and hampers innovation in medical research.[126] Studies indicate, however, that patent protection increases an individual's access to necessary diagnostic testing.[127]

A. SOCIAL POLICY: HEALTH AND WELL-BEING

Public health and well being have been of considerable importance in the media's depiction of the *AMP* case.[128] But the role of patent law in improving health outcomes and increasing access to necessary therapeutic and diagnostic tests is left out of this picture.

A study conducted in light of *AMP*, by Robert Cook-Deegan and colleagues, suggests that patent law may actually increase accessibility of clinical diagnostics.[129] The study examined the BRCA patents in light of other

124. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010).

125. Cook-Deegan & Heaney, *supra* note 15, at S1–S2.

126. *See generally* Pins, *supra* note 71; *see also* Walpole et al, *supra* note 115, at 203–05.

127. Cook Deegan et al, *supra* note 15, at S15.

128. John Schwartz, *Cancer Patient Challenge the Patenting of a Gene*, N.Y. TIMES, May 13, 2009, at A16; *see also* Lynne Peeples, *The Gene Hunt: Should Finder's Be Keeper's?*, SCI. AM., July 29, 2009, at 2 (discussing the arguments posed in the case and noting the number of patients affected and the limited licensing in which Myriad has engaged).

129. Cook Deegan et al., *supra* note 15, at S15.

similar patents.[130] The study found that the BRCA patents, which were predominately held only by Myriad (compared to the other patents which were held by multiple organizations and institutions) were both more affordable and more readily available to individuals with insurance.[131] The price reduction was likely correlated with Myriad's monopoly, since the exclusive rights allowed the company to make up any loss in cost through sheer volume of tests it conducted. [132] This study suggests that patent holders, like Myriad, who invest in marketing to educate the public about the conditions for which their testing targets, actually increases access, affordability, and frequency of clinical testing, such as that for BRCA.[133]

B. ACCESS

1. The Role of Academia

Although restrictions placed on the flow and exchange of research findings may delay scientific progress in the manner already described, these obstructions are not necessarily a result of patent protection and may be more of a result of the setting where this research takes place: academia. There is little empirical evidence of patents substantially slowing the progress of genetic research.[134] Studies examining the frequency of access problems, in the context of patent enforcement, find them to be rare, even for industry scientists, and especially for academic scientists. [135]

Empirical studies suggest that priority of discovery and the internal motivations within the field of academia play a far more important role in influencing the exclusionary practices of researchers than patent law.[136] For decades, the priority of discovery has been widely recognized as a significant motivation for scientific research since it confers both tangible and intangible benefits to academics.[137] In addition to improving an academic's reputation among peers, discovery increases the likelihood of promotion, tenure, and receipt of grant money.[138] These benefits are self-reinforcing; reputation and

130. *Id.*
131. *Id.* at S23; *see also* Cook-Deagen & Heaney, *supra* note 15, at 409.
132. Cook Deegan et al, *supra* note 15*,* at S17.
133. *Id.* at S18.
134. Cook-Deagen & Heaney, *supra* note 15, at 409 (citing Caulfied et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NAT'L BIOTECHNOLOGY 1091 (2006)).
135. *See supra* note 15.
136. *See also* Cohen & Walsh, *supra* note 15, at 3.
137. *Id.*
138. *Id.* at 5.

grant money attracts quality students who, in turn, increase a researcher's likelihood of success.[139]

To generate the private good of reputation in the priority based system of academia, a researcher must publish.[140] Publication serves to reinforce a sense of sharing and inclusion among academic peers, but this sense of collegiality extends only to a limited degree. While academics are required to disclose a sufficient amount of material in order to persuade the academic community of the merit and validity of their discoveries, scientific competition dampens a researcher's willingness to disclose or share intermediate inputs that are potentially vital to following research projects.[141] Academic scientists often refuse to discuss ongoing research until priority has been established through publication.[142] Thus, Heller and Eisenberg's "anti-commons" may exist, but not in the context they imagined.

In 2005, the National Academy of Sciences' Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions published a study concerning the impact of patents and licenses on researchers studying signaling proteins.[143] The study focused on responses of academic scientists and found few issues of access.[144] Although nearly 30% of respondents complained about restricted access to patented technologies and findings, few of the respondents felt that the restrictions actually caused them to stop a promising line of research.[145] Additionally, they found no instance where industrial or academic researchers stopped investigating certain fields due to an inability to gain access to a large number of patents for a research project.[146] The study found that although a patent can signal to scientists which areas of technology may require more research and development, fewer than 5% of researchers surveyed actually checked for relevant patents on a consistent basis.[147] These findings indicate that although a patent may confer a legal right to exclude, it does not confer actual excludability in

139. *Id.*
140. *Id.* at 6.
141. *Id.*
142. *Id.*
143. WALSH ET AL., PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH: FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES' COMMITTEE INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS (2005), *available at* http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8.
144. *Id.*
145. *Id.* at 3, 22.
146. *Id.* at 17.
147. *Id.* at 16.

academic research settings.[148] Since most scientists do not regularly check for patents during the course of their research, it is likely that they have or continue to infringe upon the patent rights of others in the course of their work. [149]

Patent law, itself, may encourage this practice of unlicensed use. Generally, for-profit firms do not threaten infringement action for unlicensed use largely due to the high costs and limited damages available through litigation. [150] Additionally, patent protection also provides a means for the holder to capture improvements upon their discovery since the original patent holder holds an effective block to the commercial release of any improvement upon the original patented product.[151] Thus, those who improve upon the patented product are eventually forced into licensing negotiations if they wish to place the product on the market during the term of the patent.[152] This allows the patent holder to capture the profits from the improvement while permitting the innovator to market his improvement before the end of the patent period.

In conclusion, while the exclusionary behavior of Myriad may have had an impact on the activities of researchers, it does not appear, based on empirical studies, that patent protection generally impedes on access or innovation in the field of biomedical research. Exclusionary behavior in academic research is most commonly linked to internal motivations of academia including priority of discovery. Furthermore, patent prosecution is an expensive venture with limited rewards.[153] Thus, patents should facilitate licensing discussion rather than outright exclusion.

2. Accessibility of Clinical Data

Accessibility of research data becomes more complex in a clinical setting. For example, a 2001 telephone survey found that patents and licenses have a significant effect on the ability of clinical laboratories to conduct research, as well as develop and provide genetic tests that can identify particular gene

148. *Id.*

149. This study did not examine whether or not these researchers chose to infringe instead of allow the patents to restrict their research. Some researchers do believe that they are exempt from patent enforcement.

150. Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: an Empirical Survey*, 24 NATURE BIOTECHNOLOGY, Jan. 2006, at 35.

151. *Id.*

152. *Id.*

153. *Id.* at 39.

sequence mutations.[154] When asked "Has notification from a patent holder or licensee ever prevented you from continuing to perform any clinical test or service that you had developed and were offering?" 25% of respondents answered, "Yes."[155] Of the respondents that reported being prevented from performing a test, 57% reported being prevented from performing one test and 40% reported being prevented from performing more than one test.[156] Laboratory directors at companies were more likely to report being prevented from performing a test (71%) than laboratory directors at universities (24%).[157] Similarly, of the 53% of respondents that claimed that, due to a patent, they decided not to develop or perform a test for clinical purposes, corporate laboratories were more likely (63%) than laboratories at universities to report blockage.[158] The study concluded that the patents and licenses significantly and negatively affected the ability of clinical laboratories to continue to perform already developed genetic tests.[159] However, this study did not examine whether patents provided a major incentive for initial research that led to the development of the genetic tests at issue.

Other studies come to the opposite conclusion regarding patent protection—that fragmentation of patent rights has not inhibited access or the commercialization of genetic testing.[160] An analysis of case studies on four clinical applications of genetic testing conducted by the University of Washington and the Fred Hutchinson Cancer Research Institute found that in each case, all patent rights critical to performing the tests were unified via licensing without intervention from the government (i.e. compulsory licenses) or groups of patent holders (i.e. patent pools—when companies agree to cross license their patents to one another).[161] The study also found that when faced with exclusion researchers adapted their practices in order to

154. Mildred Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 3 (2003).

155. *Id.* at 5.

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.* at 8.

160. S*ee generally* WALSH ET AL., *supra* note 142; 8 WESLEY M. COHEN & JOHN P. WALSH, *Real Impediments to Academic Research*, *in* INNOVATION POLICY AND THE ECONOMY 1–30 (Adam B. Jaffe et al. eds., 2008) *available at* http://www.nber.org/~marschke/mice/Papers/cohenwalsh.pdf; Cook-Deegan et. al, *supra* note 15*,* at S15–S38; Pierce et al., *supra* note 22.

161. *See* Pierce et al., *supra* note 22, at 10.

avoid obstructions to their research and testing, such as "inventing around the claims of the patent."[162]

The ability to "invent around" the claims of a patent depends on the scope of its claims.[163] Broad claims make such practices difficult. If we consider genes, however, even if a broad claim has been issued, patents related to a specific mutation can still be granted if the proposed patent improves the prior technology in a new and non-obvious way.[164] Under such a circumstance, the owner of the broad patent may practice the patented technology without infringement, provided they avoid using any technologies claimed in the subsequent patents.[165]

The breadth of Myriad's claims to BRCA was an issue in *AMP*.[166] Some contend that the broad scope of the claim language precluded researchers from "inventing around" or improving upon the technology without risk of infringement.[167] As such, it has been suggested in this Note that Myriad's claims could be adjusted to encompass a more specific method of diagnostic use rather than therapeutic use, especially given that Myriad was not pursuing research in treatment of breast and ovarian cancer.[168]

C. CHOICE OF TOPIC

Some scholars argue that even if patents do not stop ongoing research, the very prospect of the financial costs of navigating through licensing arrangements or risking infringement may limit progress by dissuading researchers from choosing particular projects. To explore this possibility, a study conducted by Walsh and Cohen asked academic respondents to indicate the importance of different factors for their choice of research

162. *Id.* at 7; *see also* Nicol & Nielsen, *supra* note 15, at 212 (stating that many of the researchers interviewed stated that they invented around patents in order to accomplish their research); Walpole et al, *supra* note 115, at, 204; John P. Walsh & Wesley M. Cohen, *supra* note 15, at 19, 31, 40.

163. Heller & Eisenberg, *supra* note 120, at 700 (stating that broad patents "aimed at understanding the basis of disease" are challenging to invent around); Nicol & Nielsen, *supra* note 15, at 159, 213 (stating that patents in the U.S. are easier to invent around because they are more narrowly defined); *see also,* Pierce et al., *supra* note 22, at 9 (the nature of the claims may make them difficult to invent around).

164. 35 U.S.C. § 101 (2006).

165. *Id.*

166. Ass'n of Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 213, 235 (S.D.N.Y. 2010).

167. *Id.* at 205, 208 (citing the enforcement of the patent as well as disagreement over the affect on research); *see also* Pins, *supra* note 71, at 381.

168. Pins, *supra* note 71, at 414.

projects.[169] The most pervasive reasons were scientific importance (97%), interest (95%), feasibility (88%), and access to funding (80%).[170] The patentability of research results was more than moderately important for only 7% of respondents.[171]

To investigate further, the same academic researchers were asked to assess the importance of reasons that may have dissuaded them from pursuing the most recent project they considered but did not pursue.[172] In order of importance, their responses were a lack of funding (62%) or lack of time (60%), and scientific competition in the form of too many researchers already pursuing the same topic (29%).[173] Technology control rights and patents were significantly less likely to be mentioned (10% and 3%, respectively) as an influencing factor, although respondents pursuing pharmaceutical research were somewhat more likely to report unreasonable licensing terms as an important reason for them not to pursue a project.[174]

The Walsh and Cohen study indicates that, contrary to the claims made by the plaintiffs in *AMP*, the existence of patents does not influence researchers in their choice of topics to pursue and, therefore, does not impede innovation in terms of the direction of research.

D. BEHAVIORAL ADJUSTMENTS TO PATENT LAW

Patents do not limit access to published research results because researchers in firms and academia employ a suite of working solutions to access and utilize research products.[175] These solutions include "inventing around" the claims (especially those that are broad), challenging patent validity through litigation, and knowingly (or innocently) infringing patents that can potentially block future research.[176] Patent law, therefore, has a built-in structure that enables scientists to avoid problems of exclusion inherent in the field of academia and continue to pursue their research of interest.

These behavioral adjustments cannot be utilized, however, when the breadth of a patent forecloses them. In the *AMP* case, the broad scope of Myriad's patents precluded any use of the BRCA patents which was not

169. *See also* Cohen & Walsh, *supra* note 15, at 13.
170. *Id.*
171. *Id.*
172. *Id.* at 14.
173. *Id.*
174. *Id.*
175. *Id.* at 12; *see also* Pierce et al., *supra* note 22, at 17.
176. Pammolli & Rossi, *supra* note 99, at 3.

specifically licensed by Myriad.[177] Myriad's reputation for enforcing its patents, and the subsequent realistic fear of litigation, also discouraged scientists and physicians from pursuing research that they might otherwise have followed.[178]

E. LICENSING

Licenses have proven valuable for developing drugs and biologics that might not otherwise be developed and continue to have such an effect in other areas of science as well.[179] Studies indicate that the existence of licensing is an attractive arrangement for many scientists.[180] Through licensing arrangements, scientists gain access to research data and input that might otherwise be unavailable. The issuance of licenses can also help patent holders prevent overly repetitive research and thereby increase efficiency in research efforts.[181] Licensing often involves the pooling of resources by both the licensee and licensor into a promising field of research.[182] Many patent holders require their licensees reach certain "diligence milestones" to ensure the productive use of time and money.[183] If licensees do not show progress toward the milestones, the licensor will extend the license to another company.[184]

Licenses of purified gene sequences provide the patent holders with an additional incentive to share their knowledge for the public benefit. Through license arrangements, gene patent holders maintain control of their invention while encouraging innovation for the public good. Without licensing arrangements, gene researchers would either use patents purely to block improvements on their inventions or (in the absence of patents) rely on trade secret protection and refuse to share their knowledge with the public.

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177. Ass'n of Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 204–05 (S.D.N.Y. 2010).

178. *Id.*

179. *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005).

180. *See* Pierce et al., *supra* note 22, at 8 (discussing the attractiveness of enacting compulsory licenses as a form of patent reform); *see also* Cohen & Walsh, *supra* note 15; Cook-Deegan et. al, *supra* note 15, at S15–S38; Walsh et al., *supra* note 15.

181. Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 824 (2001).

182. Pressman et al., *supra* note 150, at 37–38.

183. *Id.*

184. *Id.*

F. NECESSITY FOR INNOVATION

While patent protections may not impede innovation, this does not mean that patents are unnecessary for innovation. Most of the studies discussed in this Note focused on whether or not the existence of patent protection impedes innovation in the field of biomedicine. The majority of these studies indicate that patent protection does not impede access or innovation. These studies have indicated that patents, such as those held by Myriad, (1) encourage the disclosure of discoveries in an otherwise highly exclusionary field of academia; (2) decrease the cost and increase the availability of genetic testing; and (3) incentivize investors to continue to fund research and development by providing them with an opportunity to recoup their investments. Thus, patents are necessary for innovation.

G. RESOLVING MYRIAD

One concern regarding the patents issued to Myriad is the broad scope of their composition claims and their relevance to furthering the goals of intellectual property law.[185] The USPTO commonly grants patents covering genetic sequences provided that the sequences are purified from their natural source and have at least one potential novel and useful application.[186] The scope of protection, however, is not limited to the utility disclosed in the application and extends to uses not indicated in the patent.[187] As such, composition claims have a broad impact in terms of the scope of behavior they exclude, which may include uses of the composition which were not anticipated by the patent applicant.[188] This can be resolved, however, by limiting claims to a particular usage of the composition rather than the composition itself.[189] Such a policy would provide notice to the public of the metes and bounds of the claim, and simultaneously fulfill one of the other goals of patent law, promoting innovation, since the patent holder would still maintain exclusive control over the particular use.

Another concern is the effect of the process claims on both preventing the availability of secondary testing and permitting Myriad to charge high fees

185. Ass'n of Molecular Pathology v. USPTO, 702 F. Supp. 2d 181, 206–11 (S.D.N.Y. 2010).

186. Util. Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (notice); *see also Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 211.

187. Pammolli & Rossi, *supra* note 99, at 24.

188. *Id.*

189. *See generally id.*; *see also* Holman, *supra* note at 54, at 313 (discussing the scope of patent claims).

for testing (which currently stands at $3000 per test).[190] These concerns, however, are not specific to gene patents but apply to patents in general, particularly those claiming molecular biology methods used in drug development.[191]

In practice, human gene patents have a positive impact on the cost and availability of therapeutic drugs and medical devices. Patents play a central role in this because (1) they encourage disclosure of discoveries in an otherwise highly secretive and exclusive field of academia and (2) they incentivize investors to continue to fund research and development by providing them with an opportunity to recoup their investments.[192] Consequently, more products end up in the market and prices decrease as funds gained through monopolizing the market and licensing fees increase.

In conclusion, genetic sequences should be patentable to the extent that the metes and bounds of the claims are confined to a particular application of the composition rather than the composition in its entirety. With regard to the Myriad patents, this would require Myriad to confine their claims to the application of BRCA for identification of the mutation in a human being. Under these terms, researchers utilizing BRCA to investigate therapeutic treatments for breast and ovarian cancer would be free to do so without the risk of infringement. Such a policy permits the existence of patents and their beneficial effects while providing sufficient notice to the public of the metes and bounds of the claims.

V. CONCLUSION

This Note has attempted to address one of the largest public concerns voiced against the granting of patents: the concern regarding a potential lack of reasonable access to technology for the research and development of therapeutic and diagnostic products. Although empirical studies reveal that patents do not, in the aggregate, harm innovation, the broad issuance of composition claims, such as those held by Myriad in *AMP*, may prevent researchers from pursuing areas that the patent holder is not pursuing (such as research into medical treatment). This type of predicament could be resolved through the limitation of gene patent claims to the application of the genetic sequence rather than the sequence itself.

190. *Ass'n of Molecular Pathology*, 702 F. Supp. 2d at 203.
191. *See* Bendekgey & Hamlet-Cox, *supra* note 16, at 1377.
192. *See* Pammolli & Rossi, *supra* note 99, at 4, 13.