Journal of Gender, Social Policy & the Law

Volume 19 | Issue 3 Article 10

2011

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RACE TO THE CURE: WHY GENE PATENTS PAVE THE WAY FOR BREAST CANCER RESEARCH

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I. INTRODUCTION

Between 1975 and 2003, nearly half a million women forty years of age and older were diagnosed with breast cancer in the United States.[1] Early diagnosis can allow women who are genetically predisposed to breast cancer to take preventive measures and reduce their risks of cancer by as much as ninety percent.[2] In 1994, Myriad Genetics isolated and sequenced a breast cancer susceptibility gene and subsequently developed a test that allows women to determine whether they are at risk.[3] Because of the extensive time, money, and energy Myriad placed into its research, women can determine their susceptibility, and possibly even diagnose the cancer, at earlier stages.[4] As a reward for its efforts, Myriad received patents on the isolated gene sequences and breast cancer predisposition testing method, and these patents are now the subjects of contentious litigation.[5]

1. *See* Ahmedin Jemal, et al., *Recent Trends in Breast Cancer Incidence Rates by Age and Tumor Characteristics Among U.S. Women*, Breast Cancer Research, 3 (May 3, 2007), http://breast-cancer-research.com/content/pdf/bcr1672 (illustrating that 394,891 of breast-cancer diagnoses were invasive breast cancer while 59,837 were *in situ* breast cancer).

2. Myriad Genetics, *Why Take a Breast/Ovarian Cancer Risk Assessment Test?*, BRACANALYSIS, http://www.bracnow.com/considering-testing/why-take-a-breast-ovarian-cancer-risk-test.php.

3. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010) (noting that researchers first discovered the gene's existence on chromosome seventeen in 1990).

4. *See id.* at 203 (illustrating that women with the breast cancer mutation have an eighty-five percent chance of developing breast cancer and a fifty percent chance of developing ovarian cancer).

5. *See id.* at 185-86 (contending that gene patents issued to Myriad Genetics for a breast cancer susceptibility gene are unpatentable because they are laws of nature).

Scientific opponents of Myriad's patents argue that its exclusive licenses on the gene sequences and predictive testing hinder research because other institutions cannot continue research on the gene or second-guess Myriad's tests.[6] Legal opponents assert that these isolated sequences are laws of nature and, thus, unpatentable subject matter.[7] Nevertheless, the driving force behind both arguments is the notion that Myriad should not be rewarded for winning the race because other research institutions were equally capable of isolating and sequencing the gene.[8] Patent law, however, was not developed under principles of fairness or equality.[9]

The concept that researchers should be rewarded for their ingenuity in furtherance of societal good is at the heart of patent law.[10] The patent is the reward, and as such, it provides the impetus for researchers to receive funding for their work.[11] Currently, 6,000 gene sequences are the subjects of patents, thereby demonstrating the success of patent law in accelerating research in the field.[12] Eliminating genetic researchers' ability to patent isolated gene sequences will destroy the incentives that led to their successes in the first place.[13]

This Comment argues that the Southern District of New York's decision invalidating Myriad's patents claiming isolated breast-cancer gene sequences and breast-cancer predisposition tests is erroneous as a matter of

6. *Cf.* David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing a Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1038 (2004) (describing patents' inhibitive effects on subsequent research).

7. *See* Jennifer Giordano-Coltart, et al., *No Legal Monopoly for Genes: Court Rules Genes Are Unpatentable Subject Matter*, 22 INTELL. PROP. & TECH. L.J. 8, 9-10 (2010) (emphasizing the scientific community's anger with Myriad's refusal to share data or license the patents).

8. *See* Hoffman, *supra* note 6, at 1023 (discussing patents' triggering effects on the race to invent in the biotechnology industry).

9. *Cf. id.* at 1023-24 (illustrating that, in the race triggered by patents, no prize exists for second place).

10. *See, e.g.*, Melissa Wetkowski, Note, *Unfitting: Gene Patent Limitations Too Tight for United States' Biotechnology Innovation and Growth in Light of International Patenting Policies*, 16 SW. J. INT'L L. 181, 182 (2010) (arguing that a ban on gene patents effectively destroys research incentives).

11. *See, e.g.*, *id.* (asserting that patents create assurances of stability, such that patents have meaning and stability of enforcement to incentivize research).

12. *See* Lauren M. Nowierski, Note, *A Defense of Patenting Human Gene Sequences Under U.S. Law: Support for the Patenting of Isolated and Purified Substances*, 26 CARDOZO ARTS & ENT. L.J. 473, 475 (2008) (adding that the Human Genome Project also led to an increase in gene patents).

13. *See* Lisa Larrimore Ouellette, Note, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. N.1 (2010), *available at* http://stlr.stanford.edu/pdf/ouellette-access-to-bio-knowledge.pdf (depicting studies that suggest gene patents are not impediments, and that access to materials is a larger obstacle).

law and policy.[14] Part II explains the development of the legal standards defining patentable subject matter and describes the basis on which the Southern District of New York reached its holding.[15] Part III argues that the Southern District of New York's holding is erroneous as a matter of law.[16] Part IV of this Comment presents sound policy considerations in favor of patenting genes and recommends a research exemption to gene patents.[17] Finally, Part V concludes that prohibiting gene patents destroys the rewards of patent law that promote scientific research.[18]

II. BACKGROUND

A. Origins of Patentability in the United States

Article I, section 8, clause 8 of the U.S. Constitution confers upon Congress the authority to grant patents.[19] Congress has implemented patent legislation in a variety of ways over the last 200 years, but the general purpose remains unchanged: to promote scientific research and discovery in furtherance of societal good.[20] Patents grant inventors the exclusive right over their inventions or discoveries for twenty years from the date on which they file the applications that yield their patents.[21] In exchange for this exclusivity, the patentee must make a written description of his work publicly available.[22]

14. *But see* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 220-38 (S.D.N.Y. 2010) (invalidating the patents under section 101 of the U.S. Patent Act).

15. *See infra* Part II (describing the scope of 35 U.S.C. § 101 and its limitations).

16. *See infra* Part III (arguing that gene sequences are patentable when isolated, and that the breast-cancer testing methods are valid because the steps are sufficiently definite).

17. *See infra* Part IV (detailing how a research exemption could balance the trade-offs of patent law for genetic research).

18. *See infra* Part V (concluding that gene patents are valid, and their prohibition destroys research incentives).

19. U.S. CONST. art. I, § 8, cl. 8 ("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.").

20. *E.g.*, 35 U.S.C.S. § 100 (LexisNexis 2010); *see* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (emphasizing that the exclusivity of patents is an incentive for ingenuity).

21. *E.g.*, § 154(a)(1), (2) (stating that a patent runs twenty years from the filing date).

22. *E.g.*, § 112; *see also* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 740-41 (1990) (arguing that the quid pro quo of the patent system increases disclosure of findings, whereas researchers have less of an incentive to otherwise publish their findings).

B. United States Patent Act Section 101 & Subject-Matter Jurisprudence

Section 101 of the U.S. Patent Act sets the initial threshold for patentable subject matter.[23] It provides four categories of new and useful patentable subject matter: machines, processes, manufactures, or compositions of matter.[24] A composition of matter includes combinations of two or more substances.[25] Meanwhile, courts carved out three exceptions to statutory subject matter: laws of nature, abstract ideas, and physical phenomena.[26]

1. Laws of Nature

The laws of nature doctrine states that products of nature, exactly as found in their natural state, constitute unpatentable subject matter.[27] A patentable composition must be the result of human ingenuity, such that it cannot be repeated by nature.[28] Courts, however, struggle in determining whether laws of nature have been sufficiently altered into patentable compositions.[29]

Courts initially determined that isolated, purified forms of products of nature are patentable when they exhibit different qualities from their naturally occurring forms.[30] In *Parke-Davis & Co. v. H.K. Mulford Co.*, Judge Learned Hand held that a purified form of adrenalin differed from its natural form because it was removed from gland-tissue, purified from associated salts, and it acquired new commercial and therapeutic uses.[31] In 1970, the court in *In re Bergstrom* held that an isolated bodily compound was patentable because it did not exist in nature as purified from tissues

23. *See* § 100; *see also* Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010) (adding that inventions must also satisfy other statutory requirements).

24. *See* § 101 (implying that patents are further subject to standards of novelty, non-obviousness, and a written description).

25. *See* Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957) (providing that the term covers all composite articles as well)

26. *See Bilski*, 130 S. Ct. at 3225 (elaborating that these exceptions are not required by statutory text).

27. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 593 (1978) (establishing that newly discovered products of nature are not the discoveries section 101 was intended to protect).

28. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) (explaining that patented compositions must result from human intervention).

29. *Compare id.* (validating a patent for a combination of bacterium that perform a new function of breaking down crude oil), *with* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (invalidating a patent for a bacteria mixture that performs its original function of inoculating plant seeds).

30. *See, e.g.*, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (noting that, at the time, no rule excluded unchanged extracted materials from patent protection).

31. *See id.* (drawing the line between different compositions from common uses of man, rather than from considerations of dialectic).

and proteins.[32]

In 1980, the Supreme Court, in *Diamond v. Chakrabarty*, attempted to qualify this standard, holding that nonnaturally occurring compositions, the products of human ingenuity, are patentable subject matter.[33] The Court upheld the patentability of a combination of bacterium used to break down crude oil, determining that they contained "markedly different" characteristics from their natural forms and had potentially significant utility.[34] While the Court recognized the implications of its holding, specifically for genetic research, its failure to precisely define "markedly different" left courts unclear as to its application.[35]

Nevertheless, in 2001, the U.S. Patent and Trademark Office (PTO) published the Utility Examination Guidelines, which addressed patentability of isolated gene sequences. The PTO determined that isolated gene sequences are chemical compositions and constitute patentable subject matter, so long as such sequences meet other statutory requirements. While the Guidelines are not binding on the courts, they are given credence to the extent to which they do not conflict with statutory subject matter under section 101.[36]

2. Process Claims

Although laws of nature are unpatentable, process claims that employ laws of nature may still be patent-eligible.[37] Section 100 of the U.S. Patent Act defines processes as arts or methods, which include known processes, machines, manufactures, or compositions of matter.[38] Abstract principles, which are considered fundamental truths, are unpatentable as they effectively preempt entire fields of research and development.[39] Courts

32. *See* 427 F.2d 1394, 1395-96, 1401-02 (C.C.P.A. 1970) (asserting that the defendants did not merely discover prostaglandin).

33. *See* 447 U.S. at 309-10 (adding that the composition had a distinct character, name, and use).

34. *See id.* at 310 (explaining that a new composition will differ in quality and use).

35. *See, e.g.*, *id.* at 317 (suggesting that the legislature is the proper forum to weigh competing interests of subject matter).

36. *See In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (referring to both the Manual of Patent Examining Procedure and the Utility Examination Guidelines).

37. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that mixing existing strains of bacteria to inoculate plant seeds did not acquire different uses or functional improvements).

38. *See* 35 U.S.C.S. § 100 (LexisNexis 2010) (providing definitions of several terms used within the title); State St. Bank & Trust Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (describing a patentable process as one that creates a "useful, concrete, and tangible result").

39. *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (implying that the law does not recognize monopolies over abstract principles until they are applied to new and useful ends).

advise that process claims be confined within sufficiently definite bounds to avoid issues of preemption.[40]

The Federal Circuit in *In re Bilski* devised the "machine-or-transformation" test, which delineated rigid guidelines under which to evaluate process claims.[41] Pursuant to this test, a process is patent-eligible if (1) it is linked to a machine or other apparatus, or (2) it includes a transformative step, changing an article into a different state.[42] In *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, the Federal Circuit applied the machine-or-transformation test to a process of medical diagnostic testing that involved identifying levels of a metabolite used to treat gastrointestinal disorders.[43] The method passed the machine-or-transformation test because the steps of administering the drug and determining metabolite levels were transformative in that they were central to the entire process and could not be done by mere inspection.[44]

In *Bilski v. Kappos*, the Supreme Court rejected the machine-or-transformation test as the exclusive or exhaustive test for process claims.[45] The Court reasoned that the test is inflexible and contradicts the meaning of the word "process" in section 100, because the statute does not contemplate tying processes to machines or transformative steps.[46] While the machine-or-transformation test is still valid, it now serves as only a clue to patentability for process claims, rather than as the exclusive or exhaustive test.[47]

C. Association for Molecular Pathology v. United States Patent & Trademark Office

Myriad Genetics and the University of Utah Research Foundation (collectively "Myriad") hold patents on breast cancer susceptibility gene

40. *See id.* at 69 (explaining that a chemical process that transforms rubber did not monopolize an entire field because the process was applied to a specific use).

41. *E.g.*, 545 F.3d 943, 964-66 (Fed. Cir. 2008) (invalidating a patent for a business method of hedging risk).

42. *See id.* at 954, 961-62 (explaining that the transformation must be central to the entire process to be patent-eligible).

43. *See* 581 F.3d 1336, 1343 (Fed. Cir. 2009) (observing that doctors use the metabolite levels to alter dosages).

44. *See id.* at 1346 (adjudicating that the administration of metabolites caused transformative physical changes in the body).

45. *See* 130 S. Ct. 3218, 3220 (2010) (decrying the machine-or-transformation test's exclusive use, but failing to provide new guidelines), *rev'g In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

46. *See Bilski*, 130 S. Ct. at 3220 (recognizing that the ordinary meaning of the word "process" does not mean machine or transformation).

47. *See id.* (invalidating a business-method patent on hedging because it patented an abstract idea).

sequences and the cancer susceptibility tests that utilize those sequences.[48] Plaintiff Association for Molecular Pathology, along with several other research institutions and breast- and ovarian-cancer patients, filed a lawsuit against the U.S. Patent and Trademark Office and Myriad Genetics in the Southern District of New York to declare Myriad's patents invalid in light of: (1) section 101 of the U.S. Patent Act, (2) Article 1, section 8, clause 8 of the U.S. Constitution, and (3) the First and Fourteenth Amendments of the U.S. Constitution.[49] At the heart of their claims, Plaintiffs asserted that the gene and testing-method patents represent laws of nature and abstract principles, respectively, and thus fall under the exceptions to statutory subject matter.[50] The Southern District of New York granted the motion and invalidated Myriad Genetics' patents.[51]

1. The Patents-In-Suit

Myriad's patents encompass two types of claims: composition claims and method claims.[52] The composition claims are for isolated, purified BRCA1 and BRCA2 gene sequences.[53] The method claims, which relate to Myriad's Comprehensive BRACAnalysis Rearrangement Test and its 2006 BRACAnalysis Rearrangement Test ("BART"), cover the process of isolating the patient's DNA, inserting an altered BRCA gene into the host cell, and "analyzing" and "comparing" the BRCA1 and BRCA2 sequences against human samples for the growth of cancer therapeutics.[54]

2. Opinion

The Southern District of New York held that gene sequences are laws of nature and, thus, unpatentable subject matter.[55] The court reasoned that the

48. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010) (referring to fifteen claims within Myriad's seven patents).

49. *See, e.g.*, *id.* (refusing to address the Constitutional claims after invalidating the gene patents as laws of nature).

50. *See generally id.* (focusing primarily on the claims brought under section 101 of the United States Patent Act).

51. *See id.* at 186 (denying defendants' cross-motion for summary judgment).

52. *See id.* at 211 n.25 (acknowledging that the patents were approved pursuant to the Patent and Trademark Office's policy that allows for patents on "isolated and purified" DNA).

53. *See, e.g.*, U.S. Patent No. 5,693,473 (filed June 7, 1995) (issued Dec. 2, 1997); *see also Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 231 (noting this gene sequences corresponds with other DNA sequences containing the same nucleotide sequence).

54. *See, e.g.*, '473 Patent; *see also Ass'n for Molecular Pathology,* 702 F. Supp. 2d at 213 (explaining that each of the method patents are similarly structured, describing methods of comparing human samples with the BRCA1 and BRCA2 sequences).

55. *See Ass'n for Molecular Pathology,* 702 F. Supp. 2d at 185 (dismissing Myriad's claims that "laws" and "products" of nature are distinguishable).

isolated sequences did not contain markedly different characteristics from their naturally-occurring forms and, as such, were an embodiment of their original characteristics.[56] The court stated that DNA's composition is unique in nature and refused to treat it similar to chemical compositions, whereby isolation from associated components turns chemicals into patentable compositions.[57]

Moreover, the court held that Myriad's method claims were invalid because, pursuant to the now-denigrated machine-or-transformation test, the method does not involve transformative steps.[58] The court stated that although Myriad's test requires isolating patient tissue samples, this is a preparatory step, rather than one that is central and transformative.[59] The court added that Myriad's BRCA testing methods represented abstract processes of comparison and analysis, thus falling under the judicially created exceptions to patentable subject matter.[60]

III. ANALYSIS

A. The Southern District of New York Erred in Invalidating the BRCA1 and BRCA2 Patents Because Isolated Gene Sequences are Compositions of Matter Under Section 101 and Do Not Fall Within the Laws of Nature Exception.

The Southern District of New York, in its 152-page, policy-driven opinion, arbitrarily dismissed basic tenets of patent law jurisprudence. Patent law is designed to provide rewards for new inventions or discoveries that are products of human ingenuity.[61] Both the framers of the Constitution and Congress intended for the patentability of newly discovered compositions.[62] The Patent Clause of the Constitution states

56. *See id.* at 228 (citing Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)) (establishing that the fundamental characteristic of DNA as "physical carriers of information" has been preserved in the isolated gene sequence).

57. *See id.* (distinguishing DNA from other chemical compositions because DNA encodes information about construction of the human body, not its molecular structure).

58. *See id.* at 235 (rejecting Myriad's claim that the BRCA tests require transformation of tissue and blood samples).

59. *See id.* at 234, 236 (citing *In re* Grams, 888 F.2d 835, 840 (1989)) (determining that the test is nothing more than data-gathering and analysis).

60. *See id.* at 234 (citing *In re* Bilski, 545 F.3d 943, 953 (Fed. Cir. 2008)) (reasoning that the plain and ordinary meaning of the terms relates only to abstract mental processes and not transformative ones).

61. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (explaining that products become patentable when their functions, uses, or transformations into new compositions are products of human labor).

62. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (expounding that the language of the Constitution and section 101 intentionally include

that inventors shall have an exclusive right over their discoveries.[63] When Congress later enacted the U.S. Patent Act, it stated that one may receive a patent for any process, machine, composition of matter, or manufacture that he invents or discovers.[64] The broad language of these texts evinces that both the framers and Congress left the door open for inclusion of discoveries as patentable subject matter.[65] While new compositions are not patentable in their natural states, isolated, purified compositions have since been recognized as patentable when they exhibit nonnaturally occurring uses and qualities.[66] Myriad should, thus, be rewarded for its first-in-time discovery and isolation of the BRCA1 and BRCA2 gene sequences.

1. The Isolated, Purified BRCA Gene Sequences Are Patentable Subject Matter Because They Have Been Removed from All Associated Content and Are, Thus, Different from Their Naturally Occurring Forms.

Myriad's BRCA1 and BRCA2 gene sequences are patentable subject matter because the DNA molecules have been isolated and purified from associated components on the chromosome. Courts have recognized chemical compositions as patentable subject matter when they have been isolated and purified from associated components in their natural states.[67] In *Parke-Davis & Co. v. H.K. Mulford Co.*, the court held that isolated adrenalin was characteristically different because it was purified from its salt-based, naturally-occurring state.[68] In *In re Bergstrom*, the Court of Customs and Patent Appeals upheld a patent on a bodily composition because the patented form was isolated and removed from associated tissues and proteins.[69]

Similarly, a purified, isolated gene sequence is distinguishable from its

discoveries).

63. *See* U.S. CONST. art. I, § 8, cl. 8 (proclaiming authors and inventors should have the exclusive rights over their writings and discoveries); Utility Examination Guidelines, 66 Fed. Reg. at 1093 (explaining that the discovery of a gene may be the basis for patentable subject matter).

64. *See* 35 U.S.C.S. § 101 (LexisNexis 2010) (stating one may obtain a patent when he invents or discovers a new or useful composition); Utility Examination Guidelines, 66 Fed. Reg. at 1093 (noting that a gene patent is valid so long as it also satisfies the utility requirement).

65. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1093 (contending that discoveries with specific, substantial uses were meant to be patented).

66. *See In re* Bergstrom, 427 F.2d 1394, 1398 (C.C.P.A. 1970) (articulating that purified compositions are considered different if they exhibit new properties).

67. *See, e.g.*, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1918); *see also Bergstrom*, 427 F.2d at 1398.

68. *See id.* at 103 (articulating that the practical differences, not the scholastic distinctions, between the pure and impure form support upholding the patent on adrenalin).

69. *See Bergstrom*, 427 F.2d at 1398 (contending that a separate factor to consider is the composition's usefulness in lowering blood pressure).

impure form on a chromosome.[70] DNA has both structural and functional properties: (1) it is structurally a chemical composition, and (2) it serves a biological function of encoding proteins.[71] While the court acknowledged these functional properties of DNA, it refused to treat gene sequences as chemical compositions and to accept the notion that the isolation of the sequence's chemical structure creates a patentable composition.[72]

Myriad's patents claim the isolated, chemical structure of the BRCA sequences.[73] The BRCA1 and BRCA2 gene sequences, as chemical compositions, fall within the scope of section 101 as a composition of matter because these DNA molecules are a combination of nucleotide sequences.[74] While these compositions are not patentable compositions when left on their respective chromosomes, they, like other chemical compositions, constitute patentable subject matter when removed and purified from their natural states.[75]

The BRCA1 and BRCA2 sequences, when found on their respective chromosomes, are products of nature, and as such, their primary purpose is to carry information within the full gene sequence.[76] Their existence in that natural state on the chromosomes is the product of biological functions, and is thus, nature's work.[77] Once researchers isolate and purify a gene sequence from its original state, the resulting product is a new manufacture or composition of matter.[78] The sequence has been isolated from any

70. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1093 (explaining that the isolated compound described by the DNA sequence constitutes patentable subject matter); *cf. Bergstrom*, 427 F.2d at 1401-02 (clarifying that a purified chemical compound, known as prostaglandin, is patentable because it cannot be found in purified form in the body).

71. *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 228 (S.D.N.Y. 2010) (describing the testimony by Myriad's expert that DNA is multifunctional).

72. See, *e.g.*, *id.* at 231-32 (stating that DNA retains its property of encoding proteins and carrying information).

73. *But see id.* at 229 (asserting that DNA carries a unique function and that the functions of other chemical compounds are not comparable).

74. *Cf.* Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957) (defining a composition of matter as a combination of two or more substances, including call composite articles, regardless of whether they are gases, fluids, powders, or solids).

75. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1093 (contending that Congress intended for patents on isolated chemical structures).

76. *See, e.g.*, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 228-29 (describing the biological function of DNA for coding proteins and directing the synthesis bodily molecules).

77. *Cf.* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (reasoning that non-naturally occurring compositions are patentable because they require human ingenuity); Utility Examination Guidelines, 66 Fed. Reg. at 1093 (proclaiming that isolated DNA is non-naturally occurring).

78. *See In re* Bergstrom, 427 F.2d 1394, 1401 (C.C.P.A. 1970) (implying that purified prostaglandin is a new composition because it has been removed from all associated components in its natural form in the body).

adjacent, or even overlapping, gene sequences, and it has been purified of any associated components.[79] This purified sequence cannot be repeated by or found in nature.[80] The isolated form of the BRCA1 and BRCA2 gene sequences is solely the result of human ingenuity, experimentation, and manipulation.[81]

Furthermore, PTO practice and guidelines similarly recognize an isolated gene sequence as patentable subject matter.[82] The PTO, in its Utility Examination Guidelines, stated that the broad scope of section 101 supports its practice that DNA sequences are patentable once isolated and purified from their natural states.[83] The Guidelines further clarify that the sequence data, or just the descriptive information of the sequence, is not patentable; the Guidelines only support patenting an isolated DNA molecule.[84] Thus, under PTO practice and guidelines, Myriad's isolated gene sequence, which patents an isolated DNA molecule, is patentable subject matter.[85] Because isolated gene sequences constitute patentable subject matter, the Southern District of New York erroneously invalidated Myriad's gene patents.

2. The Isolated BRCA Gene Sequences Are Patentable Because Their Acquisition of a New Utility for Cancer Testing Constitutes a Different Characteristic That Is Solely the Result of Human Manipulation.

The Southern District of New York improperly applied the *Chakrabarty* standard not only by holding that isolated gene sequences are not markedly different, but also by failing to recognize that an isolated gene sequence acquires a significant new utility.[86] The *Chakrabarty* Court validated a

79. *See, e.g.*, U.S. Patent No. 5,693,473 (filed June 7, 1995) (issued Dec. 2, 1997) (defining an isolated sequence as one that is separated from other cellular components).

80. *See Chakrabarty*, 447 U.S. at 313 (elaborating that the new bacterium was a human-made invention because it required the patentee's ingenuity).

81. *See id.* (explaining that Congress recognized human ingenuity as the difference between products of nature and patentable inventions).

82. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (responding to public comments and concerns over the patentability of gene sequences); *cf. In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (recognizing the Utility Examination Guidelines to the extent that they do not conflict with patent statutes).

83. *See* Utility Examination Guidelines, 66 Fed. Reg. at 1093 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)) (explaining that Congress intended to patent anything under the sun, which includes non-naturally occurring gene sequences).

84. *See id.* (reasoning that the gene sequence data, which only includes information on the strings of letters and pairs, is nonfunctional descriptive information and is unpatentable).

85. *See, e.g.*, U.S. Patent No. 5,693,473 (filed June 7, 1995) (issued Dec. 2, 1997) (claiming an invention relating to methods and materials used to isolate and detect BRCA1).

86. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (distinguishing Funk

patent on a bacterium combination, clarifying that it not only had markedly different characteristics but also a potentially significant utility to break down crude oil.[87] The Supreme Court envisioned this standard for patentability encompassing more than just a change in characteristics.[88] It includes the acquisition of different uses beyond those originally produced by nature.[89] In *Parke-Davis*, the court also emphasized that isolated, purified adrenalin was effectively different and, therefore, patentable because it gained commercial and therapeutic new uses for blood pressure treatment.[90]

Likewise, a gene sequence becomes commercially and therapeutically new upon isolation and purification.[91] The isolated gene sequences possess significant utility as means to a new end: markers for the breast cancer gene.[92] The BRCA sequences then serve as the guideposts against which to test for predispositions to breast or ovarian cancer.[93] The patentees utilize the BRCA1 and BRCA2 gene sequences in their breast cancer susceptibility test to perform this guidepost function.[94] These isolated, purified gene sequences no longer serve the ends nature originally provided, but rather serve a significant new utility through the patentees' manipulation.[95] The Southern District of New York, thus, erred in

Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948)) (deciding that the patentee genetically manipulated the bacterium to acquire a significant new utility). *But see* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010) (likening Myriad's patent claim to the bacterial mixture in *Funk Bros.*).

87. *See Chakrabarty*, 447 U.S. at 305 (emphasizing the bacterium's value for treatment of oil spills).

88. *See id.* at 310 (requiring a showing that the discovery yields both a new characteristic and a new utility in order to be patentable); *see also* Hoffman, *supra* note 6, at 1018 (speculating that isolating and purifying a gene sequence sufficiently applies a "law of a nature to a new and useful end").

89. *See Chakrabarty*, 447 U.S. at 313 (countering the argument that Congress intended to distinguish between living and inanimate things and instead suggesting that Congress intended to distinguish between "products of nature" and "human-made inventions").

90. *See* 189 F. 95, 103 (S.D.N.Y. 1911) (holding that once the patentee extracted the compound from inorganic matter, it was changed from an inert substance to a potentially useful one).

91. *Cf. id.* (insisting that practical differences between an isolated composition and its natural form serve as keys to determining patentability); Merck & Co., Inc. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 163-64 (4th Cir. 1958) (explaining that a purified composition with new utility is an invention because, without isolation, it would not have such a use).

92. *Cf. Merck*, 253 F.2d at 164 (upholding a patent for vitamin B(12) in purified form that had potential medical uses).

93. *See, e.g.*, U.S. Patent No. 5,693,473 (filed Jun. 7, 1995) (issued Dec. 2, 1997) (claiming diagnosis of predisposition to breast and ovarian cancer as a utility of the isolated gene).

94. *See id.*

95. *Cf. Chakrabarty*, 447 U.S. at 310 (explaining that compositions are patentable

invalidating Myriad's gene patents by ignoring the marked differences in the isolated sequences.

B. The Southern District of New York Erred in Invalidating Myriad's Method Claims Because the Test Involves Transformative Steps and the Claims Do Not Seek to Patent Abstract Mental Processes.

1. Myriad's Method Claims Are Patentable Under the Machine-or-Transformation Test Because the Process of Isolating Patient Tissue Samples Is a Central, Transformative Step.

The Southern District of New York improperly dismissed Myriad's method claims under the machine-or-transformation test by failing to consider the claim as a whole and holding that the methods did not contain transformative steps.[96] Although the court was bound to apply the machine-or-transformation test at the time of its decision, the court incorrectly applied the test by discarding the methods' central processes as irrelevant.[97]

The Federal Circuit in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services* stated that a process of determining metabolite levels in a body is considered a transformative step.[98] The metabolite determination was transformative because it was central to the treatment process, and the determination could not be done by mere inspection of the patients.[99] Similarly, Myriad's process claim, whereby it must compare and analyze DNA, is transformative.[100] Myriad described the method as transforming patient tissue and blood samples to isolate the patient's

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when they cannot be repeated by nature without human intervention).

96. *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 233 (S.D.N.Y. 2010) (contending that steps of comparison and analysis were the underlying bases of the method claims).

97. *See In re* Bilski, 545 F.3d 943, 961-62 (Fed. Cir. 2008) (ruling that the machine-or-transformation test is the exclusive test for process claims), *remanded sub nom.* Bilski v. Kappos, No. 08-964, 2010 U.S. LEXIS 5521, at *16-18 (Jun. 28, 2010) (rejecting the machine-or-transformation test because it creates too much uncertainty in the Information Age). *But see* Ass'n for Molecular Pathology, 702 F. Supp. 2d at 234-35 (reasoning that isolation of tissue indicates the source of the tissue, but is not central to the method).

98. *E.g.*, 581 F.3d 1336, 1346 (Fed. Cir. 2009) (explaining that the human body and the drug's metabolites underwent physical and chemical changes), *vacated*, No. 09-490, 2010 U.S. LEXIS (Jun. 29, 2010) (remanding the case for reconsideration in light of *Bilski v. Kappos*, No. 08-964, 2010 U.S. LEXIS 5521 (Jun. 28, 2010)).

99. *See Prometheus*, 581 F.3d at 1347 (holding that a method for measuring metabolite levels survived the machine-or-transformation test).

100. *But see Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 234 n.56 (limiting its interpretation to DNA sequences, thereby ignoring similar claims related to RNA and cDNA).

DNA.[101] The court, however, explained that the process of isolation could not be attributed to a transformation because the isolation merely describes where the DNA came from.[102] The court further stated that Myriad's entire claim was directed to abstract mental processes of comparison and analysis.[103]

The court should not have dismissed the isolation of patient tissue samples as lacking transformation because the process of isolating the patient tissue and DNA sample is central to the diagnostic testing.[104] Just as the metabolite levels in *Prometheus* could not be tested by mere inspection, testing the patient's DNA requires more than inspection.[105] Although isolating the patient samples is the first step of the process, it is more than just a preparatory step.[106] The process involves taking the patient's tissue and blood samples, manipulating the samples to isolate the corresponding DNA molecules, inserting an altered BRCA1 gene into the cell, and testing for a cancerous predisposition.[107] Isolating the DNA molecules from the patient samples is central to the overall process because researchers cannot successfully accomplish testing without this initial, critical step.[108]

The court further limited the claim's terms and stated that the isolation process in the method claim cannot be differentiated from the isolated DNA in the composition claims.[109] While the same term is used, each claim is distinct. The composition claim was entirely directed toward isolated, purified BRCA1 and BRCA2 gene sequences.[110] The method

101. *See id.* (reiterating Myriad's argument that comparison and analysis are central to the transformation).

102. *E.g.*, *id.* at 236 (citation omitted) (decrying that Myriad attempted to import claim limitations).

103. *See id.* at 237 (alleging the claims would fail the test even if the court considered the isolation process transformative).

104. *Cf. Prometheus*, 581 F.3d at 1347 (explaining that a step required to determine levels is not merely a data-gathering step because it is part of the treatment).

105. *See id.* (indicating that some form of manipulation is required to extract metabolite samples and determine the levels within the body).

106. *Cf. id.* (holding that a diagnostic test that incorporates a step of determining metabolite levels is central to a process because it is necessary for therapeutic treatment).

107. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 233 (describing Myriad's argument that isolating the patient's DNA molecules is a physically transformative step because the DNA cannot be isolated without the transformation of the tissue samples).

108. *But see id.* at 235 (contending that the purpose was to detect germline alterations, while the actual method claimed was one of comparison and analysis).

109. *Compare* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (implying that courts should not violate principles of patent interpretation by reading limitations into the patent's scope), *with Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 236 (alleging that Myriad seeks to change the scope of the claims).

110. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203 (describing two

incorporates a process of isolation that is central to the researchers' ability to compare the patient's DNA to the BRCA1 and BRCA2 gene sequences encompassed in the composition claims.[111] Thus, the Southern District of New York incorrectly invalidated Myriad's method claim.

2. Myriad's Method Claims Are Patentable in the Wake of Bilski Because They Are Confined Within Sufficiently Definite Bounds.

Pursuant to the Supreme Court's recent decision in *Bilski v. Kappos*, the machine-or-transformation test should not be used exclusively to evaluate the validity of method claims.[112] The machine-or-transformation test now serves merely as a clue to patentability for method claims.[113] The Court reasoned that the test proves too narrow and rigid, and its use as an exhaustive test would preclude patents for innumerable inventions that would otherwise be patentable.[114] In the wake of *Bilski*, courts should consider the patent claims as a whole without confining their interpretations to the inflexible machine-or-transformation test.[115]

Courts should determine whether the method either covers an abstract principle or is directed toward some other process that otherwise constitutes statutory subject matter.[116] An abstract principle is considered a fundamental truth, over which no one can claim an exclusive right.[117] Alternatively, a process is a manner of treating materials to produce a given result, and the tools used in producing such a result are considered to be of

separate patents-in-suit: claims for isolated gene sequences and claims for predisposition tests applying the sequences).

111. *See, e.g.*, U.S. Patent No. 5,709,999 (filed June 7, 1995) (issued Jan. 20, 1998) (detailing the process of detecting germline alterations as incorporating the obtainment of a human sample and detecting the alteration by amplifying all or part of the BRCA1 gene).

112. *See* 130 S. Ct. 3218, 3226 (2010) (observing that use of the machine-or-transformation test would read a limitation into section 101).

113. *E.g.*, *id.* (citing Corley v. United States, 129 S. Ct. 1558 (2009)) (noting that the machine-or-transformation test would also render section 273 of the U.S. Patent Act superfluous, which allows for infringement claims for methods in patents).

114. *See, e.g.*, *id.* (emphasizing that exclusive use of the machine-or-transformation test precludes patentability of diagnostic medical techniques and other unforeseen inventions).

115. *See, e.g.*, *id. See generally* King Pharm. v. Eon Labs, Inc., 616 F.3d 1267 (Fed. Cir. 2010) (applying the Supreme Court's *Bilski* holding, although disagreeing with the rationale behind disallowing the machine-or-transformation tests exclusive use for process claims).

116. *See generally* Diamond v. Diehr, 450 U.S. 175, 187 (1981) (determining that when an abstract principle is applied to a specific, patentable process, the patent does not preempt a field and is valid).

117. *E.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (quoting Le Roy v. Tatham, 55 U.S. 156, 175 (1853)) (holding that a mathematical algorithm is a fundamental truth, and thus, an unpatentable abstract principle).

secondary consequence.[118] While an abstract principle is itself unpatentable, application of an abstract principle to a process claim may still constitute patentable subject matter.[119] The key to patentability is whether the abstract principle is applied to a specific process or used to refine such a process.[120] If an abstract principle is applied to a patentable method, the patent may still be valid if it seeks to patent the process itself and not the applied abstract principle.[121] A process claim that is too general may be unpatentable if it wholly preempts an entire field.[122] Courts have, thus, cautioned that process claims must be confined to sufficiently definite bounds.[123]

Illustratively, a process claim seeking to patent a mathematical formula, without application to a specific invention or use, is unpatentable because it effectively patents the algorithm itself, thus limiting its use in other formulas.[124] Meanwhile, the use of magnetism to transmit sounds, specifically applied to a telephone, is patentable because it does not seek to patent electricity, but rather an electrical current used in a specified, narrow circumstance.[125]

Under this broader analysis, Myriad's process claims are even more clearly patentable. Myriad's BART test includes three basic steps for researchers: (1) isolate the patient's blood and tissue sample; (2) insert an altered BRCA1 gene, which simulates cancerous cells, into the host cell to test for the presence or absence of cancer therapeutics; and (3) compare and analyze growth rates in the host cell for the presence of a cancer

118. *See, e.g.*, Cochrane v. Deener, 94 U.S. 780, 787-88 (1877) (providing that a process of manufacturing flour is patentable because it reduced the grain to a different state).

119. *See In re* Grams, 888 F.2d 835, 840 (Fed. Cir. 1989) (holding that a test for diagnosing abnormalities is not patentable because the steps involving a mathematical algorithm did not have specific applications and were only data-gathering steps).

120. *See id*. at 838 (citing *In re* Walter, 618 F.2d 758 (C.C.P.A. 1980)) (ruling that a mathematical algorithm must either be specifically applied to define structural relationships of a claim or to refine or limit patentable claim steps).

121. *Compare Diehr*, 450 U.S. at 187 (upholding a patent for an algorithm applied to a process for curing synthetic rubber), *with Gottschalk*, 409 U.S. at 67, 71-72 (invalidating a patent for a mathematical formula because it could only be applied in connection with computers, which were not the object of the patent).

122. *See* Parker v. Flook, 437 U.S. 584, 589-90 (1978) (explaining that a process using a mathematical algorithm was unpatentable because there was no invention, and the patent would wholly preempt the use of the algorithm in other equations).

123. *See Gottschalk*, 409 U.S. at 71-72 (describing how a process utilizing a mathematical formula could not be patented because the claim was so broad as to cover both known and unknown uses of the conversion formula).

124. *See id.* at 68 (invalidating a patent for a process of converting binary-coded decimal numerals into binary numbers because it was overly broad and encompassed an entire algorithm).

125. *See id.* at 68-69 (stating that the patent associated with Bell's telephone was valid because it was not for all telephonic use of electricity).

therapeutic, whereby a slower growth rate is indicative of its presence.[126] The steps involve treating materials in order to achieve a deliberate result: a triggered response by the host cell.[127] The patient's blood and tissue sample is isolated, and the BRCA gene is inserted to test growth rates for cancer therapeutics, thereby specifically determining whether a patient is susceptible to breast or ovarian cancer.[128] By applying the machine-or-transformation test as a clue to patentability, the testing method, which includes processes of isolating the patient's tissue samples and inserting a gene sequence to change growth rates, involves transformative steps.[129] However, the court reasoned that Myriad's method claim was not patentable because the third step, which describes a process of comparing growth rates, is an abstract mental process.[130]

Myriad's process claims do not seek to patent abstract mental processes simply because they incorporate steps of comparison and analysis.[131] Myriad's claims, taken as a whole, are confined to sufficiently definite bounds, such that they will not preempt the fields of genetics or medical diagnostic testing.[132] The method claims primarily patent the process of isolating the patient's tissue sample, inserting the cancer-mimicking gene, and testing growth rates.[133] These abstract principles are applied in Myriad's claims to growth-rate tests after a BRCA1 gene sequence is inserted into the host cell.[134] Myriad simply used analysis and comparison as a tool to achieve the result of breast and ovarian cancer susceptibility testing.[135] Myriad refined its use of abstract processes of comparison and

126. *But see* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 236 (S.D.N.Y. 2010) (dismissing Myriad's claims and stating that the isolation of the patient samples is not transformative and is, instead, merely data-gathering).

127. *Cf.* Cochrane v. Deener, 94 U.S. 780, 787-88 (1877) (defining a process as a method of treating materials towards the production of a given result).

128. *See, e.g.*, U.S. Patent No. 5,709,999 (filed June 7, 1995) (issued Jan. 20, 1998) (specifying the process under which researchers test for breast cancer predispositions).

129. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218, 3226 (2010) (cautioning that the machine-or-transformation test should not be used exclusively).

130. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 237 (asserting Myriad's description of comparing growth rates is an attempt to patent the scientific method).

131. *Cf. In re* Grams, 888 F.2d 835, 840 (Fed. Cir. 1989) (providing that an abstract process may be used to refine other patentable processes).

132. *See* Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (avoiding the issue of whether the Court is the proper forum to extend the application of patent law to mathematical algorithms because it does not have the power to conduct hearings and canvass opposing views).

133. *See, e.g.*, King Pharm. v. Eon Labs, Inc., 616 F.3d 1267, 1277 (Fed. Cir. 2010) (reaffirming the idea that patents must be looked at in their entirety, rather than by isolating each claim and assessing them separately).

134. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 237 (conceding that the steps taken prior to comparing the growth rates of cells may be transformative).

analysis to its otherwise patentable processes.[136]

The process claim explicitly describes a series of specific steps that allow researchers and doctors to determine whether a patient is genetically predisposed to breast or ovarian cancer.[137] The process claims do not purport to preempt abstract mental processes of comparison and analysis.[138] Thus, in the wake of *Bilski v. Kappos*, Myriad's process claims for BRCA1 and BRCA2 cancer predisposition testing are patentable.[139] Accordingly, under the tests established by the Supreme Court in *Chakrabarty* and *Bilski*, the Southern District of New York erred in its decision as to both the composition and method claims as a matter of law.[140]

IV. POLICY IMPLICATIONS AND RECOMMENDATIONS

Sound policy reasoning further supports the patentability of Myriad's claims. Congress enacted the U.S. Patent Act to promote the progress of science and society, thus leaving open the scope of patentable subject matter.[141] While patents on gene sequences could arguably inhibit scientific research, their prohibitions effectively serve an equal or greater harm to society.[142]

Genetics research is time- and cost-intensive.[143] Research institutions

135. *Cf.* Cochrane v. Deener, 94 U.S. 780, 787-88 (1877) (holding that the tools used to manufacture grain are only secondary to the actual manufacture the patentee sought to patent).

136. *Cf. Grams*, 888 F.2d at 840 (determining that the test of patentability should be read as requiring that a principle be applied in any manner to physical process steps).

137. *See, e.g.*, U.S. Patent No. 5,693,473 (filed June 7, 1995) (issued Dec. 2, 1997) (describing the process of detecting germline alterations using the BRCA1 gene).

138. *Cf.* Diamond v. Diehr, 450 U.S. 175, 187 (1981) (reasoning that the application of a mathematical algorithm to a process of curing synthetic rubber only claims the exclusive right to use that equation for the rubber curing process).

139. *See* 130 S. Ct. 3218, 3231 (2010) (asserting that the test is too rigid for exclusive use).

140. *See* Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (setting the markedly different standard); *In re* Bilski, 545 F.3d 943, 953 (Fed. Cir. 2008) (applying the machine-or-transformation test exclusively), *remanded sub nom. In re* Bilski, 130 S. Ct. 3218, 3226 (condemning the machine-or-transformation test's exclusive use for method claims). *But see* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010) (explaining that DNA, even in its isolated form, is the embodiment of biological information).

141. *See Chakrabarty*, 447 U.S. at 308-09 (articulating that the scope of patentability is open to "anything under the sun"). *But see Bilski*, 130 S. Ct. at 3229 (setting a high bar for patentability to prevent slowing creativity).

142. *See Chakrabarty*, 447 U.S. at 317 (suggesting genetic research is dependent on rewards and incentives); *see also* Alex Osterlind, *Staking a Claim on the Building Blocks of Life: Human Genetic Material within the United States Patent System*, 75 MO. L. REV. 617, 619 (2010) (describing the difficulties in reconciling the competing interests of gene patents).

143. *See* Hoffman, *supra* note 6, at 996 (discussing the benefits obtained by the public from patenting inventions that might not have otherwise been produced because

may be unwilling, or even unable, to engage in such beneficial research without the necessary incentives.[144] Patents provide two interconnected, reward-based incentives: (1) the patent itself rewards patentees for their labor through a grant of exclusivity over their inventions or discoveries, and (2) patents provide the means necessary for researchers to receive the monetary backing for the continuation of their work.[145] A patentee may be less likely to receive funding for his research without the necessary end-result of exclusivity over his invention or discovery.[146]

Myriad, like the other institutions that raced to sequence the breast cancer susceptibility gene, worked tirelessly knowing that if it could sequence the gene first, it would be rewarded with a patent.[147] The prospect of the patent then made it possible for Myriad to receive funding for its efforts.[148] This funding also exists because Myriad, as the institution with control of the gene sequence and corresponding test, can balance the costs of research with the profits received from exclusively conducting the BART test.[149] Without these incentives, Myriad and other researchers may not have sequenced the gene as expediently, or at all.[150]

Nevertheless, opponents argue that patents hinder research because they prohibit other institutions from using the gene sequence for inquisitive research.[151] For the BRCA1 and BRCA2 sequences, patient samples must be sent to Myriad's facilities for testing at a high cost.[152] Patients are then

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of high production costs).

144. *E.g.*, Wetkowski, *supra* note 10, at 182 (acknowledging the potential for the United States to fall behind other countries in the field of genetic research if scientists cannot obtain patents and, consequently, funding for research).

145. *See* Nowierski, *supra* note 12, at 506 (adding that patents are an incentive for public disclosure); *see also* Wetkowski, *supra* note 10, at 182 (asserting that researchers will not be willing to engage in research and development without patents).

146. *See* Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 346 (1995) (noting that the ability to receive commercial rewards is the foundation of all of patent law and not just exclusive to biotechnology patents).

147. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 210 (S.D.N.Y. 2010) (describing the competition from institutions receiving federal grants).

148. *See, e.g.*, *id.* at 201 (referring to the total $122 million in funding that Myriad received during a three-year period).

149. *See, e.g.*, *id.* at 203 (noting that Myriad's 2008 costs of providing the test was $32 million, while its revenues, after charging over $3,000 per test, were $222 million).

150. *Cf.* Wetkowski, *supra* note 10, at 183 (asserting that the United States has surpassed other countries in the field of biotechnology because the reliability of obtaining patents encourages investment).

151. *See* Lauren M. Dunne, Note, *"Come, Let Us Return to Reason": Association of Molecular Pathology v. USPTO*, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 473, 503-04 (2010) (contending that patents are not true monopolies because they are limited in time, scope, and exercise).

152. *See id.* at 487 (elaborating that Myriad's Comprehensive BRACAnalysis Test costs approximately $3,000, while its BRACAnalysis Rearrangement Test costs around

unable to receive secondary opinions because Myriad is the only laboratory that can perform such testing.[153]

The most practical solution to the ostensible monopoly of patents on gene sequences and correlative testing is to create a research exception.[154] Currently, no other researchers have the right to use the gene sequence and test in any manner.[155] Under a research exemption, the patent grants the inventor exclusive rights over his discovery or invention for a limited time, but it would not preclude the use of the sequences to determine whether scientists can obtain new information from the sequence, such that Myriad's testing could be improved.[156] This exception would allow Myriad to maintain exclusive commercial use of its patents, while serving the common good of society by opening the field to collaborative research by similar institutions.[157] Because of the unclear status of gene patents, Congress should legislate and uphold gene patents, while creating a research exemption, such that researchers may coordinate their efforts in furtherance of a societal good.[158]

V. CONCLUSION

The Southern District of New York erred in holding that (1) patents on gene sequences are invalid because they are laws of nature, and (2) a process of testing for breast cancer susceptibility is unpatentable because it is not transformative and utilizes abstract ideas.[159] Isolated, purified gene

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$600).

153. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 188-89 (S.D.N.Y. 2010) (citing Plaintiffs' complaints that they cannot afford the high costs charged by Myriad and discussing Myriad's inability to receive Medicaid coverage for its test).

154. *See* Hoffman, *supra* note 6, at 1037 (contending that a research exemption will accomplish two goals of patent law: providing financial incentives and advancing the body of scientific knowledge).

155. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 204-06 (referring to instances whereby Myriad sought to enforce its patents through litigation).

156. *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (D. Mass. 1813) (doubting that patent law was meant to punish one who uses a patent to satisfy mere curiosity); *see also* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1054 (1989) (adding that such access to patents for research could be useful when the scientific community needs researchers to challenge the theories and practices of their competitors).

157. *See* Eisenberg, *supra* note 156, at 1054-55 (explaining that cooperation among the scientific community through "licensed access" to patents can help to reduce research costs).

158. *See* Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) (implying that Congress, not the courts, is the proper forum to balance the trade-offs and weigh competing interests).

159. *But see Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 218 (dismissing the additional constitutional claims against the U.S. Patent & Trademark Office because the patents were held invalid as claiming laws of nature).

sequences are patentable subject matter because they have been removed from all associated content and adjacent sequences.[160] The gene sequences then acquire a new utility for research and testing, which results solely from the patentee's manipulation.[161] Moreover, diagnostic testing process claims that analyze growth rates of cancerous DNA molecules are patentable because the use of abstract mental processes of comparison and analysis is sufficiently refined to cancer predisposition testing.[162]

Patents provide incentives to engage in and receive funding for research, and prohibiting gene patents could destroy any and all incentives, thus slowing the pace of the U.S. biotechnology industry.[163] Courts should continue to uphold Congress's intended broad scope of patent law and allow for the patentability of gene sequences, as such patents lead to great advancements in medical research.[164] Meanwhile, Congress should codify the patentability of gene sequences and allow a research exemption, so as to properly balance the trade-offs between the rewards and monopolies of patents and weigh the competing interests of different sectors.[165]

160. *See In re* Bergstrom, 427 F.2d 1394, 1395-97 (C.C.P.A. 1970) (holding that an isolated bodily composition was patentable because it was removed from associated gland-tissue).

161. *See* Nowierski, *supra* note 12, at 503 (contending that patented sequences gain specific functions after extensive experiments); *cf.* Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1918) (illustrating that when Takamine removed adrenalin from other gland tissue, the adrenalin was different in kind in that it acquired commercially and therapeutically new uses).

162. *See* Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972) (cautioning that a method patent becomes a patent on an abstract principle when it entirely preempts a field of research).

163. *See* Wetkowski, *supra* note 10, at 182 (arguing that the United States should follow other countries by allowing gene patents).

164. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) (explaining Jefferson's conception that ingenuity should receive liberal encouragement); *cf.* Hoffman, *supra* note 6, at 1041-42 (suggesting that biotechnology patents should have a narrower written description requirement so as to reduce conflict among those seeking to improve upon inventions in the field).

165. *See* Hoffman, *supra* note 6, at 1030 (contending that biotechnology companies are becoming increasingly private, thus creating a need to avoid a tragedy of the anti-commons); *see also* Davis, *supra* note 146, at 323 (noting the Supreme Court's ruling that patents on living organisms are valid until prohibited by Congressional legislation).