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Finders Keepers, or Finders Weepers? A Proposed Answer to a Question Raised by Myriad Genetics

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FINDERS KEEPERS, OR FINDERS WEEPERS? A PROPOSED ANSWER TO A QUESTION RAISED BY *MYRIAD GENETICS*

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I. INTRODUCTION

The first gene patent was issued to the Regents of the University of California on bacterium in 1982.[1] Since then, increasing knowledge about the characteristics of gene sequences and their therapeutic effects has fueled economic and noneconomic interests in them.[2] One way to preserve the economic value of a newly discovered gene is to procure patent protection on a particular gene segment,[3] which would give owners of gene patents exclusive rights to use and profit from them.[4] The exclusivity of gene patents has far-reaching implications. Opponents of gene patents argue that gene patents increase downstream transaction costs and thus become major barriers in the development of biotechnology.[5] Proponents of gene patents, however, seek patent rights to protect their returns on millions of dollars of investment.[6]

The Supreme Court took up this hotly debated question of the patent-eligibility of gene segments for the first time in *Myriad Genetics*.[7] The Court held that "a naturally occurring Deoxyribonucleic Acid (DNA) segment is a product of nature and not patent eligible merely because it has been isolated"[8] because "laws of nature, natural phenomena, and abstract ideas" have long been held unpatentable.[9] However, the Court distinguished complementary DNA, which

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[1] Edward Weck, Note, *Exclusive Licensing of DNA Diagnostics: Is There a Negative Effect on Quantity and Quality of Healthcare Delivery That Compels NIH Rulemaking?*, 31 WM. MITCHELL L. REV. 1057, 1062 (2005); *see also* U.S. Patent No. 4,363,877 (filed Apr. 19, 1978) (issued Dec. 14, 1982).

[2] *See, e.g.*, Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 20 (2002); Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 190–91 (2010); Cara Koss, Note, *Oysters & Oligonucleotides: Concerns and Proposals for Patenting Research Tools*, 25 CARDOZO ARTS & ENT. L.J. 747, 754 (2007).

[3] Omid E. Khalifeh, *The Gene Wars: Science, the Law and the Human Genome*, 9 LOY. L. & TECH. ANN. 91, 102 (2010); Cydney A. Fowler, Comment, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 AM. U. INT'L L. REV. 1073, 1084 (2010).

[4] 35 U.S.C. § 271 (2006 & Supp. V 2011).

[5] WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 298–300 (2003). The public may ultimately receive some benefit of expired patents. During the lifetime of the patent, however, the broader the scope of the patent and the lower the competition, the less benefit the public will receive.

[6] *See* Ass'n for Molecular Pathology v. USPTO (Myriad I), 702 F. Supp. 2d 181, 196–97 (S.D.N.Y. 2010) (discussing various uses for isolated and purified DNA), *aff'd in part*, *rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.*, Ass'n for Molecular Pathology v. Myriad Genetics Inc., 132 S. Ct. 1794 (2012).

[7] Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

[8] *Id.* at 2111. *See also* 35 U.S.C. § 101 (2011).

[9] *Myriad Genetics*, 133 S. Ct. at 2116.

is not naturally occurring, and thus patent-eligible.[10] The impact of the Supreme Court's ruling on future DNA isolation and commercialization remains to be seen. One advantage of holding isolated DNA ineligible for patent protection is that by removing the exclusive protection that patents provide to owners of newly discovered genes, scientists can develop advanced tests based on the genetic information coded in the isolated genes without incurring patent liability and litigation costs. However, this holding may discourage private entities from investing in the discovery and isolation of DNA.[11] Alternatively, private entities may keep their newly discovered DNA as trade secrets, frustrating patent law's goal of encouraging the dissemination of information for the purpose of future genetic research.

This Note proposes an approach for the protection of gene discoveries without discouraging private investments: the formation of a Board consisting of technical and legal experts that determines how to award an entity that registers and publishes a newly discovered DNA segment with the Board. This solution, called the registration-reward system, is better than other purposed solutions, and would resolve *Myriad Genetics*'s negative implications for genetic researchers.

Part II of this Note discusses the patent eligibility requirements under 35 U.S.C. § 101 and the science of isolating DNA for the purpose of gene patents. Additionally, this part describes the *Myriad Genetics* case and the lack of incentives for private investments in the discovery and isolation of DNA under the *Myriad Genetics* ruling. Part III partially justifies the Supreme Court's ruling in *Myriad Genetics*, while demonstrating the insufficiency of the patent system to address the lack of investment incentives for genetic researchers. Finally Part III, proposes a registration-reward system administered by a newly formed USPTO Board to award protection to an entity who registers a new DNA segment, and why this registration-reward system is the best solution among alternatives to promoting future genetic research in light of *Myriad Genetics*'s categorical rejection of patents on naturally occurring DNA segments.

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[10] *Id.* at 2111.

[11] SEC'YS ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, GEE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 1 (2010) [hereinafter SACGHS REPORT], *available at* https://repository.library.georgetown.edu/bitstream/handle/10822/515456/SACGHS_Final_Gene_Patents_Report_April2010.pdf?sequence=1.

II. BACKGROUND

A. PATENT ELIGIBLE SUBJECT MATTER UNDER § 101

Patent-eligible subject matter includes "any new or useful process, machine, manufacture, or composition of matter."[12] The Supreme Court has long recognized three exceptions to this general principle: laws of nature, natural phenomena, and abstract ideas.[13] Interpreting the meaning of these three exceptions, however, has long puzzled the courts.[14] The Court in *Diamond v. Chakrabarty* declared that Congress intended statutory subject matter to "include anything under the sun that is made by man,"[15] but, in an effort to clarify the doctrine of unpatentable subject matter, the Court has stepped back from this holding throughout cases decided in the last half-century.[16] Three of these cases are important precedents for understanding the *Myriad Genetics* Court's holding that isolated DNA is a product of nature and thus patent ineligible.[17]

First, the composition patent in *Funk Brothers* concerned an inoculant for leguminous plants comprising a selection of mutually non-inhibitive strains of different species of bacteria of genus Rhizobium.[18] The Supreme Court held that "[d]iscovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect of the properties of either" is "no more than the discovery of some of the handiwork of nature and hence is not patentable."[19] In other words, the Court held that the composition was not patent eligible because the patent holder 'did not alter the bacteria in any way,' and thus it fell within the law of nature exception.[20] The Court reasoned, "[i]f there is to be an invention from such discovery, it must come from the application of the law of nature to a new and useful end."[21]

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12 35 U.S.C. § 101.

13 Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) (quoting Howard T. Markey, *Why Not the Statute?*, 65 J. PAT. & TRADEMARK OFF. SOC'Y 331, 334 (1983)).

14 Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 725 (1990).

15 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399) (internal quotation marks omitted).

16 *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948); Gottschalk v. Benson, 409 U.S. 63, 64 (1972); Parker v. Flook, 437 U.S. 584 (1978); *Chakrabarty*, 447 U.S. at 303; Diamond v. Diehr, 450 U.S. 175 (1981); Bilski v. Kappos, 130 S. Ct. 3218 (2010); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

17 *Myriad Genetics*, 133 S. Ct. 2107.

18 *Funk Bros.*, 333 U.S. at 127.

19 *Id.* at 131.

20 *Myriad Genetics*, 133 S. Ct. at 2117 (citing *Funk Bros.*, 333 U.S. at 132).

21 *Funk Bros.*, 333 U.S. at. 130.

The Court in *Chakrakarty*, on the other hand, found that when "scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil," the modified bacterium was patent eligible.[22] The Court explained, the "claim is not a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinctive name, character, and use."[23] Importantly, the bacterium had additional characteristics not found in nature, this creating a "new . . . composition of matter."[24]

Third, the patented invention in *Mayo* was a method of administering a drug to a patient and measuring how the drug is metabolized against a known threshold for efficacy.[25] The Supreme Court stated that the application did not add any inventive concept to the claimed method but instead, the application only relied on the elements that had been known in the field.[26] Thus, the invention preempted a law of nature and was ineligible subject matter.[27] As the Court explained, "phenomena of nature, though just discovered . . . are not patentable, as they are the basic tools of scientific and technological work. And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[28] The Court, in laying the foundation for a two-step test later clarified and expanded upon by the Court in a subsequent case,[29] declared that "the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field," and that "upholding the patents would risk disproportionately tying up use of the underlying natural laws, inhibiting their use in the making of further discoveries."[30]

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[22] *Myriad*, 133 S. Ct. 2107, 2116 (citing *Chakrabarty*, 447 U.S. 303).

[23] *Chakrabarty*, 447 U.S. 303, 309–10 (citations omitted) (internal quotations omitted).

[24] 35 U.S.C. § 101.

[25] *Mayo*, 132 S. Ct. 1289.

[26] *Id.*

[27] *Id.*

[28] *Id.* at 1293.

[29] *See* Alice Corp. Pty. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) ("First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, what else is there in the claims before us? To answer that question, we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. We have described step two of this analysis as a search for an 'inventive concept.' " (citing *Mayo*, 132 S. Ct. 1289, 1296–97)).

[30] *Mayo*, 132 S. Ct. 1289, 1294.

Once a patentee meets the requirement of eligibility, a patentee must also demonstrate that an invention is novel,[31] nonobvious,[32] and enabling.[33] These three patentability requirements are separate and distinct from the § 101 analysis, and other bases for invalidating a patent. If a patentee meets all of the statutory requirements, he or she will receive an exclusive right to use the invention for twenty years,[34] and empowering the patentee to license the invention to others at a significant fee.

B. THE SCIENCE OF GENE PATENTS

Gene patents, although now patent-ineligible in light of *Myriad Genetics*, were categorized as a "composition of matter" under § 101.[35] The science behind isolating DNA segments is thus important to understanding the Court's rejection of gene patents. A DNA molecule consists of two strands of long polymer chains that are made of four types of nucleotides attached to backbone chains.[36] The two strands are twisted in a spiral ladder shape, giving rise to "double helix" chains of nucleotides.[37] DNA consisting of different series of nucleotides provides a set of genetic instructions for the production of proteins[38] through a two-step process known as transcription and translation. In transcription, the DNA is split and the coding strand is copied to form RNA molecules that contain only a single gene rather than hundreds of genes.[39] The RNA molecule is modified further to form messenger RNA (mRNA).[40] The resulting mRNA is a fundamentally different molecule from its DNA template.[41] MRNA consists of only exons, a different molecule as its backbone, and other structural changes from its DNA template.[42] MRNA is then translated to form amino acids, which are basic building blocks of proteins.[43]

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31 35 U.S.C. § 102 (2006).
32 *Id.* § 103.
33 *Id.* § 112.
34 *Id.* § 154.
35 *Id.* § 101; *Myriad Genetics*, 133 S. Ct. 2109, 2113.
36 BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 197 (5th ed. 2008).
37 *Id.* at 197–98.
38 Erik Lillquist & Charles A. Sullivan, *The Law and Genetics of Radical Profiling in Medicine*, 39 HARV. C.R.-C.L. L. REV. 391, 410 (2004) ("Human beings, by current estimates, have between 26,000 and 40,000 separate genes, spread across twenty-three chromosomes . . . ." (footnote omitted)).
39 *See* ALBERTS ET AL., *supra* note 36, at 17.
40 *Id.* at 347–48.
41 *Id.* at 345.
42 *Id.*
43 *Id.* at 304.

A mutation in the genetic code, whether by alteration of a nucleotide or by changing sequences of nucleotides, often results in coding for defective or nonfunctional proteins.[44] "Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical break-through."[45] To diagnose genetic disorders, knowledge of mutations as well as the normal sequence is required.[46] It is, however, difficult to locate a mutated gene sequence. Genes consist of coding strands and non-coding strands, and both strands have non-coding regions (introns) interspersed between coding regions (exons), therefore making it difficult to identify which strand is the coding strand for a particular protein.[47]

In order to locate a particular gene sequence, scientists create complementary DNA (cDNA), which is a completely man-made molecule that differs from native DNA and RNA molecule.[48] The process to manufacture cDNA is now well-known;[49] scientists reverse transcribe a strand of mRNA and create a DNA string that would be an identical copy of a non-coding DNA strand's coding region.[50] Although it was created from mRNA, cDNA differs from mRNA in three aspects: the cDNA is complementary to the mRNA,[51] it uses thymine nucleotides rather than uracil,[52] and the sugar backbones of the RNA and DNA stands differ.[53] Also, cDNA differs from native DNA because it is missing introns,[54] it is not subjected to cellular regulation, it is not a part of a larger structure (such as a chromosome), and it has a tail region not present in the DNA. While cDNA lacks introns, it contains overlapping sequences with native DNA and can attach itself with native DNA.[55] Scientists thus use cDNA as a probe for identifying mutated DNA. Scientists look at the various points

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[44] *Id.*

[45] *Myriad Genetics*, 133 S. Ct. 2107, 2112.

[46] Nat'l Human Genome Research Inst., *DNA Sequencing*, GENOME.GOV, http://www.genome.gov/10001177 (last visited Oct. 5, 2014).

[47] Lauren M. Dunne, Case Note, *"Come, Let Us Return to Reason":* Association of Molecular Pathology v. USPTO, 20 DEPAUL J. ART TECH. & INTELL. PROP. L. 473, 479–80 (2010) (stating that neighboring genes can be located on opposing strands, and that many regulatory aspects of RNA synthesis have not been well defined).

[48] *See* ALBERTS ET AL., *supra* note 36, at 535–37.

[49] *Id.*

[50] *Id.*

[51] *Id.* at 543 (discussing and illustrating the reverse transcription process).

[52] *See id.* at 332.

[53] *Id.* at 197.

[54] Since the cDNA is complementary to the mRNA and mRNA is a genetic molecule from which introns have been spliced out, the cDNA does not have introns either.

[55] *See* ALBERTS ET AL., *supra* note 36, at 537.

of attachment, find the endpoints of each gene, and then extract the newly discovered gene with the help of specific and well-known enzymes.[56]

The knowledge of a genetic sequence helps advance research in genetic testing.[57] Genetic testing is useful in at least three different ways: (1) predictive testing of a patient with a predisposition to a particular disease, (2) diagnostic testing of a patient with suspected presence of mutated genes, and (3) genetic testing of patients diagnosed with certain diseases to optimize drug therapy in pharmacogenomics applications.[58] Despite these important uses, private entities hesitate to conduct genetic testing due to its cost.

A microarray-based test, however, is a promising test that allows for marking DNA, RNA, and protein in a single experiment, and has demonstrated a tremendous cost advantage over traditional genetic tests.[59] A microarray-based test permits simultaneous analysis of thousands of gene sequences.[60] The resulting access to greater amounts of information from microarray-based testing allows for better diagnosis and treatment. But, to further develop the test, researchers would be required to obtain multiple licenses from gene patents owners—one for each DNA sequence used in the test.[61] With current advances in DNA sequencing technologies, researchers are likely to discover the complete human genome in the near future.[62] In the meantime, every human gene sequence may be subject to patent protection.[63] Thus, the exclusive rights

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[56] *See* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 114–15 (2001) (discussing automation and routinization of DNA sequencing).

[57] *See, e.g.*, Michael Tomasson, *Legal, Ethical, and Conceptual Bottlenecks to the Development of Useful Genomic Tests*, 18 ANNALS HEALTH L. 231, 236 (2009); Courtney C. Scala, Note, *Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacogenomics*, 41 CONN. L. REV. 1631, 1661 n.167 (2009).

[58] *See* Eileen M. Kane, *Patent-Mediated Standards in Genetic Testing*, 2008 UTAH L. REV. 835, 837 (noting that genetic testing can serve a number of purposes, including optimizing drug therapy, diagnostic testing, and predictive testing).

[59] SACGHS REPORT, *supra* note 11, at 11, 50, 51–52 (stating that "gene-by-gene testing" is more costly than multiplex genetic testing).

[60] DON ROSE, MICROARRAY BIOCHIP TECHNOLOGY 19 (Mark Schena ed., 2000).

[61] *See* 35 U.S.C. § 154(a)(1) (2006) (providing that U.S. patent law prohibits one from making, using, offering for sale, or selling the patented invention except by lawful authorization by the patent holder).

[62] *How Many Genes Are in the Human Genome?*, HUMAN GENOME PROJECT INFORMATION, http://www.ornl.gov/sci/techresources/Human_Genome/project/index.shtml (last modified July 23, 2013) (reporting that the sequencing of the human chromosomes is "essentially 'finished' ").

[63] *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005) (finding that 20% of the genes identified in the human genome are claimed in patents); Stefan Lovgren, *One-Fifth of Human Genes Have Been Patented, Study Reveals*,

of gene patent owners present substantial barriers to further development of the microarray-based testing, especially when the patent owners refuse to license their inventions to others. Myriad Genetics Incorporated, the defendant in the *Myriad Genetics* case, is one of such patent owners. Therefore, the case's determination of the patent-eligibility of DNA presents far-reaching implications.

C. THE CONTEXT OF THE *MYRIAD GENETICS* CASE

Myriad Genetics Inc. owned the patents for BRCA1 and BRCA2, the two gene sequences that indicate one's predisposition to breast and ovarian cancer.[64] "Before Myriad's discovery of the . . . genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers."[65] Unlike most gene patents owners who are willing to license their patents to diagnostic laboratories,[66] Myriad chose to fully exercise its legal rights by excluding others from using BRCA1 and BRCA2 in diagnostic tests.[67] Myriad marketed multiple diagnostic tests,[68] one of which is a comprehensive test that provides the full sequence of both BRCA1 and BRCA2 genes and costs $2,400.[69] When Myriad began to offer gene diagnostic tests, other laboratories were performing BRCA1 and BRCA2 diagnostic sequencing. Upon realizing this, Myriad sent cease and desist letters, but specified that the notification did not apply to research testing for non-commercial research programs.[70] Association for Molecular Pathology, along with other medical organizations, researchers, genetic counselors, and patients, sued Myriad in 2010, alleging that Myriad's patents on BRCA1 and BRCA2 were invalid.[71]

NAT'L GEOGRAPHIC NEWS (Oct. 13, 2005), http://news.nationalgeographic.com/news/2005/10/1013_051013_gene_patent.html (reporting that 4,000 genes have been claimed in U.S. patents).

[64] Olga Bogard, Comment, *Patenting the Human Body: The Constitutionality of Gene Patents and Suggested Remedies for Reform*, 63 SMU L. REV. 1319, 1327 (2010).

[65] *Myriad Genetics*, 133 S. Ct. 2107, 2122.

[66] *See* Bogard, *supra* note 64, at 1326.

[67] *Id.* at 1327.

[68] *See* E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. S39, S41 (2010).

[69] *Id.*

[70] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187 (S.D.N.Y. 2012).

[71] *See generally Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 181.

The publicity surrounding the *Myriad Genetics* case fueled a public debate, primarily because the issue at question was framed as a social dilemma.[72] Major news agencies covered the case, the majority of which (77.6%) portrayed Myriad's patents in a negative light.[73] Some news sources, for example, characterized Myriad as owning a patent on a piece of the human body.[74] Two publications from the ACLU titled *Tell Congress: My Genes Aren't For Sale* and *Liberate the Breast Cancer Genes* focused instead on patients' inability to receive second opinions or access to the genetic test, as well as the misinformation in the progress.[75]

Additionally relevant to understanding the context of the *Myriad Genetics* case is the passage of the Leahy-Smith America Invents Act (AIA), signed on September 16, 2011 by President Barack Obama.[76] Section 27 specifies that "the Director [of the USPTO] shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist."[77] Notably, the study calls for "research into second opinions on diagnostic tests and nothing more."[78] Compared to the extensive patent reform, this statement is "extremely narrow."[79] Prompted by the public controversy and AIA's suggestion for some restrictions on gene patents, the Supreme Court took up the hotly debated question of patent eligibility of genes in 2013.[80]

D. THE *MYRIAD GENETICS* CASE AND ITS IMPACTS

To understand the impacts of *Myriad*, it is helpful to know the case's procedural history. The Southern District of New York court held that neither isolated genes nor synthetic genes (cDNA) were patent eligible subject matter under § 101. In comparing the isolated DNA and cDNA to the claimed

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[72] *See* Timothy Caulfield et al., *Myriad and the Mass Media: The Covering of a Gene Patent Controversy*, 9 GENETICS IN MED. 850, 852–53 (2007).

[73] *Id.* ("The majority of articles (77.6%) had a negative overall tenor . . . .").

[74] *Id.*

[75] *See* Sandra Fulton, *Tell Congress: My Genes Aren't for Sale*, AM. CIVIL LIB. UNION (Apr. 27, 2010), http://www.aclu.org/blog/free-speech-womens-rights/tell-congress-my-genes-arent-sale/; Joe Engardio, *Liberate the Breast Cancer Genes*, AM. CIVIL LIB. UNION (May 13, 2009), http://www.aclu.org/2009/05/13/liberate-the-breast-cancer-genes/.

[76] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 27(a), 125 Stat. 283, 338 (2001).

[77] *Id.*

[78] Johanna Jacob, *Should Our Genes Be Part of the Patent Bargain? Maximizing Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable*, 28 SANTA CLARA COMPUTER & HIGH TECH L.J. 403, 434 (2012).

[79] *Id.*

[80] Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

discovery in *Funk Brothers* and distinguishing from the bacteria in *Chakrabarty*, the court reasoned that neither were "markedly different" from native DNA, and thus were ineligible products of nature.[81]

In contrast, the U.S. Court of Appeals for the Federal Circuit held that both isolated DNA and cDNA were patentable subject matter,[82] but each Judge wrote separately, disputing over "whether the act of *isolating* DNA . . . is an inventive act that entitles the individual who first isolates it to a patent."[83] Judge Lourie opined that Myriad's patent claims covered, "molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature" and are drawn to patent eligible subject matter.[84] Judge Lourie further stated that since cDNA did not exist in nature it was also patent-eligible. Judge Moore, concurring in part, disagreed that the different chemical structure rendered the isolated DNA sufficiently different from the native DNA to transform otherwise patent ineligible subject matter to patent eligible subject matter.[85] Nonetheless, the long held tradition supporting the patent-eligibility of isolated DNA led Judge Moore to decide that isolated DNA was patent eligible.[86] On the other hand, Judge Bryson dissented in part, believing that isolated DNA should not be patent-eligible, because the discovery of the sequence is "an unprotectable fact," and it would "likely . . . have substantial adverse effects on research and treatment in this important field."[87]

Eventually, arguments reached the Supreme Court. The plaintiffs, along with most researchers in the biology field, argued that including isolated DNA within the scope of patentable subject matter would block public access to important genes and prevent the development of medical testing.[88] The defendants, however, focused on their extensive efforts to uncover these genes and the lower courts' previous opinions holding that isolated DNA was patentable subject matter.[89] The Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it

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[81] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 228–37 (S.D.N.Y. 2010).

[82] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1333 (Fed. Cir. 2011) (affirming in part and reversing in part on remand in light of *Mayo*).

[83] *Myriad*, 133 S. Ct. 2107, 2114.

[84] 653 F.3d 1329, 1351.

[85] *Id.* at 1364–65.

[86] *Id.* at 1367.

[87] *Id.* at 1373–74.

[88] *See* Mary Mitchell & Dana A Remus, Commentary, *Interstitial Exclusivities After Association for Molecular Pathology*, 109 MICH. L. REV. 34, 34–35 (2010), http://www.michiganlawreview.org/assets/fi/109/mitchellremus.pdf.

[89] *Ass'n for Molecular Pathology*, 653 F.3d at 1333.

has been isolated," but that cDNA is patent eligible because it is not naturally occurring.[90] Although products of nature are a judicial exception to patent-eligible subject matter, the Court noted that "too broad an interpretation of this exclusionary principle could eviscerate patent law."[91] Thus, "patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery" and "impeding the flow of information that might permit, indeed spur, invention."[92] Essentially, the Court characterized Myriad's contribution as uncovering the precise location and genetic sequence of BRCA1 and BRCA2 genes, but noted that "Myriad did not create anything qualifying as a new composition of matter."[93] "[E]xtensive effort alone," the Court declared, "is insufficient to satisfy the demands of § 101."[94]

Overall the biotechnology field welcomed the Court's holding.[95] For example, some scholars concerned with the danger of anticommons applauded the result because they argue that gene patents lessen access to the knowledge about gene sequences, which are basic components for diagnostic testing and genetic drug development.[96] The tragedy of the anticommons forms when "multiple owners each have a right to exclude others from a scarce resource and no one has an effective privileged use."[97] Michael Heller and Rebecca Eisenberg first argued that exclusive rights of private parties protected by patents "may be stifling life-saving innovations further downstream in the

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[90] *Myriad Genetics*, 133 S. Ct. 2107, 2111.

[91] *Id.* at 2116 (quoting *Mayo*, 132 S. Ct. 1289, 1293).

[92] *Id.*

[93] *Id.*; *see also* 35 U.S.C. § 101.

[94] *Myriad Genetics*, 133 S. Ct. 2118.

[95] Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2-4, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585711 (arguing that DNA and human genes are unpatentable under 35 U.S.C. § 101 and the patents should be declared unenforceable, because public health necessitates their invalidation); Brief for the S. Baptist Convention as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585712 (arguing that gene sequence patents are unpatentable subject matter and are harmful to individuals no matter what their religious beliefs); Brief of Amici Curiae E. Richard Gold et al. in Support of Appellees and Affirmance at 26, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 5558511 (arguing that the genetic sequence contained in DNA should be considered information and should therefore be excluded as unpatentable abstract subject matter unless the claim has a specific function).

[96] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anitcommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998).

[97] *Id.*

course of research and product development."[98] Patents on basic building blocks such as DNA on which further development of gene testing relies increases these costs due to administrative red tape, deadlines, and researches' unfamiliarity with patent licensing practices.[99] In the anticommons, holdout situations where researchers have to negotiate licenses independently with multiple patentee contribute to these high transaction costs.[100] The Court's holding that DNA is not patent-eligible, hence, alleviates these costs and instead encourages genetic testing.

The Court's holding also attracted criticism.[101] Some commentators argued that even if genes should not be patentable, § 101 is the incorrect vehicle to invalidate gene patents; rather, the Court should use the nonobviousness requirement (§ 103).[102] Section 103 requires a comparison between prior art and the subject matter to be patented, asking whether the latter would have been obvious to a person of ordinary skill in the art at the time of the invention.[103] The court will inquire whether the inventor's work resulted in the creation of something new and whether the result is a fairly significant improvement from prior arts.[104] "[T]o allow otherwise would not only add nothing to the sum of human knowledge," but "would in fact injure the public by removing existing knowledge from public use."[105] The Supreme Court in *KSR* stated that whenever "there are a finite number of identified, predictable solutions . . . [that] lead[ ] to the anticipated success," the invention is viewed as "obvious to try" and is not patentable.[106] Since the process used by Myriad to

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[98] *Id.*

[99] Peter Lee, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 675 (2004).

[100] *Id.*

[101] Brief of Amici Curiae Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal at 14-28, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853324 (arguing that isolated DNA is patentable subject matter, and patents promote innovation).

[102] Linda J. Demaine & Arron Xaxier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 408 (2002) ("[A] molecular biologist uses a well-known method of creating a cDNA replica of the gene, which contains only the expressed portions of the sequence (i.e., the exons)."); Amy Nelson, *Obviousness or Inventive Steps as Applied to Nucleic Acid Molecules: A Global Perspective*, 6 N.C. J.L. & TECH. 1, 28 (2004) ("[I]t is well-known to prepare cDNA libraries from human organs and to randomly isolate and sequence DNAs transform.").

[103] 35 U.S.C. § 103 (2011).

[104] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[105] Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 DUKE L.J. 919, 931 (2011) (quoting Bonita Boats v. Thunder Craft Boards, 489 U.S. 141, 148 (1989)).

[106] *KRS Int'l Co.*, 550 U.S. at 421.

isolate DNA was obvious and routine, the result is not patentable under § 103, according to these scholars.

Another major critique argues that excluding isolated DNA from patentable subject matter would defeat the purpose of patent law and disincentivize innovation.[107] Without patent rights, private entities will stop investing capital and decrease efforts to uncover these important genes.[108] In the same line of argument, some commentators cite the impacts of the Bayh-Dole Act to prove that patent protection is the primary driving force for private investments.[109] The Act followed a situation where most of the funding for biotechnology was from the government.[110] Prior to the passage of the Bayh-Dole Act, the biotechnology section operated under a commons model, with the federal government funding "upstream" research that "encouraged broad dissemination of results in the public domain."[111] The Act allowed the universities or entities that generated these results to patent them.[112] These commentators argue that the passage of the Act has had "a tremendous effect on the appropriation of technology."[113] For example, biotechnology patent applications "increased by more than 300 percent in the first five years after the enactment of the [Act,] as compared with the five years prior to the passage of the Act."[114] Private funds currently account for 71% of all research and development funding in the United States.[115] Myriad's holding, scholars argue, will significantly reduce this number.[116] Faced with conflicting arguments, scholars have started to search for solutions.

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[107] Brief of Amici Curiae Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal, *supra* note 101, at 8–9.

[108] *Id.*

[109] Michael S. Mireles, *An Estimation of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovations*, 38 U. MICH. J.L. REFORM 141, 155–56 (2004).

[110] *Id.*

[111] Heller & Eisenberg, *supra* note 96, at 698.

[112] *Id.*

[113] *See* Mireles, *supra* note 109, at 155–56.

[114] *Id.* at 160–61.

[115] *See generally* Nat'l Sci. Bd., *Science and Engineering Indicators 2008: Chapter 4. Research and Development: National Trends and International Linkages*, NSF.GOV (Jan. 2008), http://www.nsf.gov/statistics/seind08/c4/c4h.htm.

[116] Brief of Amici Curiae Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal, *supra* note 101.

E. PROPOSED SOLUTIONS

Scholars have recommended several solutions to the likely reduction of private funding for genetic testing following *Myriad Genetics'* holding.[117] Most scholars argue that the Court should allow patents for isolated DNA, but should also try to minimize the negative effects of patent rights. Ideas for minimizing the negative effects have included creating a patent pool,[118] clearinghouses that provide a two-sided platform for licensees and patent owners,[119] compulsory licensing schemes,[120] and patent donations, where patentees are encouraged to donate their patents to the public.[121] Each of these approaches support the patent eligibility of genes and the resulting exclusive rights of patentees, while attempting to mitigate the impacts of monopolistic patent rights. This Note next discusses each of these ideas in more detail.

The idea of patent pool originated to meet the needs of a user of multiple patents.[122] Patents of certain technical fields are pooled together and receive royalties from the bundle of patents. When companies pool patents together, the user can license multiple patents from the pool rather than being limited to asking for a single license from each owner.[123] This approach was once successful in facilitating complex licensing schemes, but has been criticized as anticompetitive because users rarely look outside the pool for relevant technologies, thus discriminating against non-members.[124]

Clearinghouse systems, originating from the banking industry, have been suggested as a solution to the problem with patent pools.[125] Such systems, provide a two-sided platform between patentees and licensees to maximize their own profits.[126] The system has many promising characteristics similar to a patent pool, such as dividing royalties between the members within

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[117] The following is a brief survey of the proposed solutions. For a comparison between them and the solution that this Note proposes see *infra* Part V.

[118] *See generally* Courtney C. Scala, Note, *Making the Jump from Gene Pools to Patent Pools: How Patent Pools Can Facilitate the Development of Pharmacogenomics*, 41 CONN. L. REV. 1631 (2009).

[119] *See generally* Kourtney Baltzer, *A Clearinghouse: The Solution to Clearing up Confusion in Gene Patent Licensing*, 24 HARV. J.L. & TECH. 519 (2011).

[120] Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953, 970 (2010).

[121] Kyle Wamstad, *Priority Review Vouchers — A Piece of the Incentive Puzzle*, 14 VA. J.L. & TECH. 126, 139 (2009).

[122] *See* Scala, *supra* note 118, at 1631.

[123] *Id.* at 1646–47.

[124] *Id.* at 1653.

[125] *See* Baltzer, *supra* note 119, at 531.

[126] *See id.*

clearinghouses, and an internal committee to facilitate licensing deals.[127] Although it may cure the problem of a monopolic patent pool, it is still based on exclusive rights.[128]

Another potential solution is compulsory licensing, where patent holders license their technologies according to statutory requirements.[129] This approach weakens patent rights and, as one scholar argues, fails to adequately reward inventors for their labor. In all, some scholars argue this approach challenges the rationale for granting patents in the first place.[130]

Patent donation, another alternative, relies on the patent owners' good will to donate his or her patents to the public domain.[131] The patent owners would benefit from a good reputation and other brand-building advantages by donating.[132] Similarly, a voucher system gives a patent owner who donates his or her patents into the public domain a priority voucher—entitling him or her a speedy proceeding for other, future patents.[133] Both patent donations and the voucher systems rely on the patent owners' charitable intent, thus introducing a great amount of uncertainty as to what type of knowledge will enter the public domain.

Another solution, suggested by an academic scholar, expands the gatekeeping role of the Food and Drug Administration (FDA). He urges Congress to authorize the FDA to approve an entity's products and services related to a gene if the entity was the first discoverer of the gene, and to reject other entities' products and services related to the same gene.[134] This approach, he argues, eliminates the costly patent prosecution process for newly discovered gene sequences. However, an entity must notify the FDA when it discovers a gene. Since non-profit research is not subject to the FDA's approval, the approach clears barriers for pure medical testing related to the particular gene segment. This solution, however, creates waste, particularly in two scenarios. First, a gene sequence has to be discovered again for non-commercialized purposes, even though an entity has already discovered it. Second, a discoverer of a gene sequence cannot profit from the discovery if he does not provide

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127 *Id.* at 537.

128 *Id.* at 521.

129 *See* Wamstad, *supra* note 121, at 134.

130 *See id.* at 131.

131 Johanna Jacob, Comment, *Should Our Genes Be Part of the Patent Bargain?: Maximizing Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable*, 28 SANTA CLARA COMPUTER & HIGH TECH. L.J. 403, 440 (2012).

132 *Id.*

133 *See* Wamstad, *supra* note 121, at 141–42.

134 Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1449–50 (2013).

products or services related to the gene sequencing. Whether the upfront cost saved by eliminating the necessity of patent prosecution will override waste created in these two scenarios will ultimately depend on the commercial value of a gene sequence, among other factors.

III. ANALYSIS

Patent law strives to balance the competing concerns of public access to new inventions and incentivizing patent owners to invent. *Myriad Genetics'* holding, although partially justifiable for attempting to promote and innovation and the dissemination of technologies, fails to maintain incentives to attract sufficient investments in future genetic research. This Note proposes a registration-reward system to reinstate the balance. Part III begins by analyzing the limitation of *Myriad Genetics'* holding. Next, it interprets Congress's intent demonstrated by the passage of the AIA to act upon the guidance provided by the Supreme Court in *Myriad Genetics*. Finally, Part III urges Congress to empower a newly created USPTO Board to adopt a registration-reward system, comparing the proposed system with other alternative solutions, and explaining why any potential concerns with system will be overridden by its benefits.

A. THE COURT'S RULING IN *MYRIAD GENETICS* IS PARTIALLY JUSTIFIED, BUT FAILS TO INCENTIVIZE FUTURE GENETIC RESEARCH

The Court's holding in *Myriad Genetics* that genes are not patentable subject matter is justified in that it better serves the goals of patent law than allowing genes to be patented. The goal of the patent system is to promote innovation, production, and dissemination of technologies.[135] Gene patents impede innovation more than they promote it because early development of genetic technology depends on the wide availability of information encoded in these important genes. Unlike other already developed fields, genetic testing is at its beginning stage of cumulating genetic information encoded in DNA.[136] Patents for isolated DNA would greatly increase downstream transaction costs by monopolizing the basic information encoded in the genes which could be used by many entities to develop gene testing methods, genetic drugs, and medical devices.[137]

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[135] Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. ECON. PERSP. 131, 136 (2002).

[136] *See* SACGHS REPORT, *supra* note 11, at 2.

[137] *See* Lee, *supra* note 99, at 675.

The Court, moreover, has a justifiable reason to set a high threshold of patentability in *Myriad Genetics* because patents shield patentees from competition for twenty years.[138] For a fast-advancing field such as biotechnology, this head start in many cases gives a patentee a right to monopolize a specific area for more than twenty years to come. Therefore, the stricter requirement for eligibility in *Myriad Genetics* balances the competing goals of patent law by promoting the dissemination of new knowledge and technology.

Furthermore, the Court's categorical ruling in *Myriad Genetics* is justified because newly discovered gene sequences would likely also not pass the nonobviousness test under § 103.[139] The *Myriad Genetics* Court's ruling suggests that the routine use of the isolation process, regardless of its complexity, it not an inventive act sufficient to meet the requirement of nonobviousness. While Myriad argued that they invested extensive capital and efforts in discovering BRCA1 and BRCA2,[140] a routine use of a process to generate a material of known characteristics that is obvious to one with "ordinary skill in the art" will not meet the requirements of § 103.[141]

Although the Court rightly held isolated DNA patent ineligible due to these justifications, the Court should have likewise held cDNA ineligible because the process of creating cDNA is also well-known and routine "to a person having ordinary skill in the art."[142] It is true that, unlike isolated DNA, which shares similar gene sequences with native DNA, cDNA's sequences of nucleotides are different. One major difference is that cDNA only contains coding regions (exons).[143] Since any given gene consists of over 90% of non-coding regions, the chemical structure of cDNA differs dramatically from that of native DNA. Nevertheless, measuring against the standard from *KSR*, cDNA would have difficulty meeting § 103's requirement of nonobviousness. A person with ordinary skill in gene sequencing who knows the process of creating a cDNA based on its matching DNA will be capable of using the same process to make cDNA to BRCA1 and BRCA2.[144] Therefore, despite other valid justifications,

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138 35 U.S.C. § 154.

139 35 U.S.C. § 103 (2011).

140 *See* ALBERTS ET AL., *supra* note 36, at 535–37.

141 35 U.S.C. § 103.

142 *Id.*; *see also* ALBERTS ET AL., *supra* note 36, at 535–37.

143 ALBERTS ET AL., *supra* note 36, at 537.

144 Some lower courts refuse to follow the Supreme Court's ruling on cDNA. *See* Ariosa Diagnostics, Inc. v. Sequenom, Inc., No. C 11-06391 SI, 2013 WL 5863022, V11 n.8 (N.D. Cal. Oct. 30, 2013).

the holding in *Myriad Genetics* failed to include cDNA within the scope of ineligible subject matter.

Most importantly, *Myriad Genetics*' holding will drive away private investments in the discovery of gene sequences, and thus shrink the pool of available gene sequences to use for further research and the development of new technology. Discovering a particular gene is a time-consuming and expensive, albeit conventional, process.[145] Moreover, it is uncertain whether the process will successfully find a particular gene. The strong, exclusive rights afforded by patents used to be sufficient to incentivize private entities to invest in the searching processes. The high threshold for patent eligibility set by *Myriad Genetics*' holding, however, will undoubtedly increase the risk for private entities in the genetic research field and potentially even remove their incentives to continue their efforts. Some scholars argue that the negative impact of *Myriad Genetics*' holding is inevitable, but patent rights are not and should not be the only incentive sufficient to attract private investments. An alternative type of protection for isolated gene sequences to attract private investments in future genetic research can work.

Contrary to what was argued by some scholars,[146] the effects of the Bayh-Dole Act do not prove that patent rights for newly discovered genes are necessary to maintain innovation in genetic research. It is true that after the passage of the Act, private funding increased greatly, as did patent applications; but, those patents were based on the successful results from the basic research supported by the government.[147] This government-funded research accumulated a rich knowledge base in the public domain that fueled the later development and patent applications after the passage of the Act.[148] Therefore, the increase in the number of patents after the passage of the Act is insufficient evidence to support the argument that patent protection caused the rapid development of biological research. Private funding is beneficial for biological research because it attracts talent and enables the researchers to procure better equipment, but patent rights are not necessarily the only way to attract private funds. There may be alternative ways outside the patent system to incentivize private players while facilitating the goal of patent law. This Note proposes an alternative type of protection for gene sequences that equally attracts private investment.

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145 *Id.* at *1.
146 *See generally* Mireles, *supra* note 109.
147 *See* Heller & Eisenberg, *supra* note 96, at 698.
148 *Id.*

B. CONGRESS SHOULD TAKE LEGISLATIVE ACTION

Since Congress did not pass any provision in the Leahy-Smith America Invents Act (AIA) to clarify the patent eligibility of DNA, it likely intended to defer to the judicial expertise on this hotly debated issue. However, as evidenced by the impact of *Myriad Genetics*' holding, the patent-eligibility of DNA is a policy question that is better left to the legislature. Thus, Congress should act upon the Court's guidance and resolve remaining issues left by the Court's ruling in *Myriad Genetics*. The divide between both scientific and legal minds in separately written judicial opinions by the Federal Circuit judges, amicus briefs, and disagreements within the branches of government demonstrate how "reasonable people differ on how science and patent law should align"[149] on the patent eligibility of genes. Legal analysis and strong emotions are in play behind the issue. For example, Federal Circuit Judge Lourie's opinion in *Myriad* "fell on the side of deference to long-held property rights," while Judge Bryson's dissenting opinion emphasized that "public policy outweighed that deference."[150] In all, the patent-eligibility of DNA is "inextricably intertwined with policy."[151]

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[149] *Compare*, *e.g.*, Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2-4, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585711 (arguing that DNA and human genes are unpatentable under 35 U.S.C. § 101 and the patents should be declared unenforceable because public health necessitates their invalidation); Brief for the S. Baptist Convention as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 585712 (arguing that gene sequence patents are unpatentable subject matter and are harmful to individuals no matter their religious beliefs); Brief of Amici Curiae E. Richard Gold et al. in Support of Appellees and Affirmance at 26, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 5558511 (arguing that the genetic sequence contained in DNA should be considered information and should therefore be excluded as unpatentable abstract subject matter unless the claim has a specific function), *with*, *e.g.*, Brief for the United States as Amicus Curiae in Support of Neither Party at 9-11, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320; Brief of Amici Curiae Rosetta Genomics, Ltd. et al. in Support of Defendants-Appellants, Supporting Reversal at 14-28, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853324 (arguing that isolated DNA is patentable subject matter, and that patents stimulate innovation). *See, e.g.*, Heidi Ledford, *Has the US Government Abandoned Gene Patents?*, NATURE.COM NEWSBLOG (Nov. 1, 2010), http://blogs.nature.com/news/2010/11/will_the_us_government_abandon.html ("No lawyers from the patent office are listed on the brief — a possible sign that the position has few fans at the USPTO, which has granted thousands of gene patents over the years.").

[150] *Ass'n for Molecular Pathology*, 653 F.3d at 1373 (Bryson, J., concurring in part and dissenting in part) ("In my view, those claims are not directed to patentable subject matter, and if sustained the

Seemingly, the lack of action from Congress indicates its acquiescence to granting patents to isolated DNA. In support of the contention that gene patents "cause more harm than good to society and technological development"[152] are concerns including the "preemption of future research; quality of care and patient access; and an unearned extended patent monopoly."[153] However, Congress, faced with the above concerns, took a very narrow approach in the passage of AIA. As mentioned, the language in section 27 states that the "Director [of the USPTO] shall conduct a study on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist."[154] It continues, "Notably, the study calls for research into second opinions on diagnostic tests and nothing more."[155] Compared to the rest of the extensive patent reform brought by the Leahy-Smith America Invents Act, this statement is "extremely narrow,"[156] despite awareness in Congress of the issue involved in the *Myriad* case.[157]

But, Congress's acquiescence to granting patents for isolated DNA may suggest that it intended to receive guidance from the Court on the doctrine of patent-eligible subject matter. Its statement, although narrow, fully expressed its concern about the harmful consequences of granting gene patents. Since the Court began to define the subject matter doctrine in *Funk Brothers*, it has refined its interpretation of § 101 numerous times in recent years.[158] The Court, therefore, arguably has valuable experience in judging the patent eligibility of DNA, and can provide much-needed guidance to the Congress.

Upon receiving the guidance from the Court in *Myriad Genetics* that gene sequences are not patent-eligible, Congress should now craft a legislative

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court's decision will likely have broad consequences, such as preempting methods for whole-genome sequencing, even though Myriad's contribution to the field is not remotely consonant with such effects.").

151 Jacob, *supra* note 131, at 426.

152 Mitchell & Remus, *supra* note 88, at 35.

153 Jacob, *supra* note 131, at 434.

154 Leahy-Smith America Invents Act, § 27(a).

155 Jacob, *supra* note 131, at 434.

156 *Id.*

157 See bills submitted by both parties pertaining to the issue, e.g., Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007) (sponsored by one Republican and five Democratic Representatives) and Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002) (sponsored by one Republican and two Democratic Representatives).

158 *See Funk Bros. Seed Co.*, 333 U.S. at 127; *Benson*, 409 U.S. at 63; *Flook*, 437 U.S. at 584; *Chakrabarty*, 447 U.S. at 303; *Diehr*, 450 U.S. at 175; *Bilski*, 130 S. Ct. at 3218; *Mayo Collaborative Servs.*, 132 S. Ct. at 1289; *Myriad Genetics*, 133 S. Ct. at 2107.

solution to address the reduced incentives to invest in the discovery of new gene sequences caused by *Myriad Genetics*' holding. This Note proposes a reward system whereby a Board within the USPTO would provide royalties to discoverers of new genes in order to attract an equivalent scale of efforts and investment to that under the current patent system.

C. SOLUTION: THE REGISTRATION-REWARD SYSTEM

1. The Framework of the Registration-Reward System. Congress should authorize the USPTO to form a Board consisting of economists, patent attorneys, and technical experts to administer a registration and reward system ("the reward system"). Under the reward system the Board would determine the economic value of a discovery of a gene sequence and designate a royalty i.e., a small percentage of profit that is to be paid to the Board by anyone using a discovery that is registered with the Board, taking into account the efforts necessary to make the discovery and the existing and potential markets for the particular discovery.

The licensing division of the U.S. Copyright Office, which administers the compulsory and statutory licenses in the Copyright Act, can serve as a model for the newly created USPTO Board. However, it should also differ in several aspects. First, the Board should be set up within the USPTO because the patent office is in the best position to recruit patent attorneys and technical experts to answer questions about any particular genes. The USPTO has years of experience of reviewing biological inventions, so a decision made on the economic value of a gene sequence by the Board will have credibility from the get-go.

Second, the registrant will receive entitlement to a royalty from the Board, unlike a registrant with the Copyright Office who gains stronger legal recourse against potential infringers.[159] The Board should build an economic model to quantitatively value a newly discovered and registered gene sequence, taking into account several primary factors: the amount of reasonably necessary efforts needed to locate the gene, the types of application for which the gene can be used, and the level of creativity involved in the discovery. Additional factors include the current price of diagnostic testing, the number of competitors working on the same sequence, possible advancements in diagnostic testing, derivatives markets, the extent of the disclosure, and the likelihood of

[159] In compulsory licensing situations, the registrant will also be entitled to a royalty, but compulsory license differs from the Registration-Reward system. *See supra* Part II.

commercialization. The requirements for patentability[160] are useful to determine the amount of reward, but failure to meet any of them will not prevent registration. Unlike the patent system, where an inventor either receives protection for twenty years or nothing, the flexible registration-reward system will adjust the amount of royalty according to the extent to which the requirements of patentability are satisfied. The Board could enlist help from economists, or fund research to develop the economic model. Such a model would be constantly updated by data related to each registered gene sequence. Over time, the model could become fairly robust. The Board, owning this model, will then be the true experts in valuation of new gene sequences. This Note will next discuss some of the factors in the economic model, the registration process, and the accessibility of registered gene sequences.

The Board should hire outside experts to determine necessary efforts reasonably required by a person with an ordinary skill of art to uncover a gene sequence. Technical experts on a particular gene sequence may be competitors of the registrant. Since the methods of marking genetic sequences are well-known and repetitive, the likelihood that several competitors search for one particular gene is high, as witnessed in *Myriad Genetics*.[161] The Board should therefore have little difficulty in hiring one of the competitors to give an expert opinion, which the Board will use to negotiate a fair royalty with a registrant. The major concern is that biotechnology develops so rapidly that any attempt to estimate the reasonable efforts required to locate a gene sequence may produce inaccurate results; but using experts who are familiar with the latest developments in genetic research will likely mitigate this concern. The greater the necessary efforts required in locating a gene, the higher the royalty the discoverer is entitled to. A market analysis is then needed to nail down the amount of royalty that will be granted.

Two important factors in estimating the value of a discovery of a particular gene are the current and future market demand. The board would hire disinterested firms to perform this market analysis. These firms often perform similar analysis of newly invented technologies for investment firms and corporations, so this type of analysis will be familiar to them. To ensure accuracy, multiple testimonies are necessary. If multiple inputs vary drastically, the Board has the option to take the average. Not surprisingly, costs may be an issue because the services of these firms are not cheap, but there are two ways in which they can be paid. First, firms can either receive direct payment, just as

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[160] *See supra* Part II.

[161] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187 (S.D.N.Y. 2010).

they would for providing services to any other clients. Alternatively, the Board can agree to share part of the royalty that they will collect from the users of a registered gene sequence. Either way, the reward system will require an initial round of funding to start, which Congress will have to initiate and provide.

The accuracy of market analysis is inevitably limited. Market analysis for genes that have known applications or possible applications will be more accurate than that for genes with no immediately identifiable utilities. Even a gene sequence with known applications can quickly be replaced with a later-discovered gene because of the rapid advancement in the biotechnology field. The discoverer of a new gene sequence bears the burden of the inaccuracy of the valuation by the Board. This should incentivize entities to thoroughly analyze risks before their investment.

The Board will then offer the determined amount of royalty to the discoverer of a new gene sequence. The discoverer can reject the offer and keep its discovery as a trade secret, or the discoverer can alternatively negotiate with the Board. In order to prevent negotiation gridlocks, the Board will allow an entity that discovered the same or substantially similar gene sequence later than the original discoverer to register preliminarily while a negotiation between the Board and the original discoverer takes place. If the original discoverer cannot reach an agreement with the Board one year after the entity's preliminary registration, the preliminary registration will automatically be converted to an official registration, and the original discoverer loses the right to register. The Board can refer to precedents in patent infringement case law to determine whether two discoveries are substantially similar. This rule would prevent any intentional delay by a discoverer in reaching an agreement with the Board.

Third, the registration process with the Board should be as straightforward as the process with the Copyright Office. Any discovery of a gene sequence could be registered. Registration requires disclosing the discovery, paying a registration fee, and negotiating a royalty with the Board. A registered gene sequence will fall into the public domain after 150 years from the date of the registration, which is similar to the life of a copyrighted work.[162]

Fourth, like the works registered with the Copyright office, all gene sequences that are filed with the Board should be indexed in multiple ways and searchable by the public. The gene search system can be indexed by the genetic code, i.e., the long sequence of various combinations of A, G, T, and C, or they can be indexed according to their chemical groups and domain names. For

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[162] 17 U.S.C. § 302 (copyright in a work "endures for a term consisting of the life of the author and 70 years after the author's death").

example, the BRCA1 gene will be indexed as C3H4 (Zinc finger) and BRCT (BRCA1 C Terminus). Thus anyone who is interested in discovering a sequence containing this domain can search to see whether it has already been discovered. The same gene sequence will be assigned a number that will appear consistently regardless of how one searched for it. Each registration will contain standard categories of information, including the royalty to the board (in percentage format), how it was discovered, potential applications recommended by the Board, the predicted market, the nonobviousness and novelty of the sequence, and anything important to promote the understanding of the searcher about the gene sequence. The standardized information will make registered gene sequence easier to understand for searchers, thus improving the efficiency of the system. It also provides searchers notice about the discovery of a particular gene sequence and prevents efforts to reinvent the wheel.

Fifth, unlike the copyright registration system, the reward system imposes an obligation on a searcher to pay royalties if he or she uses a registered gene sequence and profits from that usage. A searcher must subscribe to the system in order to search for any relevant gene sequences. When he or she signs up for the system, a small subscription fee will be required to authenticate a subscription agreement that states that he or she agrees to pay according to the royalty assigned to each registered discovery if he or she generates any profits. Any subscriber to the gene search system prima facie used all discoveries in the system. Therefore, the reward system is quasi-open to the public.

Non-subscribing entities that use any registered discovery to generate profits must also pay the royalty, or will be subjected to a fine. The reward system will also reward any whistleblower for reporting undisclosed usage. The whistleblower must file a complaint grounded on concrete facts and will only be rewarded if the complaint turns out to be true, risking a penalty if it does not. An alternative approach could be to collect a percentage of profits only from subscribers. The latter is a bright-line rule and easier to work with, but may discourage subscription.

Sixth, just as the licensing division of the U.S. Copyright Office is authorized to collect royalties for compulsory licenses, the Board should be empowered by the legislature to collect a royalty from anyone who uses any registered discovery. Any use will be subject to collection. "Use" should be defined as direct incorporation of any registered sequence to a product or a service,

including diagnostic tests for a trade purpose.[163] The Board will collect royalties from any patents that incorporate any registered sequence. Indirect use of the gene sequence, such as using the registered gene sequence for finding another gene sequence, is not "use," and thus will not subject the indirect user to royalty payments.

Seventh, each discovery should be assigned a royalty rate at which any user of this discovery is subject to pay to the Board. Although the royalty may be small most of the time, the cumulative economic return over 150 years may be even more than what a patent could obtain through licensing. Thus, this royalty will provide incentives to private entities to invest efforts and capital to locate these gene sequences. On the other hand, if the entity using the sequence does not generate profits, it is not obligated to pay the Board. Therefore, early-stage companies and research institutions can potentially gain great benefits from public access to these sequences.

Users of multiple registered sequences will pay an apportioned royalty rather than the sum of royalties assigned to each registered gene. For example, consider a product using five registered gene segments with the assigned royalty of 0.2%, 0.3%, 0.4%, 0.5%, and 0.6%, respectively. The calculation is easy: each assigned royalty divided by the sum of all assigned royalties constitutes the apportioned royalty. Thus, the seller of the product in this example must pay the Board the apportioned royalty of 0.1%, 0.15%, 0.2%, 0.25%, and 0.3% for the five registered gene sequences. Therefore, users of multiple registered gene segments need not deplete all of their profits to pay royalties to the Board when the accumulative royalty is equal to or greater than 100%. Although the royalty to each registered gene is reduced significantly by apportionment, it is not unfair because each particular registered gene is only one of many used in the product

Also akin to the licensing division of the Copyright Office, the Board will set up an account for each registered gene to deposit royalties and periodically distribute them to registrants. Since the USPTO has no expertise in finance management, it shall be up to the registrants to choose whether to hire wealth management experts, or allow the Board to keep the cash in the accounts under prevailing interest rates and distribute the royalties each year to the registrants, unless they withdraw all funds from the accounts before the distribution date.

Like the USPTO, the decision by the Board is subject to judicial review. Private entities should not be deprived of their rights to a jury if they allege they were forced by the Board to forfeit their rights to a reward or to a higher

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[163] This definition is narrower than that from the patent law as appeared in 35 U.S.C. § 271 ("Except as otherwise provided in this title, whoever without authority makes, uses, offer to sell . . . infringes the patent.").

reward. The judicial review process will focus on issues such as whether the agreement between the registrants and the Board was unconscionable, was made under duress, or was made as the result of mistake. These issues will be less technical than inquiries for patent prosecution.

The reward system will further the goal of the patent system to promote innovation in genetic testing. As previously discussed, gene sequences are critical for downstream scientific users and excluding them from the public only hurts society as a whole. However, discoverers should not be left empty-handed, or they will refuse to invest in or disclose their discoveries. The process of locating a gene on DNA, although routine and well known, is difficult and time-consuming. Similar to treasure hunting, those with sufficient resources and the strongest commitment usually succeed. As treasure hunters are rewarded by their findings, discoverers of new gene sequences should likewise receive some type of reward. In light of the Court's ruling that gene sequences are patent-ineligible subject matter in *Myriad Genetics*, the legislature should therefore act to set up the reward system within the USPTO to promote innovations in genetic research without excluding newly discovered gene sequences from the public. The reward system will address the remaining public concern in wake of *Myriad Genetics* and is the most effective approach, among multiple proposed solutions, to serve the goal of the patent system.

2. The Advantage of the Registration-Reward System over Alternative Policy Choices. The reward system is overall the best solution compared to patent pools, compulsory licensing, patent donation, and other proposed solutions. The reward system is a better alternative to patent pools because the system is not anticompetitive. Patent pools discriminate against non-member entities because licensees will prefer to shop within the patent bundles and negotiate a single license covering multiple technologies, rather than select individual technologies outside the pools. The pool is a one-sided platform that aims to maximize the benefits for the members of the pools.[164] By contrast, the reward system is a two-sided platform. The Board both pays royalties to registrants and ensures public access to registered gene sequences. The registrants are out of the picture when potential users shop for their gene sequences of interest. Actual users must pay the royalty to the Board.

Second, the proposed system offers more advantages than compulsory licensing. Registrants are not forced to license their discoveries for the public interest. Although they are encouraged to register, discovers of gene sequences can choose to keep their discoveries as trade secrets without any legal obligations. This alternative of trade secret protection may be beneficial if they

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[164] *See* Scalia, *supra* note 118, at 1661 n.167.

deem that the potential award of registration is not worth the benefits reaped from keeping their discovery in secret. The owners of these discoveries are compensated at a rate that they have agreed to prior to their disclosure, and are less coerced than if they had to accept an imposed licensing fee. Due to its contractual, non-coercive nature,[165] the reward system will attract many gene sequences into its pool. Most importantly, this reward system is a more direct and cheaper approach than compulsory licensing. Registration with the Board does not involve expensive patent prosecution. As a result, the users of the registration-reward system will likely be subject to lower royalty than licensees of compulsory licenses. In addition, this system will avoid massive patent litigation costs because the registrants with the reward system have agreed to a designated royalty prior to the public disclosure of their discoveries. Overall, the reward system will be much more affordable than compulsory licensing.

Third, the reward system is also better than the alternatives of a patent donation or voucher system. Unlike a patent donation or voucher system, the reward system does not rely on the registers' charitable efforts, which contain too much uncertainty and will fail to attract a great number of newly discovered gene sequences.[166] The reward system even has the potential to include all newly discovered gene sequences over time because the cumulative royalty payment for a registered gene sequence over 150 years can be high.

Finally, the closest approach to the reward system is the FDA-exclusive right system.[167] This approach allows the FDA to approve or reject a gene produce or service based on whether the owner of the product or service is the original discoverer of the gene. Like the reward system, this approach does not require discoverers to go through the patent prosecution process to obtain exclusive rights. It is also similar in the sense that it imposes no burdens on entities that use the newly discovered gene sequences on not-for-profit research.[168] Although this approach seems more convenient because it takes advantage of many existing functions served by the FDA, its attempt to confine solutions within the existing system poses new problems.

The first problem is that the FDA-exclusive right system creates waste. This approach likens monopolic patent rights but lacks the flexible alienation of patents. Because almost all products and services based on a gene require the FDA's approval, this approach essentially blocks anybody from using the gene. Seemingly, this approach still allows non-profit uses of genes; however, these

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165 *See* Yoon, *supra* note 120, at 970.

166 *See* Jacob, *supra* note 131, at 440–41.

167 Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399 (2013).

168 *Id.*

non-profit users can hardly receive funding for the lack of potential commerciality of their research. In addition, any discoverer of a gene cannot assign the gene to others because the FDA will not approve others' products based on the gene made by the discoverer. The restricted commercial exploitation to the original discoverer of a gene will create waste.

Second, the FDA-exclusive right system wrongly empowers the FDA to approve a product based not on safety but on who is the first to discover a gene sequence. The FDA has the scientific expertise to determine whether one product is safe for the market, but providing exclusive rights is essentially a legal question to which the FDA does not possess the requisite expertise. This situation would be akin to letting a film rating agency, such as Motion Picture Association of America, determine an actor's right of publicity. In all, the FDA simply lacks the expertise to perform such a role and thus should not be granted the authority to do so.

Third, the FDA-exclusive right approach tends to discriminate against individual discoverers by discouraging their applications. Individuals with little experience in dealing with the FDA may be intimidated by its complex and complicated approval process. Therefore, these individuals may hesitate to apply for the approval of any products made out of a newly discovered gene sequence. The reward system, by contrast, avoids the problems entailed by the FDA-exclusive right approach. Although it too has some limitations, they are ultimately overridden by its advantages.

3. The Benefits of the Registration-Reward System Override its Potential Problems. Some potential concerns with the registration-reword system include the costs and effectiveness of a new bureaucracy, granting too much power to such a bureaucracy, and the system's discrimination against domestic corporations.

First, although some argue that the Board may become an expensive bureaucracy, the function it serves will greatly outweigh its costs. The transaction costs it saves will be much more than the expense required to run the Board. For example, the high costs from infringement litigation over gene patents will be eliminated. Although the Board may initiate litigation to collect royalties, the scale and extent of litigation will be greatly reduced in comparison. Patent litigation cases center around the validity of a patent in question and whether the alleged infringing product contains every element claimed in a patent. Collection suits involve the more direct question of whether the would-be-defendants incorporated a gene sequence at question into their products. Faced with the less ambiguous question involved in the collection suits and thus the higher risk of fines, would-be-defendants likely will choose to pay royalties, thereby avoiding litigation. The system also saves the expense of securing licenses from a patentee. Under the reward system, each newly discovered gene sequence requires only one round of negotiation between the Board and the

registrant. After that, the gene sequence is open to any users who are willing to pay designated royalties. Users avoid dealing with the registrant. By contrast, each potential licensee of a patent must negotiate with the patentee. Thus, each use will require a separate negotiation and greatly increase transaction costs. Even for patent pools where one license covers all, each entity needs a separate blanket license. The reward system avoids this complex blanket license because the newly discovered gene sequence, once registered, is open to the public. Therefore, the cost-saving advantage of the reward system will justify its existence.

Another concern is the effectiveness of such a system. Some argue that the reward may not be a strong enough incentive for private firms. While this argument may be true in the short term, the aggregate effect of single digit profits will be significant over 150 years. For gene-sequences that have no known practical applications immediately, 150 years should be long enough to prove their worth. In addition, once the reward system is established, a new form of property rights will be created. Private entities that prefer a quick capital return can alienate their rights to royalty from the Board. Therefore, the reward is at least comparable to returns from gene patents, whether it is generated in a short or long term, and private firms will have strong enough incentives to register with the reward system,

Next, another potential concern is that the reward system will risk granting too much power to the Board. There seems to be an asymmetry of power between the Board and registrants; however, such risk is mitigated both by judicial review and by registrants' ability to either negotiate a royalty acceptable to them, or to maintain their discoveries as trade secrets. Like the patent system, the reward system includes judicial review of the reasonability of the Board's act and the royalty, which serves as a major check. Moreover, the registrants in the reward system can decide the extent of their disclosures—unlike the patent system that requires an applicant to disclose enough information to enable a person of ordinary skill in the art to reproduce the invention, the reward system has no such requirement. A registrant may choose to disclose less information in exchange for a smaller royalty. Therefore, potential asymmetry of power within the reward system is reasonably mitigated by both judicial review and the ability to decide the amount of disclosure through the negotiation process.

Another concern is the reward system's international implications because the system seems to discriminate against corporations in the United States. Similar to the patent system which differs by countries, a uniform international legal system is desired yet nonexistent. No other country has a similar reward system for gene sequences, so U.S. corporations that use any gene sequences will be subjected to collection of royalties, but foreign corporations will not.

Due to the high costs of litigating overseas, the Board may give up chasing foreign corporation for small royalties. Nevertheless, there is a solution drawn from other similar situations where U.S. law applies to foreign entities: these foreign corporations found to have directly used the gene sequences will have a judgment pending against them in the U.S., and unless they pay royalties owed to the Board, such judgment will impact their future activities in the U.S.[169] This system, when mature, has the potential to be a model from which other countries can learn and simulate.

Overall, the Court's holding in *Myriad Genetics* is partially justified for balancing goals of patent law. However, the result fails to maintain adequate incentives for private investment in genetic research, and wrongly declared cDNA patent-eligible subject matter. Upon receiving the Court's guidance, Congress should now enact the reward system to resolve the lingering concerns. Though the reward system presents some potential limitations, it is better overall than alternatives and is needed to encourage future genetic research.

IV. CONCLUSION

The Supreme Court's categorical rejection of naturally occurring DNA as patent-eligible subject matter in *Myriad Genetics* clears the roadblocks for further development of microarray testing for genetic research. However, this result will discourage private investments in the discovery of genes. Therefore, this Note proposes that Congress should take legislative action and set up a registration-reward system within the USPTO.

The registration-reward system will compensate any registrant of a newly discovered gene at a royalty rate determined by a Board consisting of technical and legal experts. The Board will consider many factors when determining the value of the gene discovery, including market demand, efforts required, and the extent of disclosure by the registrant. The registrant will then come to an agreement with the Board on a royalty to be collected from potential users of the gene and the Board will publish the gene in the system available for any subscriber of the system to search and see.

The registration-reward system is the best solution in light of *Myriad Genetics*' holding because it places the knowledge of genetic information into the public domain, while incentivizing private entities to invest in the discovery of genes, thereby balancing competing policy concerns. Additionally, it bypasses the expensive patent prosecution process and avoids massive patent litigation costs. It is less coercive than compulsory licensing, less anticompetitive than patent

[169] 28 U.S.C. § 1350.

pools, more predictable than patent donation, and more economic than the FDA-exclusive right system. Although running the registration-reward system will also incur costs, saved transaction costs through eliminating patent litigation and patent license negotiation will outweigh the operating costs of the registration-reward system. Moreover, the cumulative royalties for many products and services over 150 years will be comparable to or higher than the value of a patent on a gene, and overall enough to attract discoverers of genes into the registration-reward system.

In conclusion, the system has the potential to help the Court to deal with the issue of patent eligibility, and can finally and effectively strike "a delicate balance between creating incentives that lead to creation, invention, and discovery" and "impeding the flow of information that might permit, indeed spur, invention."[170]

[170] *Myriad Genetics*, 133 S. Ct. at 2116.