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DNA Real Estate: The Myriad Genetics Case and the Implications of Granting Patent Eligibility to Complimentary DNA.

SARAH ELIZABETH HAGAN*

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I. INTRODUCTION

In the summer of 2013, the U.S. Supreme Court decided in *Ass'n for Molecular Pathology et al., v. Myriad Genetics, Inc.*, that an isolated section of DNA would not be patent eligible, but that another variant of DNA, complimentary DNA, was not precluded from patent eligibility.¹ “[S]ynthetically created DNA known as complimentary DNA (cDNA) . . . is patent eligible because it is not naturally occurring.”² While the full im-

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1. *Ass'n. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

2. *Id.* at 2111.

pacts of this decision have yet to be played out among the scientific community, it can be hypothesized that the consequences of this decision may lead to the results for which the Justices were intending to avoid.³

As our scientific knowledge increases at a rapid pace, courts have consistently tried to keep up with the ever-changing economic implications of the financially driven market of medical treatment, discoveries, and cures. Unfortunately, the law is fluid, yet not organic enough to adapt as quickly to this industry, and the granting of complimentary DNA patent rights may be beyond the scope for which the current laws were adopted. Do we know the implications of commercializing the tools associated with DNA, and when will ownership of such components exceed the very ethical limits for which we aim to protect?

This Note will examine the decision of the recent Supreme Court ruling in *Ass'n for Molecular Pathology v. Myriad Genetics*, with a specific focus on the second holding and the implications this decision may have on the scientific community from both an economic and ethical perspective. In addition, this Note will briefly address the concern that the ruling is beyond the scope of the Court's understanding of the technology and argue that complimentary DNA (cDNA) should, in fact, be precluded from patent eligibility.

Beginning in Section II, Part A will contain a concise description of the primary genetic components relevant to the *Myriad* case; specifically, how each component arises and their functionality with respect to other genetic elements and processes. Next, Part B will provide a brief history on the development of patent law, the framers intentions, the implied exceptions to patent eligibility, and the standard balancing test courts utilize with the granting of such patent rights. Lastly in Section II, Part C will touch on the role that DNA has played throughout history with respect to patent law and discuss the transition of patent eligibility from plants to bacterium and then to higher-level multicellular organisms such as mammals. Part III will provide an in-depth exploration of *Ass'n for Molecular Pathology et al., v. Myriad Genetics, Inc.*, including prior history and specific cases that helped shape the Court's holding. Part IV will provide an analysis to the *Myriad* case and a discussion on the pros and cons of the decision, as well as hypothesize the legal and policy ramifications post decision and the options for the field of patent law moving forward. Finally, Part V will provide the conclusion to this Note.

3. *See id.* at 2116. (The first holding in this case respected the recognized balance between “creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’” (citing the discussion in *Mayo Collaborative Servs. Inc. v. Prometheus Labs. Inc.*, 132 S. Ct. 1289, 1305 (2012))).

II. BACKGROUND AND HISTORY

A. GENETICS 101

Each human cell normally has twenty-three pairs of chromosomes,⁴ which have been estimated by the Human Genome Project to contain approximately twenty thousand to twenty-five thousand genes.⁵ Genes are encoded by means of deoxyribonucleic acid, commonly known as DNA;⁶ they are the source of hereditary traits and essentially serve as the “instructions to make molecules.”⁷ DNA, which forms the shape of a double helix and can be visualized as a spiral ladder,⁸ is made up of a sugar-phosphate backbone held together by ladder rungs comprised of two bonded nucleotides.⁹ In DNA there are four possible nucleobases: adenine (A) and thymine (T) which bond together, and cytosine (C) and guanine (G) which bond together; with RNA, thymine (T) is replaced with uracil (U).¹⁰ Ribonucleic acid, generally referred to as RNA, is a single-strand version of nucleotides and will be discussed in further detail below.¹¹ The various sequences of DNA nucleotides either do or do not code for amino acids; introns code for nothing,¹² while exons code for the twenty types of amino acids.¹³ Thus, the expressed segments of the gene, known as coding regions, are the exon regions¹⁴ and the amino acids that exons code for can be combined to make proteins.¹⁵ This necessary transfer of genetic information from DNA to RNA and then into proteins is commonly titled the *Central Dogma* of Molecular Biology.¹⁶

4. U.S. DEP’T OF HEALTH & HUMAN SERVS., *Handbook-Help Me Understand Genetics* 16, reprinted in Genetics Home Reference (2014), <http://ghr.nlm.nih.gov/handbook.pdf>.

5. *Id.* at 13.

6. *Myriad*, 133 S. Ct. at 2111.

7. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 13.

8. *Id.* at 9.

9. *Myriad*, 133 S. Ct. at 2111. See also U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 9 (defining nucleotides as being made up of a base, sugar molecule, and phosphate molecule. Thus, a nucleobase is the base attached to the sugar-phosphate backbone.).

10. *Myriad*, 133 S. Ct. at 2111.

11. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 24.

12. *Myriad*, 133 S. Ct. at 2111.

13. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 18.

14. Jonathan B. Losos et al., BIOLOGY 349 (McGraw-Hill ed., 8th ed. 2007), available at http://highered.mcgraw-hill.com/sites/9834092339/student_view0/chapter18/cdna.html.

15. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 18.

16. *Id.* at 24.

The production of proteins involves a two-step sequence.¹⁷ Through a process called transcription, the double-stranded DNA helix unwinds and one strand is used as a template for the production of single-stranded pre-RNA¹⁸—this is the method of transferring the genetic information stored within DNA to an RNA molecule.¹⁹ Next, in a natural process, all the non-coding sequences—the introns—are spliced out of the single-stranded RNA and a resulting mRNA strand containing only exons is created.²⁰

During a second process known as translation, the mRNA is read by a ribosome that synthesizes (creates) certain amino acids based on an mRNA nucleotide combination of three.²¹ Complimentary DNA, also referred to as cDNA, is the mirror image of mRNA—a naturally occurring product in the transcription and translation processes of DNA replication.²² Thus, the name Complimentary DNA explains that the cDNA strand is “‘complimentary’ to the mRNA from which it is produced—that is, each base in the cDNA can bind to the corresponding base in the mRNA from which it is generated.”²³

In laboratories such as Myriad Genetics, Inc., complimentary DNA is created synthetically from the mRNA strand by assessing the nucleotide bonding properties of the isolated natural mRNA product and making a mirror (inverse) image of the mRNA. The result is the manufacturing of an exon-only strand of DNA, cDNA.²⁴

B. PATENT LAW

Through the Constitution, Congress has been afforded the authority to legislate in order “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]”²⁵ Patent law was designed as a property right and gives the owner of the patent the right to exclude others for a specified time, from making, using, or selling their invention.²⁶ In

17. *Id.*

18. *Myriad*, 133 S. Ct. at 2111.

19. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 4, at 24.

20. *Myriad*, 133 S. Ct. at 2111.

21. *Id.*

22. *Id.*

23. *Ass’n. for Molecular Pathology v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181, 198 (S.D. N.Y. 2010).

24. *Myriad*, 133 S. Ct. at 2111.

25. U.S. CONST. art. I, § 8, cl. 8.

26. Joe Miller, *Patent Law: How Patents Grew Over Time To Include Living Organisms*, COOKING UP A STORY BLOG Part 1 (2009), <http://cookingupastory.com/author/joe->

1952, patentable inventions were recodified within 35 U.S.C. § 101.²⁷ This section states that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”²⁸ Thomas Jefferson, the original author of the Patent Act of 1793, wrote the almost exact language above (“process” now replaces the word “art”) due to his personal philosophy that: “ingenuity should receive a liberal encouragement.”²⁹

To determine how broad or narrow the subject matter intended by the language was to be construed, we must look to the legislative history—specifically the Committee Reports associated with the 1952 Patent Act. These reports indicate “that Congress intended the statutory subject matter to ‘include anything under the sun that is made by man.’”³⁰ Specifically, the subject matter listed within Section 101 are outlined: (1) process, (2) machine, (3) manufacture, and (4) composition of matter.³¹ While not listed, courts do observe exceptions to this section: “We have ‘long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.’”³² Such exceptions are necessary to the field of patent law because they are the “basic tools of scientific and technological work” that are not protectable and therefore free to the general community.³³ The evolution of these recognized inherent exceptions dates back to a 1948 case where Justice Douglas stated that:

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recog-

millar. Patent law, as a property right, is based in the economic principle of incentives for inventors.

27. 35 U.S.C. § 101.

28. *Id.*

29. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting 5 Writings of Thomas Jefferson 75, 76 (Washington ed. 1871)).

30. *Id.* at 309 (quoting the Committee Reports in 1952 in relation to the subject matter of what is patent eligible). S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952).

31. 35 U.S.C. § 101.

32. *Ass’n. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (citing *Mayo Collaborative Servs. v. Prometheus Lab., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

33. *Id.*

nizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.³⁴

This discussion by Justice Douglas in *Funk Bros. Seeds v. Kalo Inoculant Co.* solidified the legal perspective that a discovery of the accomplishment of nature, whether it be a product or law, is not something that is protectable.³⁵ These exceptions, however, must also be somewhat narrowly construed so as to not impact the field of patent law in such a manner that creativity and innovation are stunted; this is because it is implicit in every invention that the application of the “laws of nature or natural phenomena” must be utilized.³⁶ The fear of an overzealous awarding of patents is that the incoming streamflow of information would be halted, and it is that very flow which also plays a critical role as the driving force for authors to invent.³⁷ Thus, a standard is established by striking a balance of the factors described above—using an interpretation of what courts apply to current patent claims to determine whether the subject matter’s eligibility for the award of a patent is sufficient.³⁸ As will be discussed, it is the technology with which we apply to the language of the statute that has changed dramatically over the years, not the statutory language itself.³⁹

C. DNA’S RELATIONSHIP WITH THE COURTS.

In the 1970’s, with the decision of *Diamond v. Chakrabarty*, the issue of patentability with respect to living organisms, specifically, genetically modified organisms (commonly known today as GMOs), was laid on the table.⁴⁰ *Diamond*’s decision was crucial to the evolution of patent law and living organisms in that a microbiologist was granted patent eligibility on a *Pseudomonas* bacterium that contained two plasmids that were not naturally found in the *Pseudomonas* bacterium without the addition performed by the scientist.⁴¹ Mr. Chakrabarty, the notable microbiologist in this case, was able to successfully implant “stable and energy-generating plasmids” into the bacterium and the resulting organism was then able to assist with the

34. *Funk Bros. Seeds v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

35. *Id.*

36. *Mayo Collaborative Servs. v. Prometheus Lab., Inc.*, 132 S. Ct. 1289, 1305 (2012).

37. *Id.*

38. *Id.*

39. *Miller*, *supra* note 26.

40. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980). This is arguably the first decision regarding such subject matter as it relates to today’s technological understanding with the recent *Myriad* case.

41. *Id.*

degradation of crude oil.⁴² It was determined that, while the bacterium was naturally occurring and therefore not patentable, the addition of the plasmids was sufficient enough to constitute both a new composition of matter and manufacture. Thus the subject matter requirement to be awarded a patent was met.⁴³

After this decision, the Patent and Trademark Office (PTO) published an Animal-Patentability notice given by Donald Quigg, the Assistant Secretary and Commissioner of Patents and Trademarks in 1987.⁴⁴ This notice stated that, while the PTO was now currently evaluating patent applications for multicellular organisms, the distinction of *non-human* must be made in order to avoid an application rejection by the PTO.⁴⁵ It was obvious in the notice that the PTO was relying heavily on the decision in *Chakrabarty*; further reiteration was provided so that only a “new form, quality, properties or combination not present in the original article existing in nature” would be eligible for a patent award.⁴⁶ The important distinction of *non-human*, as made by the PTO notice, left open the possibility for patent eligibility to now extend to animals and plants, in addition to the single-celled bacteria that Chakrabarty was awarded exclusionary rights to—this was an obvious foreshadow as to the future direction of genetic engineering.⁴⁷

In patent law there are three different types of patents: utility, plant, and design.⁴⁸ Utility patents, also known as “patents for invention,” are those that contain the four subject matter categories previously discussed and identified in Jefferson’s 1793 Act.⁴⁹ Design patents are awarded for “a new, original, and ornamental design embodied in or applied to an article of manufacture[.]”⁵⁰ Lastly, plant patents are granted for a “new and distinct, invented or discovered asexually reproduced plant including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state[.]”⁵¹

In exchange for the granting of the utility patent, the benefit to the public is the release of the author’s very detailed description of the item so as to encourage and educate others of their design and further stimulate

42. *Id.* at 322 n.1. Defining a plasmid as a “hereditary unit.”

43. *Id.* at 318.

44. Donald Quigg, 1077 Off. Gaz. Pat. & Trademark Office OG 24 (April 21, 1987).

45. *Id.*

46. *Id.*

47. *See id.*

48. Miller, *supra* note 26.

49. Electronic Information Products Division, *Types of Patents*, USPTO <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/patdesc.htm> (last visited Nov. 23, 2014).

50. *Id.*

51. *Id.*

intellectual development relating to the matter.⁵² With the addition of the plant patent to the ranks, the U.S. government was the first in the world to develop this category and award patents to plant varieties.⁵³ The statutory language of this patent criterion, however, was narrowly construed so as to exclude any naturally occurring plants that have been derived from seeds and not asexually reproduced.⁵⁴ This means that if a plant is generated that is biologically identical to an asexually reproduced plant, the naturally generated plant will be excluded from patent eligibility but the asexually reproduced plant will not be.⁵⁵ After the development of these patent criteria in the 1930s, the law evolved to incorporate the Plant Variety Protection Act (PVPA) in 1970, which, while not part of the Patent Act, still provided for a *patent-like* protection for plant varieties of “seed crops.”⁵⁶ Further exploration of plant patents is beyond the scope of this article-yet it is important to understand the background of available patents and the evolution of patents that specifically relate to living organisms, whether they are simply unicellular like bacteria,⁵⁷ or multicellular such as plant⁵⁸ and animal. The progression of our scientific and technological understanding from bacteria to plant and then to animal, and the accompanying associated economic impacts, is certainly a predictable one.

The next major transition of biological patents was to patent animals. The patent awarded in 1988 to the Oncomouse, produced in Harvard laboratories, was given to the transgenic mouse and still today marks an important step in the research leading to the treatment and cure for cancer.⁵⁹ Due to the successful transfer of human DNA to a mouse to produce an artificial organism (artificial, meaning, that the resulting mouse now contained DNA of two species and was therefore not naturally occurring), a whole array of ethical questions was generated and speculation amongst the general public arose.⁶⁰ If the ethical discussions were brewing during the plant variety developments and the genetically altered bacterium, they then boiled with the introduction of the Oncomouse; this posed the question:

52. Miller, *supra* note 26.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

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

58. USPTO, *supra* note 49.

59. Kamil Idris & Hisamitsu Arai, Bioethics and Patent Law: The Case of the Oncomouse, *WIPO MAGAZINE* Issue 3, 16 (2006), available at http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html. Transgenic is a term given when one organism is the recipient of another species genetic information, DNA, this is done artificially.

60. *Id.*

should patents be awarded for such organisms?⁶¹ Since the patent claim for the Oncomouse did not include the term human but incorporated human DNA, it is reasonable to infer that ethical issues were of great concern among the public, but also those in the scientific community.⁶² This logically was a great leap into the direction of higher-level animals, specifically mammals and a species we share a significant amount of genetic information with.⁶³ It is significant to note that some in the international community, specifically, the European Patent Office, took longer to determine patent eligibility of the Oncomouse and only awarded such eligibility after concluding that the medical benefits to cancer research were considerable enough to outweigh moral apprehensions.⁶⁴

To transition specifically to DNA, scientific development has now led us to the point of asking: is a gene patentable, and, if not, what genetic variants are?⁶⁵ The Human Genome Project (HGP), which began in the 1990s, was conducted for the purposes of mapping out the entire human genome.⁶⁶ Much of the hesitation associated with the patentability of human DNA is that our genes “are largely responsible for our individual traits” and the “code upon which the physical machine of an individual is built.”⁶⁷ Further, the public policy concerns for working with human DNA is that humans, specifically, persons, are “the typical objects of moral consideration.”⁶⁸ So where do we separate the *person* from the *gene* from the *DNA*? It was in early April of 2000 that the company Celera announced their successful completion of the entire sequencing of the human genome.⁶⁹ This private company abandoned the previously implemented approach to mapping the genome—divide and conquer—and instead implored a technique of parsing together strands by way of recognizing repeating elements.⁷⁰ Because of Celera’s acceleration in the sequencing process, a rush followed of companies trying to claim rights to specific genes upon identification; naturally

61. *Id.*

62. *Id.*

63. *Id.*

64. Idris et al., *supra* note 59.

65. *See generally* Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

66. DAVID KOEPEL, WHO OWNS YOU?: THE CORPORATE GOLD RUSH TO PATENT YOUR GENES 20 (Wiley-Blackwell ed., 2009). The HGP essentially created a map of the entire human genome by identifying and assigning different DNA fragments to different chromosomes, this resulting map now serves as a universal tool for all genetic research.

67. *Id.* at 22, 24.

68. *Id.* at 25.

69. Kristen Philipkoski, *Celera Wins Genome Race*, WIRED (Apr. 6, 2000), <http://archive.wired.com/science/discoveries/news/2000/04/35479>.

70. *Celera: A Unique Approach to Genome Sequencing*, BIOCOMPUTING, <http://www.ocf.berkeley.edu/~edy/genome/celera.html> (last updated 2006).

the law was not yet up to speed with providing the proper restrictions as to what could and could not be protected, and ethical considerations took a back seat.⁷¹ What this Note will seek to explore is that DNA should most arguably be considered a “form of commons, immune to ordinary forms of possession or ownership.”⁷²

III. MYRIAD GENETICS

In June 2013, the matter of human gene patentability reached the United States Supreme Court.⁷³ Two issues were at hand: (1) “whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 by virtue of its isolation from the rest of the human genome” and (2) the “patent eligibility of synthetically created DNA known as complementary DNA (cDNA).”⁷⁴ Complementary DNA “contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins.”⁷⁵

Petitioner Harry Ostrer, MD, as well as other physicians, advocacy groups, the American College of Medical Genetics, the American Society for Clinical Pathology, the College of American Pathologists, and several medical patients brought suit in 2009 against Myriad Genetics, Inc.⁷⁶ The petitioners sought a court declaration that the BRCA1 and BRCA2 gene patents filed in 1997 and issued to Myriad in 2000⁷⁷ be deemed invalid.⁷⁸ The District Court granted the petitioners’ summary judgment on the composition claims due to the court’s conclusion that Myriad’s claims, even those relating to cDNA, fell under the implicit law of nature exception and

71. KOEPEL, *supra* note 66, at 26.

72. *Id.* at 27.

73. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

74. *Id.* at 2111.

75. *Id.*

76. *Ass’n for Molecular Pathology, v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

77. U.S. Patent No. 6,162,897 (filed May 2, 1997) (issued Dec. 19, 2000).

78. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 186. Both BRCA1 and BRCA2 are genes that create tumor suppressor proteins in humans, mutations of these genes have been linked to breast and ovarian cancer. Normally, tumor suppressor proteins help repair damaged DNA and additionally, keep cells from multiplying at a rapid pace. If a gene mutation occurs, the overall genetic stability may become compromised and without the proper functionality, cancer may result when the cell divides uncontrollably, thus forming a tumor. Nat’l Cancer Inst., *Fact Sheet BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L INST. OF HEALTH (Jan. 22, 2014), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA/print>; *Definition of BRCA1*, MEDICINENET, <http://www.medterms.com/script/main/art.asp?articlekey=2522> (last visited Mar. 16, 2014).

were therefore erroneously granted.⁷⁹ The District Court examined the United States Patent and Trademark Office's (hereinafter USPTO) practice of awarding DNA patents so long as they were deemed *isolated DNA*, isolated implying a sequence removed from the human body.⁸⁰ The court found fault in this approach and questioned such a method for determining patent sufficiency referring to it as a "lawyer's trick,"⁸¹ inferring that a loophole exists with respect to the prohibitions on granting a patent on DNA. Through this method, one can obtain a patent on exactly the same chemical composition of matter simply by extracting the DNA from the human.⁸² Thus, if you cannot claim the right to exclusion of a particular DNA sequence within someone, you simply remove the sequence you wish to claim, and now it becomes isolated.⁸³ While a practice seemingly sufficient for the USPTO, the District Court concluded that regardless of whether the segment of DNA is isolated or not, there is no finding of a fundamental alteration of the DNA upon extraction from the body; the information it encodes is exactly the same; thus the patent claims were declared invalid.⁸⁴ With respect to cDNA, the District Court additionally found the patent claims invalid for the same reasoning.⁸⁵ The decision of the District Court was reversed by the Federal Circuit.⁸⁶ The Supreme Court then "granted the petition for certiorari, vacated the judgment, and remanded the case."⁸⁷

In 2012, the Federal Circuit affirmed in part and reversed in part the decision of the District Court.⁸⁸ While there was no dispute that Dr. Ostrer met the standing requirements, nor was there a dispute as to cDNA meeting patent eligibility requirements, there was a variance in the judges' views pertaining to isolated DNA.⁸⁹ The Federal Circuit court judges' analysis of isolated DNA can also serve as a parallel argument for why cDNA is desired by many to be precluded from patent rights.

79. *Ass'n for Molecular Pathology*, 702 Supp. 2d at 220, 237.

80. *Id.* at 185.

81. *Id.* (citing to John M. Conley & Robert Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT & TRADEMARK OFF. SOC'Y 301, 305 (2003)).

82. *Id.* at 185.

83. *Id.* at 185.

84. *Ass'n for Molecular Pathology, v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181, 185 (S.D.N.Y. 2010).

85. *Id.*

86. *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

87. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114 (2013).

88. *Id.* All three Judges: Lourie, Moore, and Bryson wrote separately.

89. *Id.* at 2115.

Judge Lourie examined the DNA sequence as a chemical compound that is held together solely by bonds.⁹⁰ By cleaving (splitting) the bonds that keep the particular sequence intact in its natural form, a freestanding new molecule results.⁹¹ Such an alteration, as could be produced by a laboratory technician, was a dispositive finding since the resulting molecule differed from its larger and intact natural component, even though there was no change to the encoding information.⁹²

In Judge Moore's analysis, the same conclusion was found except she gave deference to the USPTO, which considered the interests of patent holders.⁹³ Lastly, Judge Bryson's opinion differed from both Judge Moore's and Judge Lourie's opinion in that Judge Bryson did not feel that the USPTO should be given deference on these matters because "the PTO lacks substantive rulemaking authority as to issues such as patentability."⁹⁴ Judge Bryson also discussed that the severing of a chemical bond was not dispositive as found by Judge Lourie; the act of breaking a bond or creating one, for that matter, did *not* create a new product since the DNA sequence remained the same, and furthermore the process of breaking a bond or creating one was not sufficient to constitute an invention. For these reasons, Judge Bryson disagreed with his colleagues' findings that isolated DNA should be patentable.⁹⁵ The process Judge Bryson used to analyze isolated DNA and reach his conclusion does not appear to be thoroughly applied in the development of his conclusion for cDNA. He wrote that cDNA was instead created in a laboratory and since its resulting product no longer contains introns, as those found in the naturally occurring specimen, the native gene and cDNA are therefore not chemically identical.⁹⁶ There was no discussion as to why his prior statement that "[t]here is no magic to a chemical bond that requires us to recognize a new product when a chemical is created or broken" is not also applicable to cDNA, which would consequently also render cDNA patent ineligible.⁹⁷

In 2013, upon grant of certiorari, the Supreme Court began its consideration of patent law and human DNA with a review of the language of the Patent Act of 1952, noting necessary adherence to the implicit exceptions of

90. *Id.*

91. *Id.*

92. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2115 (2013).

93. *Id.*

94. *Ass'n for Molecular Pathology v. United States Patent and Trademark Office*, 689 F.3d 1303, 1357 (Fed. Cir. 2012).

95. *Myriad*, 133 S. Ct. at 2115.

96. *Id.*

97. *Id.* (quoting *Ass'n for Molecular Pathology*, 689 F.3d at 1351).

“[l]aws of nature” that have been “long held.”⁹⁸ The Court also observed the discussion in *Mayo* that reiterated the fear that patents may infringe the use of basic scientific tools for the general community; such a consequence may likely stifle creative progress and innovation.⁹⁹ While there must be some limitation to the rules pertaining to patents so as to allow for innovation, since it is obvious that every invention must contain the use of the laws of nature and so forth, the Court did address the standard by which courts have historically evaluated patent eligibility claims. Patent protection must strike a “delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”¹⁰⁰

The major contribution, as supplied by Myriad, was the locating of the BRCA1 and BRCA2 genes within the chromosome; the Court was tasked with deciphering whether or not such a discovery constitutes patentability.¹⁰¹

As previously mentioned, the first biotechnology case of similar fashion was *Diamond v. Chakrabarty*. In this case, a bacterium was manipulated by the addition of plasmids; the result was an organism that could break down crude oil.¹⁰² Due to the new bacterium’s composition and the acquired ability to process oil in a different fashion than the bacterium without the added plasmids, it was found that such a “nonnaturally occurring manufacture” contained “markedly different characteristics from any found in nature” and, thus, could be granted a patent.¹⁰³ The Court distinguished *Diamond* from the facts in *Myriad*—in *Myriad*, there was not an alteration of the specimen, nothing was being created, and mere separation was not deemed sufficient to be considered an invention.¹⁰⁴

“Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”¹⁰⁵ After parsing through the millions of nucleotide base pairs that comprise chromosomes, Myriad’s patent descriptions provide detailed explanations of their particular process of dis-

98. *Id.* at 2116 (quoting *Mayo Collaborative Servs., Inc. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

99. *Id.*

100. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (citing to the discussion in *Mayo* that contrasts the monetary incentives for innovators and impacts on the economic market to policy considerations).

101. *Id.* The BRCA name stands for “BReast CAncer.” *Definition of BRCA1*, MEDICINENET, <http://www.medterms.com/script/main/art.asp?articlekey=2522> (last visited Mar. 16, 2014).

102. *Myriad*, 133 S. Ct. at 2117.

103. *Id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980)).

104. *Id.*

105. *Id.*

covery.¹⁰⁶ Yet while the location of the discovered genetic mutation was otherwise unknown until Myriad's discovery, the Court found that "extensive effort alone is insufficient to satisfy the demands of § 101."¹⁰⁷

Lastly, regarding the issue of isolated DNA, Myriad argued that deference should be given to the USPTO's practice of granting gene patents.¹⁰⁸ Such deference was formerly granted due to Congress's endorsement of prior legislation.¹⁰⁹ This was not the case in *Myriad*; there was no previous Congressional endorsement with respect to genes or isolated DNA segments, nor did this court believe that such prior practice constituted sufficient justification for isolated DNA patentability.¹¹⁰

The second holding in *Myriad* concluded that cDNA was not precluded from patent eligibility.¹¹¹ Little debate is allocated to this second issue as it appears that the overall opinion of the Justices is that cDNA is one step further into the category of *nonnaturally* occurring, since the process by which cDNA can result is through laboratory synthesis.¹¹² There are no noncoding regions contained within cDNA because these regions are removed by a laboratory technician who, upon completely removing all introns, then bonds the exon-only segments together to create the desired strand of DNA.¹¹³ One strong argument made by the petitioners is that nucleotide sequences are dictated by the laws of nature and the resulting cDNA can only be created by applying the laws necessary to carry out nucleotide base pairing.¹¹⁴ Essentially, the petitioners argue that the elementary nucleotide bonding steps carried out by a technician are not sufficient enough for a patent award to be granted to the resulting product.¹¹⁵ However, this Court refuted such an argument since a lab technician is required to create a composition of exons bonded together in order to produce cDNA.¹¹⁶ The contrasting opinions from the petitioners and the Court show that the Court is drawing a distinction whenever there is an introduction of assistance to an otherwise natural occurrence.¹¹⁷

106. *Id.*

107. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117-18 (2013).

108. *Id.* at 2118.

109. *Id.*

110. *Id.* at 2118-19.

111. *Id.* at 2119.

112. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013).

113. *Id.*

114. *Id.*

115. *Id.*

116. *Id.*

117. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013).

Methods and process patents are not discussed within this case, nor are new applications; instead the Court concludes that “genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”¹¹⁸ Thus, from this opinion, it can be inferred that a line is now able to be drawn between genetic material that is patentable—for example, material resulting from the intervention of a laboratory technician to splice away the intron segments—and material that would be precluded from patent eligibility—for example, material existing without a technician’s involvement and therefore a specimen likely to be too similar to a naturally occurring substance.

Of brief note, there is a process by which cDNA is naturally occurring, and the Court only slightly addressed such a possibility. Just as humans rely on proteins for reproduction, viruses do as well. Reverse transcriptase is an enzyme that reproduces RNA into cDNA. This rather backwards process observed by viruses generates naturally occurring cDNA; however, since it is extremely rare that a near similar cDNA specimen may result, there is no determination that cDNA should be deemed nonpatentable.¹¹⁹

With the discovery of the BRCA1 and BRCA2 gene mutations, Myriad was able to further the field of oncology by creating methods for which patients may be tested to evaluate whether or not they are carriers of the mutation. This provided many with a better calculation of their own risk,¹²⁰ particularly those patients with a family history of breast cancer. Naturally, this test allowed for patients to then engage in early planning in addition to the other common measures and precautions patients take after gaining a better awareness of their health condition. The controversy surrounding the granting of the patent rights for the gene isolation began when other medical facilities, such as the University of Pennsylvania’s Genetic Diagnostic Laboratory, started offering BRCA1 and BRCA2 screening.¹²¹ Once Myriad filed patent infringement suits, settlements were reached to enjoin the other facilities from providing BRCA diagnostic testing; the result was that Myriad became the sole company that could offer BRCA screening.¹²² It was not until several years later that a case was brought against Myriad by many members of the medical community questioning the validity of Myriad’s acquired patents, thus resulting in the *Myriad* controversy.¹²³

118. *Id.* at 2120.

119. *Id.* at 2119, n. 8.

120. *Id.* at 2114.

121. *Id.*

122. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114 (2013).

123. *Id.*

IV. MYRIAD GENETICS AND THE FUTURE OF GENETICS IN PATENT LAW

Following the *Myriad* decision of 2013, many were left with an even further blurred line as to what is patent eligible moving forward. One review, *Patenting Biologicals: Myriad Issues and Options in the Wake of Myriad*, was released shortly after the *Myriad* decision. This review hypothesized the direction eager biotechnology firms may venture to obtain quasi-genetic patents and the likely questions to arise.¹²⁴ For example, if the reasoning of the *Myriad* decision is followed, then bacteria, which, unlike humans, do not naturally contain introns within their genetic sequences, would likely have cDNA components that are patent ineligible.¹²⁵ This is because there would be no laboratory technician needed to splice out the unwanted introns to generate the resulting exon-only cDNA strand.¹²⁶ Therefore, it appears more difficult to argue for patent eligibility for a cDNA bacteria strand than for a human one since the bacterial strand does not satisfy the “human intervention” component that Justice Douglas used in his reasoning.¹²⁷ The original ethical hesitation of the courts in addressing human genetic patents seems to be overlooked in respect to this particular application of Justice Douglas’s analysis.

A. ECONOMIC IMPACTS

Diagnostic uses, such as therapeutic proteins and genetic testing, comprise the basis for most of the ethical disputes when it comes to gene patents; research also provides a source of great debate due to the consequences, both ethically, and economically, that arise from either the production or inhibition of scientific research.¹²⁸ For example, therapeutic proteins—proteins that can be used to treat a particular disease—can result in patents for the invention of such protein production.¹²⁹ The use of therapeu-

124. Z. Peter Sawicki et al., *Patenting Biologicals: Myriad Issues and Options in the Wake of Myriad*, BENCH & B. MINN. 1, 22 (Sept. 2013), available at http://mnbenchbar-digital.com/mnbenchbar/september_2013#pg1.

125. *Id.*

126. *Id.*

127. *Id.*

128. ROBERT COOK-DEEGAN, FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS 70 (Mary Crowley ed., 2008), available at http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/gene%20patents%20chapter.pdf.

129. *Id.*

tic proteins was largely demonstrated by Genentech and Amgen with respect to insulin in the early 1980s.¹³⁰

Genetic testing for diagnostic purposes, the issue in *Myriad*, raises the “concern that monopolies on genetic tests make their prices unacceptably high.”¹³¹ With approximately “5-10% of breast cancer cases” being due mutations of the BRCA1 and BRCA2 genes, such a monopoly could reasonably prevent the scientific community from further research.¹³² The common stance taken by protestors of Myriad’s patent claims, and voiced in a discussion by a medical oncologist and USC professor Dr. Agus, is that we should not “let . . . preventive measures that can save thousands of lives be priced at levels far above what normal ‘market conditions’ would suggest.”¹³³ Dr. Agus paralleled the high cost of genetic testing to the rationale that is used to keep the cost of vaccine prices at affordable levels.¹³⁴ “We don’t make vaccines prohibitively expensive so only the rich can protect themselves,” he says using this argument as a call for legislative action.¹³⁵ Before the June ruling, Dr. Agus suggested a model proposed by a USC economist which would create a licensing scheme for testing and allow insurance companies to purchase a license on behalf of their clientele.¹³⁶ If you are not a company like Myriad, such a proposal appears to be the most effective way to satisfy the greatest amount of parties involved, proving to be an acceptable economic solution; however, the proposal skirts over the ethical concerns associated with DNA ownership. The June holding, nonetheless, leaned more towards morality than economics, removing the above proposal from the table when the Court ruled that human genes are not patentable.

Research and development companies rely heavily on investors; one concern from a business perspective such as Myriad’s is that, with the recent ruling, will investment go down? Now that human genes cannot be patented, will the market of genetic testing take a hit? Such a likely outcome may then generate counterproductive results for the petitioners of the case that argued for the very foundation of patent law—to “promote the Progress of Science.”¹³⁷ While there is a possibility that investment in genetic research may decrease, the *Myriad* ruling did give biotech companies a

130. *Id.* Genentech and Amgen are both biotechnology companies. Genentech focuses on genetic technology, and Amgen focuses on biopharmaceuticals.

131. *Id.*

132. *Id.*

133. David B. Agus, Op-Ed., *The Outrageous Cost of a Gene Test*, N.Y. TIMES, May 21, 2013, at A25, available at http://www.nytimes.com/2013/05/21/opinion/the-outrageous-cost-of-a-gene-test.html?_r=0.

134. *Id.*

135. *Id.*

136. *Id.*

137. U.S. CONST. art. I, § 8, cl. 8.

fractional victory by not precluding cDNA from patent eligibility.¹³⁸ The second holding does afford biotech companies an avenue to alter and construe the components of their research so that there still remains an option for patent awards with respect to human genome exploration.¹³⁹ Additionally, the decision does not restrict biotech companies from obtaining patents for the methods of how they isolate genes, so long as the method is not already widely known; nor is there a restriction on the discovery of “new applications of knowledge gained from genetic research.”¹⁴⁰ This will hopefully satisfy the petitioner’s argument against the high price of genetic screening, as predictions are already being made that the testing prices will come down due to the fact that competitors of Myriad will now be able to offer similar testing.¹⁴¹

In the last quarter before the *Myriad* ruling, approximately “\$132 million of Myriad’s \$156 million in revenue” was from BRCA testing.¹⁴² Now that they no longer own a monopoly on the BRCA1 and BRCA2 genes, Myriad has announced plans to offer panel genetic screening for customers, which is similar to the strategy most of its competitors also plan to initiate.¹⁴³ Just how much Myriad will stand to lose in revenue as a result of this ruling and its impact on the effectiveness in swaying investors will soon be played out.

Negative impacts from this ruling will also affect all other companies that currently hold patents on human genes. For example, GeneDx runs testing for genetic skin mutations, yet, through the process of GeneDx’s testing, a result may be generated that shows an indication of possible deafness.¹⁴⁴ However, Athena Diagnostics—not GeneDx—controls the deafness gene testing, yet, after *Myriad*, Athena Diagnostics may lose revenue since they can no longer exclude companies like GeneDx from processing and resulting to physicians the genetic indications revealed by their testing.¹⁴⁵ Athena Diagnostics is just one example of many companies that will be impacted in such a way.

138. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013). The second holding of the case deals solely with cDNA and not isolated DNA.

139. Adam Liptak, *Justices, 9-0, Bar Patenting Human Genes*, N.Y. TIMES, June 14, 2013, at A1, available at <http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html>.

140. *Id.*

141. *Id.*

142. Andrew Pollack, *After DNA Patent Ruling, Availability of Gene Tests Could Broaden*, N.Y. TIMES, June 14, 2013, at A16, available at <http://www.nytimes.com/2013/06/14/business/after-dna-patent-ruling-availability-of-genetic-tests-could-broaden.html?pagewanted=all>.

143. *Id.*

144. *Id.*

145. *Id.*

Currently there are estimates of over four thousand different human gene patents that largely came about during the “genomics gold rush of the late 1990s,”¹⁴⁶ but patents only have a lifespan of twenty years.¹⁴⁷ With such a short lifespan, most of the 1990s patent rights have already begun to expire independent of *Myriad*. Of the four thousand, however, many are not for isolated human genes but for cDNA.¹⁴⁸ Thus, unless the existing patents are about to expire shortly, or are for *isolated* human DNA, many companies will be able to continue to assert their ownership of such genetic components.

Apart from the June 2013 ruling, *Myriad* does have other proprietary security options that it can stand to benefit from. Dating back to when *Myriad* obtained the two BRCA gene patents, it has conducted its testing for over one million patients.¹⁴⁹ This testing has allowed *Myriad* to develop a vast patient database, which will give *Myriad* “an extraordinary informational advantage when it comes to interpreting patients’ test results.”¹⁵⁰ This information is considered trade secret knowledge and while it has already been argued that serious scientific progress may result from such a database of genetic information, this database is still property of *Myriad* and their plans to gradually publicize their research remain their prerogative.¹⁵¹ With the introduction of genetic panel testing (multiple genes evaluated in one test), *Myriad* can implore any of its unique methods or “algorithms developed from its prodigious . . . data” and assert proprietary privileges to maintain a sturdy control of the genetic testing market.¹⁵² Since both application patents and process patents were not negatively restricted from the recent ruling, it can be assumed that *Myriad* and companies similarly situated will be seeking to obtain such rights in the very near future.

Significant objections have been raised with respect to the trade secrets biotechnology companies are privy too. Critics argue that research will be stalled, causing patients to fall victim.¹⁵³ The sooner genetic information is placed in the public domain through public disclosure or by the academic community, the better off the patient will be. Even before the ruling, such efforts have already been set into motion; sixty-nine organizations from thirteen countries agreed to “facilitate the sharing of DNA se-

146. *Id.*

147. 35 U.S.C. § 154 (2012). Design patents have a term of fourteen years once the patent has been granted. *See* 35 U.S.C. § 173 (2012).

148. Pollack, *supra* note 142.

149. Eleonore Pauwels, Op-Ed., *Our Genes, Their Secrets*, N.Y. TIMES, June 18, 2013, available at http://www.nytimes.com/2013/06/19/opinion/our-genes-their-secrets.html?_r=0.

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

quences and clinical information.”¹⁵⁴ This cooperation effort is essential for those that represented the petitioner’s stance in *Myriad*. Both funding and time will serve as obstacles for this cooperation effort, yet it can be foreseeably anticipated that the organization volume will continue to grow. Protestors also take the stance that such a genetic database of information should be regulated for economic factors, possibly through federal agencies, so that both patient privacy and safety are adequately observed.¹⁵⁵

B. ETHICAL CONSEQUENCES AND THE CDNA HOLDING

In addition to concerns raised above, what are the policy ramifications of *Myriad* and does this decision, especially with respect to the second holding, place the debate back to where we wanted to avoid? The first holding was a victory for petitioners and the like, especially on ethical grounds, but the second holding will likely serve to bring about the same ethical concerns that the Justices considered when reaching the first holding in *Myriad*.

A recent New York Times article discusses the concern that privatization of health is proportional to wealth.¹⁵⁶ Currently, someone can have his or her genome of approximately twenty thousand plus genes sequenced at an approximate cost of one thousand dollars.¹⁵⁷ Before the *Myriad* decision, Myriad Genetics, Inc. was charging approximately four thousand dollars to have only the BRCA1 and BRCA2 genes sequenced.¹⁵⁸ While patients can expect to see the prices of testing change for the better, companies like Myriad now have even more of an incentive to commercialize their methodology since they now have less control over the genes as a whole. Economists would argue that such an incentive is beneficial to both the scientific and general community. Also, the second ruling does appear to economically satisfy the respected balance the Justices recognized from *Mayo*, a balance between creating “incentives that lead to creation, invention, and discovery” and “imped[ing] the flow of information that might permit, indeed spur, invention.”¹⁵⁹ Yet, was there a proper balance observed with the second holding? Allowing cDNA to be patentable gave Myriad the ability to still prohibit other companies from using probing methods if they use the same cDNA sequence. Since there is only one complimentary match, have

154. Pauwels, *supra* note 149.

155. *Id.*

156. Joseph E. Stiglitz, *How Intellectual Property Reinforces Inequality*, N.Y. TIMES, OPINIONATOR BLOG (July 14, 2013), <http://opinionator.blogs.nytimes.com/2013/07/14/how-intellectual-property-reinforces-inequality/?ref=myriadgeneticsinc>.

157. *Id.*

158. *Id.*

159. *Mayo Collaborative Serv., Inc. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

companies like Myriad been granted the key to a lock that was found unpatentable? This answer appears to be yes, just months after the Supreme Court ruling Myriad has already filed suit against two organizations-Ambry Genetics and Gene by Gene-for conducting BRCA testing.¹⁶⁰ Myriad argues that they can assert their rights to BRCA testing so long as they hold the patents for genetic components such as cDNA.¹⁶¹ How then do competitor companies like Ambry Genetics conduct BRCA testing when they do not have the rights to the complimentary DNA strand to the genetic mutation? If such obstacles prove surmountable for competitors, then the proper balance discussed above will be achieved; only time will tell whether or not these competitors can feasibly develop alternative methods to genetic testing excluding Myriad's patented cDNA.

Since the *Myriad* ruling, another case, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, was decided in October of 2013, holding that the "[patent] claims [were] not drawn to patent eligible subject matter."¹⁶² In this case, three method patent claims were asserted: (1) "[a] method for detecting a paternally inherited nucleic acid of fetal origin," (2) "[a] method for detecting a paternally inherited nucleic acid on a maternal blood sample," and (3) "performing a prenatal diagnosis on a maternal blood sample."¹⁶³ There was a determined "presence of . . . DNA in the pregnant" mother's blood and therefore the specimen was considered a natural phenomenon.¹⁶⁴ Additionally, no claims as to the methodology were upheld since it was also determined that "conventional genetic techniques" were used.¹⁶⁵

How does the holding in this case differ from Myriad's second holding? The issue seems to be where the courts choose to draw the line with conventional techniques and those techniques distinctive to a company. If Myriad Genetics, Inc. was the first to locate and begin BRCA genetic testing, then logically their technique used would be proprietary since it is not one that is conventionally known. Furthermore, if the Justices interpreted and analyzed the synthetic creation of cDNA to be *like* a method patent (even though methods patents were not discussed in relation to cDNA in the

160. Stiglitz, *supra* note 156.

161. Andrew Pollack, *2 Competitors Sued by Genetics Company for Patent Infringement*, N.Y. TIMES, July 11, 2013, at B3, available at <http://www.nytimes.com/2013/07/11/business/2-competitors-sued-by-genetics-company-for-patent-infringement.html>.

162. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C11-06391 SI, 2013 WL 5863022, at *11 (N.D. Cal. Oct. 30, 2013).

163. *Id.* at *2.

164. Andrew Pollack, *Judge Invalidates Patent for a Down Syndrome Test*, N.Y. TIMES, Nov. 1, 2013, at B4, available at <http://www.nytimes.com/2013/11/01/business/judge-invalidates-patent-for-a-down-syndrome-test.html>.

165. *Id.*

Myriad case), and this is the only method used thus far, at what point does the method become conventional and not exclusive?

Judge Illston explored what is and is not patentable with respect to method patents in her discussion in *Sequenom*.¹⁶⁶ The process or method must contain other elements, like those “referred to as an ‘inventive concept,’” so that more than just the *natural law* is being protected.¹⁶⁷ What *Myriad* has is a claim to their cDNA components, not a method patent, but a composition patent; however, the cDNA they created in the laboratory was done by simply “appending conventional steps, specified at a high level of generality.”¹⁶⁸ The question then follows: where does the law draw the line when it comes to awarding or not awarding a patent to a company that simply appended conventional steps to create a product that can only have one result?

As previously discussed, in order to make cDNA, the rules of nucleotide base pairing *must* be followed: adenine (A) must always bind with thymine (T) and can never bind to cytosine (C) or guanine (G) and so forth.¹⁶⁹ Because this base pairing must always be followed there is no innovative method used by *Myriad* for manipulating a law of nature (since no method claims were present in the *Myriad* case, that argument is not necessary); however, the lab technician merely created something that has no innovative qualities—they simply bonded nucleotides together in an already predetermined sequence.¹⁷⁰ Why then was it determined in *Myriad* that cDNA was not precluded from patent eligibility if it is created in a way that is conventional, (barring method patent eligibility) results in a product that could arguably be found in nature, therefore constituting natural phenomena, and is made up of nothing more than the “basic tools of scientific and technological work,” barring proper patent law subject matter?¹⁷¹ After all, cDNA is made from using an mRNA template and following simple nucleotide bonding principles.¹⁷²

166. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C11-06391 SI, 2013 WL 5863022, at *8 (N.D. Cal. Oct. 30, 2013).

167. *Id.*

168. *Id.* (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119-20 (2013)).

169. *Myriad*, 133 S. Ct. at 2111. See the discussion presented in *supra*, Part II section A: Genetics 101 for further clarification of nucleotide base pairing rules.

170. *Id.* at 2119.

171. *Myriad*, 133 S. Ct. at 2116 (*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

172. Erika Manderscheid & Vishal Parikh, *Association for Molecular Pathology v. Myriad Genetics*, B.C. INTELL. PROP. & TECH. F. 1 (2013).

C. WAS THE *MYRIAD* DECISION BEYOND THE COURT'S SCOPE?

How much scientific knowledge should courts be required to have before they make a ruling? The *Myriad* decision is this decade's landmark case for genetics and intellectual property law, specifically, patent law.¹⁷³ Due to the speed of the ever-changing scientific community, it is curious that there was no discussion as to whether or not an "altered DNA sequence" could be patentable.¹⁷⁴ Applying the analysis made by the Court in *Myriad*, one could logically conclude that such an altered strand would be deemed patent eligible because "the lab technician unquestionably creates something new when cDNA is made" since the resulting complimentary DNA has all the introns removed.¹⁷⁵ Scientists and scholars are left without a way to determine if other forms of genetic material, apart from those discussed in *Myriad*—isolated and cDNA—are protectable.¹⁷⁶

A December 2013 review titled, *Association for Molecular Pathology v. Myriad Genetics*, raises the point that not only genetic components but other "isolated bodily substances such as proteins" may be affected by the *Myriad* ruling, and questions whether the USPTO will apply the same reasoning established in *Myriad* for determining patent eligibility.¹⁷⁷

Where then did the court look to for their understanding of how cDNA and isolated DNA differ for patent purposes? *Myriad's* discussion offers no scientific or law review sources for conclusory support in either holding.¹⁷⁸ In a summer publication from the Robinson Bradshaw & Hunson Law Firm, John Conley states that "[t]he cDNA/gDNA distinction has its roots in the Federal Circuit's 1991 decision in *Amgen v. Chugai*."¹⁷⁹ This case mainly focused on who was the rightful owner of the Erythropoietin (EPO) gene.¹⁸⁰ Both sequence patents and patents for the method of EPO purification existed, and the holding determined that the claim of "[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin" was sufficient subject matter to constitute the granting of a patent.¹⁸¹ Conley argues that *Amgen's* analysis for determining eligibility can be paralleled to the analysis that *Myriad* uses for the second

173. *Id.* at Implications discussion.

174. *Id.*

175. *Myriad*, 133 S. Ct. at 2119.

176. Manderscheid et al., *supra* note 172, at Implications discussion.

177. *Id.*

178. John Conley, *Myriad, Finally: Supreme Court Surprises by not Surprising*, GENOMICS LAW REPORT (Robinson Bradshaw & Hinson Law Firm Publication) (June 18, 2013), <http://www.genomicslawreport.com/index.php/2013/06/18/myriad-finally-supreme-court-surprises-by-not-surprising/>.

179. *Id.*

180. *Id.*

181. *Amgen, Inc. v. Chugal Pharm. Co.*, 927 F.2d 1200, 1204 (Fed. Cir. 1991).

holding.¹⁸² The purified sequence evaluated in *Amgen* is similar to the cDNA sequence discussed in *Myriad*.¹⁸³ The *Amgen* case really can be considered the precursor to *Myriad* to the degree that *Amgen* extended patent rights to purified DNA,¹⁸⁴ but did not discuss further options; whereas *Myriad* essentially affirmed the analysis of *Amgen* and included a further discussion as to why the leap to patenting isolated genes was just too far since they are natural phenomena.¹⁸⁵

Was the Supreme Court properly equipped to make such a ruling? *Myriad* may be the party arguing now that comments like Justice Scalia's—"I am unable to affirm those details on my own knowledge or even my own belief"—demonstrate that perhaps the Court was ruling on matters too far beyond their scope.¹⁸⁶ Yet the rapid pace of our scientific knowledge is not one that will be slowing down anytime soon and for both ethical and economic purposes, decisions regarding scientific testing, particularly when it comes to healthcare, need to be within a timely manner so that no party, the industry, nor the consumer, is left victim to the consequences of unregulated business.

One last legal obstacle that will be of near future relevance is in regard to the potentially new patent claims that may develop from companies working to synthetically create genetic products. This obstacle is the requirement of nonobviousness with respect to granting a patent.¹⁸⁷ According to 35 U.S.C. § 103, the third requirement of a patent for an invention, in addition to utility¹⁸⁸ and novelty,¹⁸⁹ is nonobviousness.¹⁹⁰ The utility requirement assesses three questions: (1) "[d]oes the invention do anything?" (2) "[d]oes the invention work?" and lastly, (3) "[d]oes the invention possess some moral utility?"¹⁹¹ Novelty evaluates whether or not the invention is something new.¹⁹² Both of these requirements are understandably met with genetic components such as cDNA, but the nonobvious requirement

182. Conley, *supra* note 178.

183. *Id.*

184. *See id.* There is the assumption that *purified* represents a portion of DNA that only contains coding regions.

185. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

186. Liptak, *supra* note 139.

187. 35 U.S.C. § 103 (2012).

188. 35 U.S.C. § 101 (2012).

189. 35 U.S.C. § 102 (2012).

190. 35 U.S.C. § 103 (2012).

191. National Paralegal College, *Utility, Novelty, Statutory Bar, & Nonobviousness* (2014), http://nationalparalegal.edu/public_documents/courseware_asp_files/patents/Patents1/Utility.asp.

192. *Id.*

may prove the hardest to demonstrate.¹⁹³ Conley brings attention to a 2009 Court of Appeals case, *In re Kubin*, which resulted in a greater difficulty of obtaining gene patents.¹⁹⁴ This is because the case held that “gene sequence was unpatentably obvious”¹⁹⁵ and that knowledge about the protein encoded, as well as isolating and sequencing techniques for genes, was commonplace.¹⁹⁶ Rightly so, Conley questions whether or not Myriad, and companies of the like, will be held to the “*Kubin* standard” as they work towards pursuing several new types of genetic component type patents.¹⁹⁷ It would not be incorrect to speculate that the Court might have chosen to leave this discussion for another day along with the various grey areas of genetic patentability, such as the previously mentioned “isolated bodily substances,”¹⁹⁸ that will need to be assessed for patent preclusion in the near future. If the *Kubin* standard is strongly applied to inventions like cDNA for example, then the second holding of the Court will certainly carry less weight as patents for synthetically created compounds may fail when the compound is determined to be too obvious.¹⁹⁹

V. CONCLUSION

After just over a year since the *Myriad* ruling, the full impacts of this decision have yet to be played out among the scientific community.²⁰⁰ What can be hypothesized is that the consequences of the second holding will likely bring about the same concerns that the Justices contemplated when deciding upon the first holding. These include economic consequences, such as providing a ruling that strikes an adequate balance between business and innovation,²⁰¹ and ethical consequences, such as the risk of increased inequality both financially and treatment-wise when it comes to ownership and privatizing genetic testing.²⁰² Additionally, the second holding leaves open several possible questions to be answered with regard to how we apply the *laboratory technician intervention* analysis discussed in

193. *Id.*

194. Conley, *supra* note 178.

195. *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

196. Conley, *supra* note 178.

197. *Id.*

198. Manderscheid et al., *supra* note 172, at Implications discussion.

199. Conley, *supra* note 178.

200. Manderscheid et al., *supra* note 172, at Implications discussion.

201. *See Mayo Collaborative Serv. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

202. *See Stiglitz supra* note 156.

Myriad,²⁰³ and was it considered synthetic versus what is considered solely natural phenomena.²⁰⁴

Overall, the *Myriad* ruling was a victory for physicians, advocacy groups, the American College of Medical Genetics, the American Society for Clinical Pathology, the College of American Pathologists, medical patients,²⁰⁵ and the like. The ruling preserved the ownership of human genes so that individuals are not denied access to the ever-growing knowledge of genetics and their particular sequence; the human genome has now essentially been deemed public domain. It was only in the second holding, concerning cDNA, that the Court leaves too much room for misinterpretation and possible economic abuse by not establishing a more concrete method for determining the distinction of patentable genetic components.²⁰⁶ Such a lack of a proper distinction further validates the argument that cDNA should in fact be precluded from patent eligibility since it so closely resembles *natural phenomena*²⁰⁷ and is created by “appending conventional steps, specified at a high level of generality”²⁰⁸ the very concepts that patent law aims to keep “free to all men and reserved exclusively to none.”²⁰⁹

203. Ass’n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2119 (2013).

204. See *Mayo*, 132 S. Ct. at 1293.

205. *Myriad*, 133 S. Ct. at 2107.

206. *Id.*

207. *Mayo*, 132 S. Ct. at 1293.

208. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, No. C11-06391 SI, 2013 WL 5863022, at *8 (N.D. Cal. Oct. 30, 2013).

209. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).