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”It’s a Trap”: cDNA Is Patent Eligible! But Is It Patentable?

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I. Introduction

On June 13, 2013, the Supreme Court issued a long-awaited decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (a.k.a. the *Myriad* gene patents case). The Court, in a rare unanimous decision, held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA¹ is patent eligible because it is not naturally occurring.”² This ruling upset thirty years of settled expectations, as inventors and companies have relied on patent protection for their work in gene isolation. This case note will explore the implications of this ruling on future research, and innovation in the wake of the Court’s decision.

II. Law Before the Case

Congress, in order “[t]o promote the Progress of Science and useful Arts,” was granted the power to award inventors’ time limited exclusive rights to their inventions in the U.S.

¹ *cDNA*, COLLINS ENG. DICTIONARY, <http://www.collinsdictionary.com/dictionary/english/cdna?> (last visited June 17, 2014) (abbreviation for “complementary DNA”) (defined as “a form of DNA artificially synthesized from a messenger RNA template and used in genetic engineering to produce gene clones”).

² *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

Constitution.³ To accomplish this, Congress passed the first Patent Act in 1790.⁴ This initial act was followed by several successive acts designed to refine and clarify the original Act,⁵ finally leading to codification of the patent law in 1952 as United States Code Title 35.⁶ While it is similar to and retains the same basic purpose as the original eighteenth century laws, Title 35 serves as the preeminent structure for today's patent law.⁷

The patent law seeks to accomplish the goal of “promot[ing] the Progress of Science and useful Arts”⁸ by granting temporary monopolies to inventors for their innovations. In exchange for the monopoly, inventors must release detailed descriptions of their inventions to the public, written in language that would allow a person of reasonable skill in the art to understand what is

³ U.S. CONST. art. I, § 8, cl. 8 (“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

⁴ See Act of Apr. 10, 1790, ch. 7, 1 Stat. 109. The Act authorized patents for “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used” and provided that the Secretary of State, the Secretary of War, and the Attorney General determined that the invention was “sufficiently useful and important.” DONALD S. CHISUM, CHISUM ON PATENTS § 2 n.12 (1998).

⁵ See CHISUM, *supra* note 4, §§ 2-6. The 1790 Act was replaced with the 1793 Act omitting “the important determination and authorized patents for ‘any useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereon], not known or used before the application.’” *Id.* § 2 (quoting Act of Feb. 21, 1793, ch. 11, 1 Stat. 318). The Patent Act in 1836 “created a Patent Office and a system of examination of patent applications for compliance with the requirement of novelty over the prior art.” *Id.* § 3 (referring to the Act of July 4, 1836, ch. 357, 5 Stat. 117). The 1870 Act replaced the 1836 Act but retained the essential provisions and requirements. *Id.* (referring to the Act of July 8, 1870, ch. 230, 16 Stat. 198). The 1952 Act, which was codified as 35 U.S.C., “rearranged existing statutory provisions and stated in statutory form matters previously recognized only in court decisions and Patent Office practice” and made several change. *Id.* § 6.

⁶ See *id.* § 6. The 1952 Act “rearranged existing statutory provisions and stated in statutory form matters previously recognized only in court decisions and Patent Office practice” and made several changes and additions, including a statutory provision on non-obviousness.

⁷ See *Bonito Boats, Inc. v. Thunder Crafts Boats, Inc.*, 489 U.S. 141, 148 (1989) (O’Connor, J., in dicta) (observing that “[t]oday’s patent statute is remarkably similar to the law as known to Jefferson in 1793”); CHISUM, *supra* note 4, § 2 (stating that the 1790 and 1793 patent statutes contain fundamental concepts that remain the basis of United States patent law today).

⁸ U.S. CONST. art. I, § 8, cl. 8.

being claimed.⁹ These detailed descriptions are the consideration for the monopoly, given by the inventor to the public, who then may benefit by the further development of ideas based on the new technology.¹⁰ The grant of a monopoly and the rights of the public to innovate, require that patent claims are clear;¹¹ thus ensuring that the patent owner knows what he owns and the public knows what he does not.¹² This is part of a delicate balance that the law attempts to maintain between inventors who rely on the law for protection of their intellectual property to make the invention known, and the public who are encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights.¹³

To determine whether a patent claim contains patent-eligible subject matter, courts and the United States Patent Office (USPTO), rely on 35 U.S.C. § 101. This section outlines the portal through which all innovation must pass en route to patent recognition. The determination has been described as a threshold inquiry, which is to be determined as a matter of law in establishing the validity of the patent.¹⁴ Section 101 places patentable subject matter into four

⁹ 35 U.S.C. § 112 (2012); *see also* Application of Barker, 559 F.2d 588, 593 (C.C.P.A. 1977) (“[W]e reaffirm our recognition that 35 U.S.C. § 112, first paragraph, contains separate requirements for a written description (1) of the invention, and (2) of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same”)

¹⁰ *See* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950), (holding that disclosure of inventions is one of the primary purposes of the patent system).

¹¹ 35 U.S.C. § 112.

¹² *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002); *see also* *McClain v. Ortmayer*, 141 U.S. 419, 424 (1891) (holding that requiring the patentee to particularly point out, and distinctly claim his invention, is “not only to secure to him all to which he is entitled, but to apprise the public of what is still open to them”).

¹³ *Bonito Boats*, 489 U.S. at 150-51 (“The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years”).

¹⁴ *In re Bilski (Bilski I)*, 545 F.3d 943, 950 (Fed. Cir. 2008) (citing *In re Comiskey*, 499 F.3d 1365, 1371 (Fed. Cir. 2007)).

broad categories, including: “new and useful process[es], machine[s], manufacture, or composition[s] of matter.”¹⁵

However, despite the broad nature of the statutory language, the Supreme Court has recognized three “fundamental principles” as exceptions to the Patent Act's subject matter eligibility requirements: “laws of nature, physical phenomena, and abstract ideas.”¹⁶ The Supreme Court has held that “[t]he concepts covered by these exceptions are ‘part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.’”¹⁷ Therefore, “even if an invention appears to claim subject matter that would be statutorily covered by the Patent Act, it will still be denied patent protection if it falls into one of the ‘fundamental principles' exceptions.”¹⁸

Although a fundamental principle cannot be patented, the Supreme Court has held that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection,” so long as that application would not preempt substantially all uses of the fundamental principle.¹⁹ In making a preemption determination, the claim must be considered as a whole, as it is “inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.”²⁰ Nonetheless,

¹⁵ 35 U.S.C. § 101; *see also* *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

¹⁶ *Bilski*, 130 S.Ct. at 3225.

¹⁷ *Bilski I*, 545 F.3d at 952 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

¹⁸ *CLS Bank Int'l v. Alice Corp. Pty. Ltd.*, 768 F. Supp. 2d 221, 230 (D.D.C. 2011).

¹⁹ *Bilski I*, 130 S. Ct. at 3230 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)) (internal quotations omitted).

²⁰ *Id.*

a scientific principle cannot be made patentable by simply limiting its use “to a particular technological environment” or by adding “insignificant post-solution activity.”²¹

To determine whether the subject matter of a claim is simply a product of nature, or has been remodeled into something more, courts have frequently applied the “machine-or-transformation” test.²² Under this test, claimed subject matter is patent-eligible pursuant to § 101 if: (1) it is tied to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing.²³ The Federal Circuit further explained:

A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not preempt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article.²⁴

This test has guided many courts in their gatekeeping function, however, the Supreme Court recently held that, although the machine or transformation test remains a “useful and important clue,” it is not the sole test for determining the patent-eligibility of process claims.²⁵ According to the Supreme Court, the primary inquiry should instead focus on whether the claimed invention falls within one of the three fundamental principles exceptions.²⁶ Expanding on this principle as the main focus of the case at hand, the Court recognized first that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,”

²¹ *Diehr*, 450 U.S. at 191.

²² *Bilski I*, 545 F.3d at 954.

²³ *Id.* (citing *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972)).

²⁴ *Id.*

²⁵ *Bilski*, 130 S. Ct. at 3227; *see also* *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1349 (Fed. Cir. 2010).

²⁶ *See Bilski*, 130 S. Ct. at 3226.

and second, “too broad an interpretation of this exclusionary principle could eviscerate patent law.”²⁷ The Court began their inquiry by applying “this well-established standard to determine whether Myriad's patents claim any ‘new and useful . . . composition of matter,’ . . . or instead claim naturally occurring phenomena.”²⁸

Since 1982, patents claiming isolated gene sequences have cleared this threshold inquiry.²⁹ Although these patents were never fully tested in the crucible of litigation until now, inventors relied on what they (and their learned counsel) considered the settled expectation of patent protection for these discoveries when they invested considerable time and treasure in their pursuit. The work and investment of these erstwhile pioneers have led to many important discoveries, which have affected not only their fields of research, but many individuals on a very personal level, through the realization of diagnosis and treatment of disease.

To further bolster the relied upon protection, in 2001, USPTO issued *Utility Examination Guidelines*; these guidelines reaffirmed the agency's position that isolated DNA molecules were patent eligible.³⁰ In the intervening years, Congress has not indicated that they disagree with the PTO's position, which has been inferred as (at the very least) tacit approval.

²⁷ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012)).

²⁸ *Id.*

²⁹ See Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19, 19 & n.3 (2010) (citing patents issued March 30 and December 14, 1982); see also STEPHEN A. BECKER, PATENT APPLICATIONS HANDBOOK § 4:19 (2010).

³⁰ Utility Examination Guidelines, 66 Fed. Reg. 1092-1102 (Jan. 5, 2001) (stating that an isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound).

Such was the state of patent law when this case began. Which leaves scholars with the pressing question: If the law is to be changed in a manner contrary to the settled expectation of the community of inventors, and inventions claiming isolated DNA as their subject matter excluded from the broad scope of § 101, should the decision come from Congress or the Court?

III. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*

A. Facts of the Case

This case began with a declaratory judgment action brought to challenge certain claims in seven patents related to Myriad's isolation of the BRCA1 and BRCA2 genes, and the correlation between specific mutations in those genes and a heightened risk of developing certain types of breast and ovarian cancers.³¹ Myriad employed many of the pre-eminent scientists in the field of genetics and expended vast amounts of time and wealth to isolate the BRCA1 and BRCA2 genes. The question the Court had to answer is whether this renders the genes patentable?³²

Myriad discovered the precise location and sequence of two human genes, BRCA1 and BRCA2, mutations of which can substantially increase the risks of breast and ovarian cancer. "The average American woman has a 12- to 13- percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 percent for breast cancer and between 20 and 50 percent for ovarian cancer."³³ The identification and isolation of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence.³⁴ In turn, that information enabled Myriad to develop medical tests that are useful for detecting

³¹ *Myriad*, 133 S. Ct. at 2109.

³² *Id.* at 2116.

³³ *Id.*

³⁴ Technically, there is no "typical" gene because nucleotide sequences vary between individuals, sometimes dramatically. Geneticists refer to the most common variations of genes as "wild types."

mutations in a patient's BRCA1 and BRCA2 genes, thus allowing a physician to assess whether the patient had an increased risk of cancer.

B. Procedural History

In 2010, Judge Sweet of the U.S. District Court for the Southern District of New York invalidated the challenged claims as patent-ineligible under 35 U.S.C. § 101.³⁵ Myriad appealed to the U.S. Court of Appeals for the Federal Circuit, which reversed in a divided decision issued on July 29, 2011.³⁶ After the Supreme Court issued their decision in *Mayo v. Prometheus*, they granted *certiorari*, vacated the July 29, 2011 Federal Circuit *Myriad* decision, and remanded the case to the Federal Circuit for reconsideration in view of *Mayo*.³⁷ *Mayo* limited the availability of patents for medical diagnostic techniques claiming a new way to apply the laws of nature, requiring that these techniques recite more than “routine, [or] conventional activity previously engaged in by researchers in the field.”³⁸

The Federal Circuit issued its *Myriad* remand decision on August 16, 2012, essentially reiterating their first decision. Judge Lourie, writing for the majority, emphasized the molecular differences between the claimed sequences and the equivalent DNA existing in human cells, finding “[i]t is the difference between knowledge of nature and reducing a portion of nature to concrete form, the latter activity being what the patent laws seek to encourage and protect.”³⁹ In her concurring opinion, Judge Moore focused on the function and utility of the isolated DNA

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1302 (2012).

³⁹ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1353 (Fed. Cir. 2011), *reh'g denied* (Sept. 13, 2011), *reh'g denied* (Sept. 16, 2011), *cert. granted, judgment vacated sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), and *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012).

sequences, the settled expectations of the inventing community, and her belief that the judiciary should defer to Congress on issues where they have acted to determine that the scales had tipped in the favor of patentability.⁴⁰ Contrary, Judge Bryson, in a dissenting opinion., argued that the DNA molecules, while structurally different, were not materially different from those found in their native environment, therefore rendering them unpatentable.⁴¹

In light of the circuit court holding, the Supreme Court again granted *certiorari*, and heard oral arguments on April 15, 2013.⁴²

C. The Decision

The Court's decision focuses on the "product of nature" exception to 35 U.S.C. § 101, and whether or not the grant of patents on naturally occurring phenomenon would be counterproductive to the stated reason for issuing patents: to promote creation.⁴³ The Court's concern was that patents on naturally occurring phenomenon, the basic tools of scientific and

⁴⁰ *Id.* at 1367 (Moore, J. concurring) ("Congress has, for centuries, authorized an expansive scope of patentable subject matter. Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified natural products for centuries. There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof. . . . I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved. Combined with my belief that we should defer to Congress, these settled expectations tip the scale in favor of patentability.").

⁴¹ *Id.* at 1378 (Bryson, J., dissenting) ("The structural differences between the claimed 'isolated' genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form.").

⁴² *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2114 (2013).

⁴³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

technological work, would “tie up” the use of such tools and thereby “inhibit future innovation premised upon them.”⁴⁴

1. Naturally Occurring DNA, Even Though Isolated, Is Not Patentable

The Court recognized that Myriad “found an important and useful gene” but then stipulated that “separating that gene from its surrounding genetic material is not an act of invention.”⁴⁵ The Court relied heavily on three prior decisions in their holding: *Diamond v. Chakrabarty*; *Funk Brothers Seed Co. v. Kalo Inoculant Co.*; and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* Each case involved the use or interpretation of a natural phenomenon, with differing levels of modification or intervention affecting each outcome.

Chakrabarty patented the genetic modification of a bacterium making it “capable of breaking down multiple components of crude oil.”⁴⁶ Funk Brothers Seed Co. distilled six different Rhizobium bacteria and combined them into a powder form that could inoculate the seeds of certain legumes, which enabled them “to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds.”⁴⁷ Finally, Prometheus Laboratories, Inc. determined the “relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm.”⁴⁸ This allowed them to define a process by which health care professionals could test their patients in order to determine the correct dosage without trial and error, thus reducing the risks associated

⁴⁴ *Myriad*, 133 S. Ct. at 2116 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

⁴⁵ *Id.* at 2117.

⁴⁶ *Chakrabarty*, 447 U.S. at 305.

⁴⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128 (1948).

⁴⁸ *Mayo*, 132 S. Ct. at 1296.

with the drug.⁴⁹ In each case, a natural phenomenon or process was significantly improved and/or combined to enhance usability, however, the Court found they were not all patent-eligible.

a) *Diamond v. Chakrabarty*

In 1972, Ananda Mohan Chakrabarty, working with the General Electric Corporation, developed a new strain of bacterium that could degrade multiple components of crude oil, thereby speeding up the process of decomposition. Naturally occurring bacteria that could accomplish the same process were known, however, no known bacterium was capable of breaking down multiple components of the crude oil complex.⁵⁰

For example, at the time of invention, biological control of oil spills required the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex.⁵¹ As part of this degradation process, oil is broken down into simpler substances that serve as food for aquatic life. However, for various reasons, only a portion of any such mixed culture survives to attack the oil spill.⁵² Conversely, Chakrabarty's micro-organism promised a

⁴⁹ *Id.*

⁵⁰ *Chakrabarty*, 447 U.S. at 305.

⁵¹ *See id.* at 305 n.2; *see also* U.S. Patent No. 3,813,316 col. 5 ll. 9-16 (filed Jun. 7, 1972).

⁵² '316 Patent col. 5 ll. 9-33. Microbial strains are known that can decompose individual components of crude oil (thus, various yeasts can degrade aliphatic straight-chain hydrocarbons, but not most of the aromatic and polynuclear hydrocarbons). *Pseudomonas* and other bacteria species are known to degrade the aliphatic, aromatic and polynuclear aromatic hydrocarbon compounds, but, unfortunately any given strain can degrade only a particular component. For this reason, prior to the instant invention, biological control of oil spills had involved the use of a mixture of bacterial strains, each capable of degrading a single component of the oil complex on the theory that the cumulative degradative actions would consume the oil and convert it to cell mass. This cell mass in turn serves as food for aquatic life. However, since bacterial strains differ from one another in (a) their rates of growth on the various hydrocarbon components, (b) nutritional requirements, production of antibiotics or other toxic material, and (c) requisite pH, temperature and mineral salts, the use of a mixed culture leads to the ultimate survival of but a portion of the initial collection of bacterial strains. As a result, when a mixed culture of

rapid and more efficient oil-spill control by breaking down multiple components of oil with a much higher survival rate.⁵³

The Supreme Court held the micro-organism to be patentable, recognizing that what Chakrabarty produced was a “new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility.”⁵⁴ In the case at hand, the Court distinguished *Myriad* by pointing out that Myriad had not created anything. They had instead merely isolated an existing natural phenomenon. Where Chakrabarty had added plasmids in order to “create” a new bacterium with greatly improved “capacity for degrading oil,”⁵⁵ by contrast, “Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”⁵⁶

b) *Funk Brothers Seed Co. v. Kalo Inoculant Co.*

Funk Brothers Seed Co. combined six different naturally occurring rhizobium bacteria that infect the roots of legumes, enhancing the plant’s ability “to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds.”⁵⁷ The bacteria occurred naturally and performed essentially the same function as Mother Nature.⁵⁸ However, the different species of bacteria only combined with specific plants.⁵⁹ In addition, when certain strains came in contact with one another they inhibited the efficacy of each other, greatly

hydrocarbon-degrading bacteria are deposited on an oil spill the bulk of the oil often remains unattacked for a long period of time (weeks) and is free to spread or sink.

⁵³ *Id.*, at col. 3 l. 5-19.

⁵⁴ *Chakrabarty*, 447 U.S. at 310.

⁵⁵ *Id.* at 305.

⁵⁶ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

⁵⁷ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128 (1948).

⁵⁸ U.S. Patent No. 2,200,532 col. 1 ll. 5-8.

⁵⁹ *Funk Bros.*, 333 U.S. at 129; *see also* '532 Patent col. 2 ll. 31-36.

reducing nitrogen fixation.⁶⁰ Funk Brothers Seed Co. determined that there were six strains that could inoculate many different types of legumes, without exhibiting the mutually inhibitory behavior.⁶¹ Consequently, Funk Brothers combined the six different types of bacteria packaged in powder form, allowing farmers to infect the seeds of their varied legume crops without worry of cross inoculation, which would cancel out the beneficial effects.⁶²

The focus of Funk Brothers work was not to create a new strain of the bacterium; instead, their work concentrated on the identification of different bacterium that would not inhibit the beneficial effects of each other and would inoculate a large number of legume varieties. Therefore, farmers would be able to purchase one inoculation product, without having to worry about cross inoculation. This work was ground breaking in the field; however, the Supreme Court held that it was not patentable.⁶³ The Court held that they had not created something new, but had instead mixed what nature had created into a very useful combination.⁶⁴

In the instant case, the Supreme Court held that *Myriad* was analogous to *Funk Brothers*. The Court found that *Myriad* had not created something new; instead, they had taken naturally

⁶⁰ See *Funk Bros.*, 333 U.S. at 129-30 (“[T]he different species of the Rhizobia bacteria produced an inhibitory effect on each other when mixed in a common base, with the result that their efficiency was reduced.”)

⁶¹ See *id.* at 130 (“[Funk Brothers] discovered that there are strains of each species of root-nodule bacteria which do not exert a mutually inhibitive effect on each other. [They] also ascertained that those mutually non-inhibitive strains can, by certain methods of selection and testing, be isolated and used in mixed cultures. Thus [they] provided a mixed culture of Rhizobia capable of inoculating the seeds of plants belonging to several cross-inoculation groups.”)

⁶² See *id.*

⁶³ See *id.* at 131 (Douglas, J) (“[H]owever ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants.”).

⁶⁴ See *id.* at 132 (“The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature’s secret of the non-inhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention.”)

occurring phenomenon and distilled them into an admittedly advantageous combination.⁶⁵ The *Myriad* Court emphasized that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry,”⁶⁶ nor does “extensive effort.”⁶⁷

3. Mayo Collaborative Services v. Prometheus Laboratories, Inc.

Prometheus Labs sued the Mayo Clinic after learning that they had developed testing procedures that infringed U.S. Patents 6,355,623 and 6,680,302. These patents claimed steps of testing blood samples that allowed physicians to determine the proper dosage for thiopurine drug treatment of immune-mediated diseases, such as Crohn’s disease and Ulcerative Colitis.⁶⁸ When ingested, the body converts the thiopurine into therapeutic metabolites that suppress the patient’s immune system and alleviate symptoms.⁶⁹ The patented test provided a means to measure the level of two such metabolites in the blood: 6-thioguanine and 6-methylmercaptopurine.⁷⁰ According to the patent, metabolite levels “greater than about 400” and “greater than about 7000” respectively, indicate that an adjustment in drug dosage may be required to avoid toxic side effects.⁷¹

After purchasing and using the Prometheus test from 1999-2004, the Mayo Clinic developed their own test utilizing similar methods, however, they used different determinative

⁶⁵ *Funk Bros.*, 333 U.S. at 128.

⁶⁶ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013).

⁶⁷ *Id.* at 2118.

⁶⁸ U.S. Patent No. 6,355,623 col. 2 ll. 16-41 (filed Apr. 8, 1999); U.S. Patent No. 6,680,302 col. 2 ll. 18-43 (filed Dec. 27, 2001).

⁶⁹ ‘623 Patent col. 8 ll. 9-20.

⁷⁰ *Id.*

⁷¹ *Id.*

metabolite levels that they claimed were more effective.⁷² Mayo announced their intention to begin using the test in their clinics, as well as offering it for sale to other potential users.⁷³ Prometheus then filed suit, and Mayo subsequently rescinded the announced deployment of their test pending the outcome of litigation. A federal judge for the Southern District of California granted summary judgment in favor of Mayo. The judgment held that although Mayo was infringing the patents, the metabolites “6-TG and 6-MMP are products of the natural metabolizing of thiopurine drugs, and the inventors merely discovered the relationship between these naturally produced metabolites and therapeutic efficacy and toxicity,” therefore the patents were invalid and unenforceable.⁷⁴

Prometheus appealed, and the U.S. Court of Appeals for the Federal Circuit reversed the lower court order.⁷⁵ The Federal Circuit held that the lower court erred in categorizing the administrative and determinative steps as data gathering steps.⁷⁶ Conversely, the court held that the administering and determining steps in the patents were part of the treatment regimes for various diseases using thiopurine drugs. Therefore, the claims were “not drawn merely to correlations between metabolite levels and toxicity or efficacy.”⁷⁷ In addition, the court held that while mental steps are not normally patentable, the mental steps in the Prometheus Patents were subsequent steps that made use of the data provided by the prior administering and determining

⁷² Prometheus Labs., Inc. v. Mayo Collaborative Servs., CIV. 04CV1200JAHRBB, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008) *rev'd*, 581 F.3d 1336 (Fed. Cir. 2009) *cert. granted, judgment vacated*, 130 S. Ct. 3543 (2010), *rev'd*, 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1339 (Fed. Cir. 2009) *cert. granted, judgment vacated*, 130 S. Ct. 3543 (2010) (reversing because the district court erred as a matter of law in finding the asserted claims to be drawn to nonstatutory subject matter)

⁷⁶ *Id.*

⁷⁷ *Id.* at 1348.

steps.⁷⁸ Therefore, the “addition of the mental steps to the claimed methods thus does not remove the prior two steps from that realm.”⁷⁹

Mayo appealed to the Supreme Court who granted *certiorari* and vacated the Federal Circuit opinion, remanding the case for review in light of Supreme Court’s 2010 decision in *Bilski v. Kappos*, which held that a key legal test utilized in the federal circuit decision, the “machine-or-transformation test,”⁸⁰ was not the sole test for deciding whether a process was patent-eligible.⁸¹ The Federal Circuit once again considered the case and came to the same conclusion they had previously, emphasizing that the Supreme Court had not invalidated the machine-or-transformation test, but rather that they had held that it was not the sole test.

Mayo once again appealed and the Supreme Court granted *certiorari*, and once again reversed the Federal Circuit Court decision, holding that the claimed processes were not novel, but “involve well-understood, routine, conventional activity previously utilized by researchers in the field.”⁸² Further, they held that “upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”⁸³ The emphasis on preemption as a reason for invalidation of patent claims is the key to understanding the importance of the Mayo decision in the current litigation.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ The “machine-or-transformation test” is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing (1) that his claim is tied to a particular machine, or (2) by showing that his claim transforms an article. *In re Bilski (Bilski I)*, 545 F.3d 943, 950 (Fed. Cir. 2008), *aff’d but criticized sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

⁸¹ *Bilski*, 130 S. Ct. at 3227.

⁸² *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

⁸³ *Id.*

Justice Thomas, in this remarkably restrained opinion, chose not to highlight preemption as the reason for the Court's holding. However, the opinion does reveal that the dangers of preemption were at least part of the Court's reason for holding the isolated DNA claims invalid. Citing *Mayo*, the Court reasoned that without the product of nature exception, "there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'"⁸⁴

In addition, Justice Thomas, contemplating the possible ways that Myriad could have couched the discovery in patentable terms, postulated that had Myriad patented the chemical compound of the gene as a unique molecule instead of the naturally occurring gene sequence, then a would be infringer "could arguably avoid at least Myriad's patent claims on entire genes . . . by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair."⁸⁵ This obviously was not the case here, but Justice Thomas' reasoning illustrated the dangers against which preemption seeks to protect, tying up a natural phenomenon such that others could not build on the work of the patentee. Or, put another way, Myriad's claims monopolized what should be "free to all men and exclusively reserved to none."⁸⁶

2. Summary of the Court's Reasoning

The Court was not swayed by Myriad's argument that similar to the bacterium in *Chakrabarty*, Myriad's "claims are drawn to man-made compositions of matter (or at least man-

⁸⁴ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo*, 132 S. Ct. at 1301).

⁸⁵ *Id.* at 2118.

⁸⁶ *Funk Bros.*, 333 U.S. at 130.

made improvements thereof).”⁸⁷ The Court literally held quite the opposite when it stated: “Myriad did not create anything. To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”⁸⁸

The Court found that Myriad’s isolated DNA claims were analogous to those in *Funk Brothers*; they had taken naturally occurring phenomenon and distilled them into an admittedly advantageous combination.⁸⁹ And like the claims in *Funk Brothers*, the Court invalidated Myriad’s claims citing the law of nature exception.⁹⁰ The Court emphasized that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry,”⁹¹ nor does “extensive effort.”⁹²

Finally, the Court made a subtle nod to the proverbial bastard child of patent law: preemption. While enumerating the reasoning for the long held implicit law of nature exception, Justice Thomas reasoned that “without [the law of nature] exception, there would be considerable danger that the grant of patents would ‘tie up’ the use of such tools and thereby ‘inhibit future innovation premised upon them.’”⁹³

⁸⁷ Brief for Respondents at 34, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S. Mar. 7, 2013), 2013 WL 860315.

⁸⁸ *Myriad*, 133 S. Ct. at 2117.

⁸⁹ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128 (1948).

⁹⁰ *Myriad*, 133 S. Ct. at 2117 (“[*Funk Brothers*] patent claim . . . fell squarely within the law of nature exception. So do Myriad’s. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes “new . . . composition[s] of matter,” § 101, that are patent eligible.”)

⁹¹ *Id.*

⁹² *Id.* at 2118.

⁹³ *Id.* at 2116 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012)).

Taken as a whole, the Court leaves us with the fungible guidance that in order to be patent-eligible natural material must be altered by the inventor “in any way.”⁹⁴ The attempts by the patenting community to define and understand this “in any way” standard, will be hotly contested, both in and out of courts of law, for years to come.

IV. Impact of the Holding Moving Forward

The decision affects three distinct groups of inventors, in very different ways. These groups are: those holding current patents which may now claim patent-ineligible matter, those who have current applications pending with similar claims, and those who are in the various stages of Research and Development in anticipation of patent filing. The following will be a brief discussion of the impact on each group.

A. Current Patent Holders

First, the group that will be impacted the most are those who currently hold patents claiming isolated genes. The claims contained in these patents that cover isolated DNA can now be invalidated, which will impact the inventors or patent holders in various ways. First, if the patented material is licensed, the licensees, who will no longer be protected by the patent in their own endeavors, will look for ways to terminate the license. This could be accomplished utilizing existing contractual terms, or in some cases, by patent challenges by the licensee themselves who seek to invalidate the patent claims so they can practice the subject matter free from the constraints of the license.⁹⁵ Second, inventors who practice the inventions claimed in the patents

⁹⁴ *Id.* at 2117 (summarizing the *Funk Brothers* holding, “that the composition was not patent eligible because the patent holder did not alter the bacteria in any way”).

⁹⁵ Article III of the Constitution requires that a case-or-controversy exist before a suit may be brought in federal court. This so called “federal standing doctrine” imposes three limitations on prospective plaintiffs. First, the plaintiff must have suffered an injury in fact - an invasion of a

themselves will likely see competitors seeking invalidation,⁹⁶ or, more likely, their competitors will simply begin to practice the claimed inventions, thus leaving the inventors in the unenviable position of deciding whether to initiate an infringement suit. However, given the cost and time-consuming nature of patent litigation, patent holders are more likely not to file suit over now questionable claims.

On the other side, there are likely many patents that contain broad claims that encompass both unpatentable material (isolated DNA), as well as patent eligible material (cDNA). Going forward these will be the most interesting cases. Patentees will most likely choose to take proactive steps to shore up their patent coverage by applying for reissuance of the patent. 35 U.S.C. § 251 governs the reissue of patents and outlines the rules USPTO will follow when deciding whether or not to grant a reissued patent. Section 251 provides that the USPTO may reissue a patent, upon surrender of the original patent, if the patent is “through error,⁹⁷ deemed

legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. If a plaintiff fails to satisfy any of these requirements, they cannot sue in federal court. In the patent context, that means they cannot challenge the validity of a patent. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1342-43 (Fed. Cir. 2011), *reh'g denied* (Sept. 13, 2011), *reh'g denied* (Sept. 16, 2011), *cert. granted, judgment vacated sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 2012). It is likely that a licensee will have little trouble meeting this burden; however, this may be more relevant to patentee's competitors discussed *infra*.

⁹⁶ Competitors may have more trouble initially meeting the limitations of the federal standing doctrine, but the inclusion of the word imminent threat of invasion of a legally protected interest will likely get many would be plaintiffs into court. *See supra* note 74.

⁹⁷ *Ball Corp. v. United States*, 729 F.2d 1429, 1435-36 (Fed. Cir. 1984) (holding, for reissue purposes, that “error is established where there is no evidence that the appellant intentionally omitted or abandoned the claimed subject matter”).

wholly or partly inoperative or invalid.”⁹⁸ Section 251 is remedial in nature, based on “fundamental principles of equity and fairness, and should be construed liberally;” nonetheless, “not every event or circumstance that might be labeled ‘error’ is correctable by reissue.”⁹⁹ Patentees with claims that are now overly broad fall into this reissue category and may be allowed, within limitations, to amend their claims to remove the patent-ineligible material while retaining the patentable subject matter.¹⁰⁰

Section 251 limits the subject matter of the amended claims to subject matter that was in the original patent stating: “no new matter shall be introduced into the application for reissue.”¹⁰¹ Careful claim drafting, designed to give the maximum coverage possible under the new guidelines, is where the need for an excellent patent lawyer comes into play. Introduction of new matter does not mean that the substitute claim can only contain the same subject matter as the original. Instead, it means that it cannot contain subject matter that was not included in the original claims and/or specifications.¹⁰² Therefore, taking into account the broad nature of patent specifications, a good patent drafter may be able to retain much of the originally covered material by crafting claims utilizing the original specifications and subject matter that the Court

⁹⁸ 35 U.S.C. § 251 (2006) (pre-AIA) (applicable to patents issued before Sep. 16, 2012); *see also* 35 U.S.C. § 251 (2012) (applicable to patents issued on or after Sep. 16, 2012). The post-America Invents Act section omits “without any deceptive intention.” Leahy-Smith America Invents Act § 20, Pub. L. No. 112-39, 125 Stat. 284, 333 (2011).

⁹⁹ *In re Weiler*, 790 F.2d 1576, 1579 (Fed. Cir. 1986).

¹⁰⁰ *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1294 (N.D. Ill. 1990), *aff’d*, 945 F.2d 416 (Fed. Cir. 1991) (“A reissue application prosecution is a corrective proceeding, with one of the express purposes being to reduce the scope of an overclaimed invention—to correct the overbreadth.”); *see also* *White v. Fafnir Bearing Co.*, 389 F.2d 750, 754-55 (2d Cir. 1968) (“[T]he purpose of the reissue patent provision is to permit an inventor to correct a mistake when his patent application covers more than the true invention.”)

¹⁰¹ *Id.*

¹⁰² *See In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 526 (Fed. Cir. 2012) (holding that the decision to claim a specific chemical compound in the reissue application was proper because it “was explicitly described in the [patent] specification as the preferred compound”).

did not exclude from patentability, i.e. chemical compositions of the isolated DNA sequence,¹⁰³ emphasizing the importance the claimed cDNA,¹⁰⁴ claiming the methods of isolation,¹⁰⁵ or, if applicable, claiming the DNA in an altered state.¹⁰⁶

While this decision might affect those holding one of the estimated 40,000 genetic material patents, it will certainly impact those who hold one of the almost 3,000 which are specifically directed to isolated DNA molecules.¹⁰⁷ The effects may be minimized by clear, unbiased, and unvarnished assessment of the continued utility of existing patents. If they are worth saving, a well thought out, and progressive looking plan of action to recapture as much protection as possible will be necessary.

¹⁰³ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2118 (2013). Justice Thomas intimated that, had Myriad's claims been expressed in terms of chemical composition, they may have survived the product-of-nature exclusion. "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA." *Id.*

¹⁰⁴ *Id.* at 2119 ("cDNA is not a 'product of nature' and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA.")

¹⁰⁵ *Id.* ("[T]here are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.")

¹⁰⁶ *Id.* at 2120 (holding that DNA may be patentable if "the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors.")

¹⁰⁷ See Rogers, *supra* note 29, at 19, 40; see also Richard Wolf, *Justices Rule Human Genes Cannot Be Patented*, USA TODAY, (Jun. 13, 2013), <http://www.usatoday.com/story/news/nation/2013/06/13/supreme-court-gene-breast-ovarian-cancer-patent/2382053/> ("Since 1984, the U.S. Patent and Trademark Office has granted more than 40,000 patents tied to genetic material."); see also Randolph V. Clower, *Impending Myriad Decision Portends Promethean Consequences for Biotech Industry*, METROPOLITAN CORP. COUNS., Mar. 2013, at 9.

B. Patent Applications in their Various Stages and Inventors Anticipating Patent

Applications

Existing patent applications and inventors who are in various stages of Research and Development (R&D) anticipating application for patent protection will take a similar approach, albeit through a different route. Pending applications will need to be amended to remove patent-ineligible subject matter, while future applications will need to be crafted to avoid their inclusion. However, those with current applications pending will first need to decide if they wish to continue the current prosecution, in which they will not be allowed to include new subject matter in claim amendment;¹⁰⁸ or, to withdraw the application, regroup, and reassess their plan of attack.

C. Continued Patentability of Gene Isolation Methods

It is important to note that this decision does not affect the patentability of the methods utilized to isolate the DNA.¹⁰⁹ Statute defines claimed inventions that fall into the process category as: a “process, art or method, and includes a new use of a known process, machine manufacture, composition of matter, or material.”¹¹⁰ The Supreme Court further explained:

¹⁰⁸ 35 U.S.C. § 132(a) (2012) (“Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. *No amendment shall introduce new matter into the disclosure of the invention.*”).

¹⁰⁹ *Myriad*, 133 S. Ct. at 2119 (“Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.”)

¹¹⁰ 35 U.S.C. § 100(b) (2012).

A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art. The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.¹¹¹

Thus, the Court left the door open to patent the methods or processes used to isolate the DNA. The reasoning behind this distinction once again returns to preemption. The patentability of the method and/or process of isolation does not preclude others from using the isolated gene, it simply limits the way in which they can accomplish the isolation of the desired gene. In light of this distinction, the methods for isolating the DNA and, more importantly, new applications of knowledge gleaned from the information obtained from the genetic sequences, remain patent-eligible.

D. Overall Effect on Innovation and Industry

The decision, while far reaching in its implication, may not have the chilling effect that many in the legal profession predicted.¹¹² Biomedical researchers, especially those at universities and government funded facilities, report that intellectual property concerns have very little, if any, impact on their research.¹¹³ In a 2003 survey, Walsh *et al.* found that of the participants in

¹¹¹ *Diamond v. Diehr*, 450 U.S. 175, 182-83 (1981) (internal quotations omitted).

¹¹² See Dalila Arguez Wendlandt & James F. Haley, Jr., *Supreme Court Rules That Isolated Human Gene Is Not Patent Eligible in AMP v. Myriad*, ROPES & GRAY ALERT (Jun. 14, 2013), http://www.ropesgray.com/news-and-insights/Insights/2013/06/~/_/media/Files/alerts/2013/06/20130614_IP_Alert.ashx; see also Clower, *supra* note 106, at 9.

¹¹³ John P. Walsh, Ashish Arora & Wesley M. Cohen, *Working Through the Patent Problem*, 299 SCIENCE 1021, 1021 (Feb. 14, 2003) (“[M]ost respondents said that infringement of research tool patents, especially by university researchers, is common. A third of the industrial

the study “almost none of [the] respondents reported worthwhile projects being stopped because of issues of access to IP rights to research tools.”¹¹⁴ This seems to be in large part because researchers choose to ignore patents, making infringement common.¹¹⁵ When those who had knowingly infringed a patent were asked why they chose to ignore the patentee’s rights most “justified such infringement by invoking a research exemption.”¹¹⁶

On the other hand, human genetics researchers, for whom gene patents are obviously particularly relevant, will likely be the ones most impacted by the decision. Unlike the biomedical researchers in the Walsh *et al.* surveys, a survey by Cho *et al.* of U.S. clinical genetics laboratories indicated that 65% had received notification of potential infringement.¹¹⁷

respondents (and all nine university or government lab respondents) acknowledged occasionally using patented research tools without a license.”)

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.* (Internal quotations omitted). This study was largely completed before the *Madey v. Duke* decision in which the U.S. Court of Appeals for the Federal Circuit held that educational institutions were not automatically exempt from infringement suits because they are not-for-profit, or the use of the patented material had no commercial application. 307 F.3d 1351, 1362 (Fed. Cir. 2002). Instead, they clarified previous holdings by specifying that a courts focus should be “on the legitimate business [the accused infringer] is involved in and whether or not the use [of the patented technology] was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* In response to this holding, Walsh *et al.* conducted another, similar study in 2005 to determine the impact of the decision on researchers’ practices. Interestingly, the holding, while most were aware of it, had little impact on a similar set of subjects. Only 2% (i.e., eight) of the participants report having begun checking for patents in the two years since *Madey v. Duke*, which suggests little impact of the decision. Five percent had been made aware of intellectual property (IP) relevant to their research through a notification letter sent either to them or their institution, which differs little from the 3% who reported having received such notification five years ago (prior to the *Madey v. Duke* decision). Furthermore, although 22% of respondents report being notified by their institutions to respect patent rights (versus 15% in the earlier study), such notification did not appreciably affect the likelihood of checking for patents - 5.9% of those receiving such instruction checked for patents versus 4.5% of those not receiving instruction. John P. Walsh, Charlene Cho & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002-03 (Sept. 29, 2005).

¹¹⁷ Mildred K. Cho, Samantha Illangasekare, Meredith A. Weaver, Debra G. B. Leonard & Jon F. Merz, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5

These are the labs that conduct important research to develop clinical tests. The Cho *et al.* study found that 25% of those labs had discontinued a test and 53% decided not to conduct research to develop a test because of the threat of patent litigation. Further, 67% felt that patents inhibited their ability to conduct genetic research and 85% indicated that patents resulted in less sharing of information among researchers.¹¹⁸ Similarly, an opinion poll conducted by Dr. Isaac Rabino, a professor of Biological and Health Sciences at Empire State College, of the members of the American Society of Human Genetics, revealed that 49% of respondents reported that patents delayed or limited their research.¹¹⁹ To the extent that such research was inhibited by the existence of a patent on a DNA sequence, the removal of that barrier could prove significant.

So with the door open and researchers ready to innovate, the burning question becomes whether anyone will pay to keep the lights on, the equipment working, and oh yes,, the researchers paid? In a perfect world, we wouldn't have to worry about the cost of research. Ideas could be developed to their fullest potential, free from monetary and time constraints, and ideas would be shared by all people who would collaborate freely. Alas, this Utopian vision does not exist and innovators cannot live on ideas alone. So where is the money coming from, and will it continue without the promise of patent protection?

Researchers are likely to be funded by a mix of grants from various government agencies, institutions, and foundations. For example, a 2007 study of the movement of carbon in the ocean was funded by the National Science Foundation, the U.S. Department of Energy, the Australian

J. MOLECULAR DIAGNOSTICS 3, 5 (2003), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907368/pdf/0108.pdf>.

¹¹⁸ *Id.*

¹¹⁹ Isaac Rabino, *How Human Geneticists in US View Commercialization of the Human Genome Project*, 29 NATURE GENETICS 15, 16 (2001).

Cooperative Research Centre, and the Australian Antarctic Division.¹²⁰ Other research is funded by private companies who generally finance research projects or studies related to their field. This type of finding is prevalent in some fields, especially medicine. In the U.S., almost 75% of clinical trials in medicine are paid for by private companies.¹²¹

V. cDNA Is Patent-Eligible! But Is It Patentable?

An overly simplified description of the difference between naturally occurring DNA and cDNA is that DNA contains the instructions for building every protein the body utilizes,¹²² as well as many unused (non-coding),¹²³ or inactive segments.¹²⁴ Synthetic DNA (aka cDNA), is made in a lab by transcribing mRNA (which is an inverse copy of the original DNA), into a complementary form (an inverse copy of the mRNA), which contains the same essential code as its naturally occurring complement (DNA) with the unused segments excluded.¹²⁵

So what makes the cDNA patent-eligible? The answer is: the hands of man! In 1799, Chief Justice Lord Kenyon penned the infamous gold-standard for determining the threshold question of patentability, “I have no doubt in saying, that this is a patent for a manufacture, which I understand to be something made by the *hands of man*.”¹²⁶ A similar sentiment, quoted with approval by the Supreme Court in *Chakrabarty* and often preached as the will of Congress,

¹²⁰ Ken O. Buesseler et al., *Revisiting Carbon Flux Through the Ocean's Twilight Zone*, 316 SCIENCE 567 (Apr. 27, 2007).

¹²¹ Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539 (2000).

¹²² BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 104 (4th ed. 2002).

¹²³ *Id.* at 341.

¹²⁴ *Id.* at 401.

¹²⁵ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013).

¹²⁶ *Hornblower v. Boulton* (K.B. 1799), 8 T.R. 95, 98-99 (emphasis added).

that patentable subject matter should “include anything under the sun that is made by man.”¹²⁷ And once again in this case, the Supreme Court dismissed the naturally occurring nucleotide sequence necessary to make the invention useful,¹²⁸ finding instead that “the lab technician unquestionably creates something new when cDNA is made.”¹²⁹

The continued patent-eligibility of cDNA has been hailed by many as a win for the biotech industry.¹³⁰ The reason most often cited being that commercially, cDNA may be the most important form of DNA used.¹³¹ While this may be true, this is a truly shortsighted view. Just because cDNA meets the threshold requirements of § 101, does not mean that it is patentable, or that existing patents will withstand an invalidity action. The Court merely held that cDNA is eligible to walk through the door; it must still survive the gauntlet that awaits once inside.

To highlight this point, let’s take a hypothetical cDNA molecule. The Court points out that cDNA does not contain introns like the naturally occurring DNA it compliments, incidentally one of the reasons they held it is not a “product of nature.”¹³² mRNA is a more useful predictor of a polypeptide sequence than DNA because the introns have been spliced out,

¹²⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing S. REP. NO. 1979, 82d Cong., at 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess., at 6 (1952)).

¹²⁸ *Myriad*, 133 S. Ct. at 2119.

¹²⁹ *Id.*

¹³⁰ Jeffrey M. Perkel, *Gene Patents Decision: Everybody Wins*, *Scientist* (Jun. 18, 2103), <http://www.the-scientist.com/?articles.view/articleNo/36076/title/Gene-Patents-Decision--Everybody-Wins/> (“Last week’s Supreme Court decision to invalidate patents on human genes was a win for patients, independent researchers, and even the wider biotech industry.”).

¹³¹ Magdalena Gugucheva, *Genewatch: The Physical Embodiment of Information*, COUNCIL FOR RESPONSIBLE GENETICS, <http://www.councilforresponsiblegenetics.org/GeneWatch/GeneWatchPage.aspx?pageId=302> (“Currently, any commercial diagnostic test must use cDNA. Isolated DNA in its natural form is not usable for these purposes. Furthermore, any research into the BRCA1/2 genes requires the use of cDNAs.”).

¹³² *Id.*

however, it is not as stable because it's single stranded structure make it more prone to undesired chemical reactions. Enter cDNA, an inverse, double stranded copy of the mRNA that is more stable.¹³³

This is all sounding very exciting if I am a researcher. I found the gene I want to study, I identified the mRNA transcript and now I can make cDNA. I know I can't get patent protection for all the work I put into discovering the gene sequence, but the Supreme Court did say that I could patent the more useful cDNA. Awesome, where is the patent application? But, and there is a big but, isn't it logical to remove the non-coding portions? They don't do anything anyway. How about making more stable copies of a useful molecule; that sounds obvious too, right? Therein lies the problem. Compliments of naturally occurring DNA are not novel, nor are they non-obvious. If you want to work with most genes, then cDNA is going to be one of the obvious tools you use. So even though the very useful tool you just created has been called patent-eligible by the Supreme Court, the hypothetical person of ordinary skill in the art is going to keep you from reaching the end of the gauntlet, and your discovery remains unpatentable.

Obviously this was a rather ridiculous, and probably not very realistic scenario, but it does serve to highlight the problem with all the rhetoric and misinformation. The Supreme Court did not hold that you will get a patent for the cDNA you created, or the DNA you described as a chemical compound instead of the natural sequence, or the methods you used to discover such. The Court only addressed the question of whether or not they were patent-eligible material. To actually be patented, the invention must meet the other requirements of Title 35 as well.

¹³³ MATTHEW B. AVISON, MEASURING GENE EXPRESSION (2007).

VI. Conclusion

Where does this decision leave the patenting community? Unfortunately, lamenting as Paul, “[f]or now we see through a glass, darkly.”¹³⁴ The decision, despite all the buildup, has given the inventing community few answers, and perhaps even more questions. Perhaps Myriad summed it up best in a post on their Facebook page saying the case was about more than patent claims: “It was about human health, and innovation to make sure that cancer tests are accessible and affordable to women who need them.”¹³⁵

The good news is the Court has defined the § 101 threshold inquiry, and decided that the hands of man must be clearly seen in an invention before the inventor may cross it. However, the Court has left inventors wondering: once an invention is eligible to cross the threshold, will §§ 102, 103, and 112 be hiding behind the door waiting to slam it in their faces? As Myriad argued in their brief opposing certiorari, “the relevance of patenting isolated human DNA is ever diminishing in light of the publication of the entire human genome in 2001 . . . , thus presenting arguable bars to patentability under other provisions of the Patent Act (such as obviousness under § 103) for any claims to isolated human DNA molecules sought after that date.”¹³⁶ This same argument will undoubtedly now be applied to cDNA. When the entire genome is mapped, and the methods and technology needed to produce complimentary versions are commonplace, where is the novelty? Further, is it not obvious to a person having ordinary skill in the art to produce these complimentary versions that are easier to work with? Only time will tell how the USPTO and the courts will handle these questions.

¹³⁴ 1 *Cor.* 13:12 (King James).

¹³⁵ Myriad Genetics Posting on Supreme Court’s *Myriad* Ruling, FACEBOOK (June 13, 2013), <https://www.facebook.com/MyriadGenetics/posts/390312274422518>.

¹³⁶ Brief in Opposition at 35, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398, (U.S. Oct. 31, 2012), 2012 WL 5375608.