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A LITTLE LIGHT ON THE *MAYO*: A METHOD FOR OVERTURNING THE FEDERAL CIRCUIT’S
LATEST *ASSOCIATION FOR MOLECULAR PATHOLOGY* DECISION

Kevin J. Georgek*

I. INTRODUCTION

Patents grant their owners the right to exclude others from practicing a claimed invention for a limited time.¹ Whether patents actually protect the economic interests of their owners, provide incentive for innovation, and foster economic growth has been extensively debated.² There are undisputedly, however, times when the same patents that may protect an entity’s exclusive interest in a claimed invention—to an important, lifesaving therapy for instance—simultaneously deprive others of access to that very invention resulting in significant harm to those excluded.³ Precedent indicates, and policy dictates, that when awarding a patent could inhibit subsequent advances in a given field to the detriment of researchers and patients, a modification to the traditional calculus for determining whether subject matter is patent-eligible is warranted.⁴ This modification involves broadening the scope of appropriate considerations to encompass extra-statutory concerns.

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¹ See U.S. CONST. art. I, § 8, cl. 8; *Boomer v. McQuewan*, 55 U.S. 539, 549 (1852) (defining a patent as a franchise granting “the right to exclude everyone from making, using, or vending the thing patented, without the permission of the patentee”).

² See Ted Sichelman & Stuart J.H. Graham, *Patenting by Entrepreneurs: An Empirical Study*, 17 MICH. TELECOMM. & TECH. L. REV. 111, 116–17 (2010) (asserting that patents afford inventors—particularly small firms and individuals—a degree of insulation from competitors who seek to sell the same invention at a lower price in the marketplace and that this protection from competition spurs innovation by enabling inventors to recover development costs without fearing that competitors will unduly benefit from their innovative ideas); see also Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130, 131 (2009) (offering empirical data to debunk the “orthodox assumption that technological innovation can be encouraged through the prospect of patent protection”).

³ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181, 188–89 (2010), *rev’d*, 653 F.3d 1329 (Fed. Cir. 2011) (listing parties who face prohibitive costs of obtaining BRCA1 and BRCA2 genetic testing as a result of their insurance companies’ failure to cover the cost of testing and by their inability to pursue alternative testing or obtain second opinions on test results since the patent holder is the only provider of testing services in the United States.).

⁴ See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

The merits of gene patenting and the broader issue of subject matter eligibility generally have been at the center of many recent debates.⁵ This Comment seeks to provide an overview of subject matter eligibility jurisprudence leading up to the Court of Appeals for the Federal Circuit’s (hereinafter “Federal Circuit”) latest decision in *Association for Molecular Pathology v. United States Patent and Trademark Office* (hereinafter “*Association for Molecular Pathology*”).⁶ It also suggests that the Supreme Court—by granting certiorari in this case on the question of whether human genes are patentable—has an opportunity to clarify the appropriate analysis for determining whether the subject matter at issue in *Association for Molecular Pathology* is patent-eligible. Part II of this Comment provides a historical perspective into the development of modern subject matter eligibility jurisprudence and details the approach the Supreme Court adopted in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (hereinafter “*Mayo*”),⁷ a recent case concerning patent eligibility. Part III discusses *Association for Molecular Pathology* and details the method for determining patent eligibility that the Federal Circuit advanced in that case. Part IV argues that the Federal Circuit erred in its dismissive treatment of the effect of *Mayo* on *Association for Molecular Pathology* because neither Supreme Court nor Federal Circuit precedent supports the Federal Circuit’s treatment of different claim types in isolation. Accordingly, this section describes three opinions from Supreme Court and Federal Circuit precedent which explicitly recognize that concerns raised in the context of

⁵ See Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, (2012); Abigail Lauer, Comment, *The Disparate Effects of Gene Patents on Different Categories of Scientific Research*, 25 HARV. J.L. & TECH. 179, (2011); W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won’t Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, (2012).

⁶ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012). Given the extensive procedural history of this case, a point of clarification at this juncture is warranted. Whenever this Comment refers to “*Association for Molecular Pathology*” it is discussing the case cited at the beginning of this footnote—the Federal Circuit’s second opinion in the case following remand by the Supreme Court.

⁷ See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

one type of patent claim are applicable in the context of different claim types.⁸ Part IV will also discuss the Supreme Court's repeated disinclination to adhere to rigid tests promulgated by the Federal Circuit in favor of more nuanced and holistic analyses—particularly in the areas of subject matter eligibility and obviousness. Part V discusses the Supreme Court's grant of certiorari in *Association for Molecular Pathology* on the question of whether human genes are patentable and predicts that the Court will answer this question in the negative after carefully weighing policy considerations when analyzing patent eligibility. Part VI briefly addresses

Ultimately, this Comment concludes that the Federal Circuit's rationale for its dismissive treatment of *Mayo* contravenes Supreme Court and Federal Circuit precedent which dictates that the reservations the Court expressed in refusing to uphold *Mayo*'s method claims are applicable to the composition claims in *Association for Molecular Pathology*. Additionally, important policy considerations including the harmful effects of Myriad's patents on genetic research, test quality, and patient access to testing, compel the conclusion that Myriad's claims to isolated BRCA1 and BRCA2 (BRCA1/2) should be rendered ineligible for patent protection. Finally, the Supreme Court's consistent skepticism of strict tests promulgated by the Federal Circuit, and the Supreme Court's decision to address the broad question of whether human genes are patentable on certiorari,⁹ signal that the Court will not limit its analysis of patent eligibility to the text of the statute, but rather will weigh important extra-statutory concerns into the subject matter eligibility analysis.

⁸ See F. SCOTT KIEFF, PAULINE NEWMAN, HERBERT F. SCHWARTZ & HENRY E. SMITH, PRINCIPLES OF PATENT LAW 92–95 (Robert C. Clark et. al. eds., 5th ed. 2011) (noting that patent claims are primarily characterized as one of five types including: composition, process (or method), apparatus, product-by-process, or means-plus-function).

⁹ See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 81 U.S.L.W. 3199 (U.S. Nov. 30, 2012) (No. 12-398).

II. PATENT-ELIGIBLE SUBJECT MATTER

A. 35 U.S.C. § 101 and Early Cases

The U.S. Constitution vests Congress with the power “To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries.”¹⁰ Congress, in turn, codified laws governing the award of these exclusive rights in Title 35 of the United States Code.¹¹ The types of discoveries that are entitled to receive this protection are described in 35 U.S.C. § 101 (“section 101”), which reads: “[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.”¹² While this language has often been interpreted broadly,¹³ courts have nonetheless consistently recognized implicit limitations to the scope of patentable subject matter, often stating that laws of nature, natural phenomena, and abstract ideas are not patentable.¹⁴

Nature’s handiwork is not patent-eligible.¹⁵ Manifestations of the laws of nature such as “the heat of the sun, electricity, [and] the qualities of metals, are part of the storehouse of

¹⁰ U.S. CONST. art. I, § 8, cl. 8.

¹¹ 35 U.S.C. § 101 (2006).

¹² *Id.*

¹³ See *infra* notes 186 and accompanying text.

¹⁴ Compare *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (awarding a patent for a process of curing synthetic rubber which, despite employing a well-known mathematical formula, applied it in a process that when considered as a whole is patent-eligible), and *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (upholding the award of a patent directed to a live, human-made microorganism capable of breaking down crude oil—a property that no naturally occurring bacteria possess), with *Parker v. Flook*, 437 U.S. 584, 598 (1978) (holding that a formula for computing alarm limits—absent any disclosure relating to the chemical processes employed, the method for monitoring variables, or the means of setting off the alarm—was not patent-eligible), and *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (“A principle . . . is a fundamental truth . . . [which] cannot be patented, as no one can claim in . . . them an exclusive right.”).

¹⁵ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

knowledge of all men . . . and [are] reserved exclusively to none.”¹⁶ Material derived from natural sources which is then transformed or reduced into a form that possess characteristics markedly different¹⁷ from those of the material as it exists in nature, however, has long been recognized by the United States Patent and Trademark Office (USPTO) as patent-eligible.¹⁸ While the precise boundaries of what constitutes “markedly different” subject matter remain unclear, the Federal Circuit defined a “markedly different” molecule as one that has “a distinct[] chemical structure and identity” from naturally occurring molecules.¹⁹

While section 101 does not, on its face, declare living matter patent-eligible, the Plant Patents Act of 1930—which declared that plants were eligible for patenting if they could be reproduced asexually—broadened the scope of patentable subject matter to include a form of living matter that had not undergone an extraction or a purification step, but that existed purely in its natural form.²⁰ The Plant Variety Protection Act of 1970 also recognized that certain forms of live plants were eligible for protection but explicitly declared that bacteria were outside the scope of the Act.²¹ Bacteria were shortly thereafter determined to be within the scope of patent-eligible subject matter, provided that they displayed “markedly different characteristics from any

¹⁶ *Id.* at 130.

¹⁷ Although the precise threshold beyond which a composition becomes “markedly different” than any naturally existing composition remains elusive, the Federal Circuit illustrated by way of analogy to case law that it lies somewhere between non-markedly different combinations of existing molecules and markedly different genetically engineered molecules. *See Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1327–28 (Fed. Cir. 2012).

¹⁸ *See, e.g., Anheuser-Busch Brewing Ass’n v. United States*, 207 U.S. 556, 562 (1908) (stating that in order to overcome the bar on patenting products of nature, an inventor must prove that the product for which he seeks a patent has become a new and distinct article with new characteristics or uses); *Park-Davis & Co. v. Mulford & Co.*, 196 F. 496, 496 (2d Cir. 1912) (holding that patents claiming a derivative of crystalline adrenaline, extracted from suprarenal tissue in animals for use as an agent to increase blood pressure, were valid); U.S. Patent #135,245 (claiming a form of brewer’s yeast “free from organic germs of disease”—despite the fact that brewer’s yeast existed in nature—which could be used to brew beer that was easier to preserve).

¹⁹ *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1328 (2012).

²⁰ *Townsend-Purnell Plant Patent Act*, Pub. L. No. 245, 46 Stat. 376 (1930) (codified as amended at 35 U.S.C. §§ 161–64 (2006)).

²¹ *Plant Variety Protection Act*, Pub. L. No. 91-577, 84 Stat. 1542 (1930) (codified as amended at 7 U.S.C.A. §§ 2321–2583 (2006)) (“The breeder of any sexually or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety . . . shall be entitled to plant variety protection for the variety . . .”).

[bacteria] found in nature.”²² The prohibition on patenting laws of nature, natural phenomenon, and abstract ideas standing alone also encompasses methods and processes that include this subject matter within their scope.²³ Such subject matter is only eligible for patenting if, when considered as a whole, the patent describes an application of the law of nature, natural phenomenon, or abstract idea and does not simply attempt to claim the naturally existing subject matter itself.²⁴

Currently, the USPTO characterizes isolated DNA that encodes specific genes as patent-eligible subject matter.²⁵ The USPTO’s Utility Examination Guidelines instruct that “an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”²⁶ While these Guidelines do not have the binding effect of law, they nevertheless remain influential in that a reviewing court may defer to the agency’s interpretation of a statute it oversees.²⁷ Despite their influence, however, the scope of the rights the Guidelines confer to a patent holder remains unclear.²⁸

In addition to its reliance on the USPTO’s Utility Examination Guidelines, the Federal Circuit—in determining that the isolated DNA at issue in *Association for Molecular Pathology*

²² *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

²³ See *infra* notes 75–86 and accompanying text.

²⁴ See *infra* notes 75–86 and accompanying text.

²⁵ See Eric J. Rogers, Comment, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC’Y 19, 28 (2010).

²⁶ U.S. Patent & Trademark Office, Dep’t of Commerce, RIN 0651-AB09, UTILITY EXAMINATION GUIDELINES (2001).

²⁷ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1325 (2012); *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (referring to the Utility Examination Guidelines).

²⁸ See Peter Edwards, Comment, *AMP v. Myriad: The Future of Medicine and Patent Law*, 12 MINN. J.L. SCI. & TECH. 811, 818 (2011) (noting the lack of clarity in the language of the Guidelines which provides that while the holder of a gene patent has the right to exclude others from using that gene, the patent holder must also promote discovery of other uses of the gene by other researchers. The Guidelines’ lack of clarity is also evident in the language which instructs that while genes are patentable, neither the DNA sequences nor the underlying genetic information are patentable. Edwards notes that “it is not clear what the researcher is patenting in a gene, however, if not genetic information”).

was patent-eligible—acknowledged that the Supreme Court’s decisions in *Funk Bros. Seed Co. v. Kalo Inoculant Co.* and *Diamond v. Chakrabarty* “set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules.”²⁹ As such, a detailed discussion of these cases is warranted.

In 1948, the Supreme Court weighed in on the distinction between patent-eligible subject matter and unpatentable products of nature in *Funk Bros.*³⁰ Kalo initiated a lawsuit against Funk Bros. alleging that Funk Bros. infringed Kalo’s patent for a bacterial inoculant³¹ for use with leguminous plants.³² Prior to the invention, in order to optimize legume growth, farmers were required to select the optimal strain of bacteria from a group of at least six species which corresponded with their desired legume.³³ Mixed bacterial cultures largely proved ineffective because the bacteria, when mixed, produced inhibitory effects on each other resulting in reduced levels of plant growth.³⁴ The invention in this case was a mixture of *Rhizobium* bacteria that did not display the commonly observed inhibitory effects of each other on legumes.³⁵ The Supreme Court acknowledged that the inventor “[did] not create [the] state of inhibition or of non-inhibition in the bacteria.”³⁶ As justification for the Court’s conclusion that “[the bacteria’s]

²⁹ *Ass’n for Molecular Pathology*, 689 F.3d at 1326.

³⁰ 333 U.S. 127 (1948).

³¹ The Court offered the following description of the challenged invention: “An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.” *Funk Bros.*, 333 U.S. at 127, n.1. An alternative explanation of the process of bacterial inoculation can be found at: <http://www.ctahr.hawaii.edu/bnf/Downloads/Training/Legume%20use/Title.Pdf> (explaining that increasing the concentration of *Rhizobia*, unique bacteria that naturally exists in the soil, can result in the infection of the root hairs of legumes. This infection results in the formation of nitrogen-fixing nodules which act as “small nitrogen factories” that produce proteins essential for plant growth.)

³² *See Funk Bros.*, 333 U.S. at 128.

³³ *Id.* at 129 (explaining that “[n]o one species [of bacteria] will infect the roots of all species of leguminous plants. But each [species of bacteria] will infect well-defined groups of those plants Thus if a farmer had crops of clover, alfalfa, and soy beans he would have to use three separate inoculants”).

³⁴ *Id.* at 129–30.

³⁵ *Id.* at 130.

³⁶ *Id.*

qualities are the work of nature [and] [t]hose qualities are of course not patentable,” the Court reasoned that “the combination of species produces no new bacteria, no change in the species of bacteria, and no enlargement of the range of their utility.”³⁷ The Court further characterized the bacteria as “manifestations of laws of nature, free to all men and reserved exclusively to none.”³⁸

The difficult task of discerning an unpatentable product of nature from a patentable product of human ingenuity was again before the Court in *Chakrabarty*.³⁹ Ananda Chakrabarty, a microbiologist at the General Electric Co., sought to patent a genetically engineered bacterium that was capable of breaking down crude oil.⁴⁰ The Court again recognized the limits to patentability, stating:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.⁴¹ Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”⁴²

In this case, however, the Court ultimately upheld the patent, finding that “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under section 101.”⁴³ In

³⁷ *Funk Bros.*, 333 U.S. 127, 131 (1948).

³⁸ *Id.* at 130.

³⁹ See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴⁰ The Court offered the following explanation of the claimed invention: “Plasmids are hereditary units physically separate from the chromosomes of the cell. In prior research, Chakrabarty and an associate discovered that plasmids control the oil degradation abilities of certain bacteria. In particular, the two researchers discovered plasmids capable of degrading camphor and octane, two components of crude oil. In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil.” *Id.* at 305, n.1.

⁴¹ *Id.* at 309.

⁴² *Id.* (quoting *Funk Bros.*, 333 U.S. at 130 (1948)).

⁴³ *Id.* at 310.

formulating its conclusion, the Court looked in part to the Committee Reports accompanying the 1952 Patent Act, which it interpreted to instruct that Congress intended patentable subject matter to broadly “include anything under the sun that is made by man.”⁴⁴

In sum, while the patent in *Funk Bros.* attempted to claim a mere mixture of naturally occurring bacteria, the patent in *Chakrabarty* was directed to a new bacterium which exhibited characteristics not found in nature. Notably, the Court approached *Funk Bros.* and *Chakrabarty* in a similar fashion; primarily relying on a comparison between the function of the claimed invention with the function of a naturally occurring analogue.

It is not immediately apparent where Myriad’s isolated DNA fits along the spectrum delineated by *Funk Bros.* and *Chakrabarty*. Whether the isolated DNA at issue has a “distinct chemical structure and identity” and meets the Federal Circuit’s definition of “markedly different” is open to debate. However, determining whether isolated BRCA1/2 DNA surpasses illusive “markedly different” threshold is not determinative of patent eligibility. The Supreme Court—in reviewing the issues presented in *Association for Molecular Pathology* on certiorari and ultimately vacating the Federal Circuit’s ruling—declined to confine its analysis to the cases offered by the Federal Circuit.⁴⁵ Instead, on remand, the Court advised that the Federal Circuit consider the issues in *Association for Molecular Pathology* in light of its recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*⁴⁶—a case that recognized a more nuanced set of criteria for determining patent eligibility than the test advanced in *Funk Bros.* and *Chakrabarty*.⁴⁷

⁴⁴ *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)); *see infra* note 180 and accompanying text.

⁴⁵ *See Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

⁴⁶ *See id.*

⁴⁷ *See infra* notes 99–103 and accompanying text.

B. Subject Matter Eligibility in Mayo

Prometheus Laboratories, Inc. develops products that enable physicians to detect, diagnose, and treat disorders in the fields of gastroenterology and oncology.⁴⁸ It also specializes in personalized medicine—a method of using an individual’s unique serologic, genetic, and inflammation markers to diagnose certain disorders and predict treatment outcomes.⁴⁹ The Prometheus patents at issue in this case were directed to a method for administering thiopurine drugs,⁵⁰ one that sought to maximize the efficacy of the drugs for each individual patient by accounting for individuals’ different rates of metabolizing thiopurines.⁵¹ The following claim in the Prometheus patent describes the invention and is one of the claims at issue:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.⁵²

Prometheus initiated an infringement lawsuit when Mayo Medical Laboratories (Mayo) announced that it planned to introduce its own test—one which used slightly higher thiopurine

⁴⁸ See *About Prometheus*, PROMETHEUSLABS.COM, <http://www.prometheuslabs.com/About.asp> (last visited Oct. 25, 2012).

⁴⁹ See *Diagnostics*, PROMETHEUSPATIENTS.COM, http://www.prometheuspatients.com/Products_Diagnostics.asp (last visited Oct. 25, 2012).

⁵⁰ Thiopurines are a class of synthetic drugs used to treat immune mediated gastro-intestinal disorders including Crohn’s disease and ulcerative colitis. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1339 (Fed. Cir. 2009), *rev’d*, 135 S. Ct. 3543 (2010) (“*Prometheus III*”).

⁵¹ See *id.*

⁵² U.S. Patent No. 6,355,623 (filed Apr. 8, 1999); see *infra* notes 78–80 and accompanying text.

metabolite levels to measure toxicity—to the marketplace.⁵³ Mayo moved for summary judgment, alleging that the Prometheus patents were invalid because they impermissibly claimed the “correlation between the recited metabolite levels and therapeutic efficacy and/or toxicity,” which it alleged was an unpatentable “natural, observable phenomenon” and that “the patents impermissibly preempt use of the correlation.”⁵⁴ Thus, Mayo alleged that the Prometheus patents did not preclude them from marketing their test.⁵⁵

The district court granted Mayo’s motion, finding that Prometheus’s claims reciting correlations between thiopurine drug metabolite levels and therapeutic efficacy or toxicity were directed to natural phenomena.⁵⁶ On appeal, the Federal Circuit—relying on the machine-or-transformation (M or T) test⁵⁷—reversed the district court’s decision.⁵⁸ As understood by the Federal Circuit, the M or T test provided that, “a claimed process is surely patent-eligible under section 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.”⁵⁹ The Federal Circuit ultimately concluded that Prometheus’s method claims satisfied the M or T test and thus, were patent-eligible.⁶⁰

In arriving at this conclusion, the Federal Circuit determined that the Prometheus patents fell within the scope of section 101 because both the “administering” and “determining” steps “transform an article into a different state or thing” and this transformation “is central to the purpose of the claimed process.”⁶¹ Regarding the “administering” step, the Federal Circuit

⁵³ Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04CV1200, 2008 WL 878910, at *1 (S.D. Cal. Mar. 28, 2008), *rev'd*, 581 F.3d 1336 (Fed. Cir. 2009) (“*Prometheus II*”).

⁵⁴ *Id.* at *5 (quoting Doc. No. 502 at 11, 13).

⁵⁵ *See id.*

⁵⁶ *See id.* at *6, *14.

⁵⁷ *See infra* note 59 and accompanying text.

⁵⁸ *See Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009).

⁵⁹ Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1342 (Fed. Cir. 2009), *rev'd*, 135 S. Ct. 3543 (2010) (*Prometheus III*) (quoting *In re Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008), *rev'd*, 130 S. Ct. 3218 (2010)).

⁶⁰ *See id.* at 1350.

⁶¹ *Id.* at 1345 (quoting *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)).

recognized that “the human body necessarily undergoes a transformation [when drugs are administered]” and dismissed “the fact that the change of the administered drug to its metabolite relies on natural process” as dispositive of patent ineligibility.⁶² The court characterized the transformation in this case as “the result of the physical administration of a drug to a subject to transform—i.e., treat—the subject, which is itself not a natural process.”⁶³ The Federal Circuit also found the “determining” step of Prometheus’s claimed method to be “transformative and central.”⁶⁴ The court stated that “[d]etermining the levels of [a drug] in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection.”⁶⁵ Rather, this determination requires a certain amount of manipulation in the form of extracting the metabolites from the human body and determining their concentration.⁶⁶ The Federal Circuit dismissed Mayo’s additional argument that the Prometheus patents preempted a natural phenomenon by stating that “because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle.”⁶⁷ Accordingly, the Federal Circuit held that Prometheus’s claims were properly directed to patent-eligible subject matter.

The Supreme Court, having re-visited the question of subject matter eligibility in its *Bilski v. Kappos* decision, which it handed down the day before, granted certiorari in the *Mayo* case, vacated the Federal Circuit’s judgment, and remanded the case to the Federal Circuit for further consideration in light of *Bilski*.⁶⁸ In its *Bilski* decision, the Supreme Court addressed the patent eligibility of business methods.⁶⁹ The claims at issue were directed to a method of risk hedging in commodities markets which included the steps of initiating a series of transactions

⁶² *Id.* at 1346.

⁶³ *Id.*

⁶⁴ *Id.* at 1347.

⁶⁵ *Prometheus Labs., Inc.*, 581 F.3d at 1347.

⁶⁶ *See Prometheus*, 581 F.3d at 1347 (Fed. Cir. 2009).

⁶⁷ *Id.* at 1349.

⁶⁸ *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 130 S. Ct. 3543 (2010).

⁶⁹ *See Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

between commodity providers and consumers who had a certain risk position, identifying market participants for the commodity who had a corresponding counter-risk position, and initiating a series of transactions between the commodity providers and market participants.⁷⁰ The Court ultimately determined that the claims were drawn towards the concept of hedging risk—an unpatentable, abstract idea.⁷¹ Notably, the Court also held that the M or T test is not the sole test for patent eligibility under section 101, but rather is a “useful and important clue, an investigative tool” for determining patent eligibility.⁷² On remand, the Federal Circuit applied largely the same analysis that it did in its first *Mayo* decision, again holding that the claims recited patent-eligible subject matter under section 101⁷³ and again relying on the M or T test to reach that conclusion.⁷⁴

On March 20, 2012, a unanimous Supreme Court, having granted certiorari, reversed the Federal Circuit’s decision and held that Prometheus’s claims were not properly drawn to patent-eligible subject matter under section 101.⁷⁵ Rather, the Court determined the patents effectively claimed ineligible laws of nature that described the relationships between levels of thiopurine metabolites and therapeutic efficacy or toxicity.⁷⁶ In arriving at this conclusion, the Court questioned whether “the patent claims add *enough* to their statement of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws.”⁷⁷ The Court, turning first to the administering step, stated that it “simply refer[ed] to the relevant

⁷⁰ See *id.* at 3223–24.

⁷¹ See *id.* at 3231.

⁷² *Id.* at 3227.

⁷³ See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1353 (Fed. Cir. 2010), *rev’d*, No. 10-1150, slip op. (U.S. Mar. 20, 2012) (*Prometheus IV*).

⁷⁴ See *id.* at 1355 (stating that Prometheus’s claimed methods “satisfy the transformation prong” of the M or T test).

⁷⁵ See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

⁷⁶ See *id.* at 1305.

⁷⁷ *Id.* at 1297.

audience” namely, doctors who are familiar with using thiopurines to treat patients.⁷⁸ The Court noted that merely limiting the use of an abstract idea to a predefined technological environment is not enough to circumvent the prohibition against patenting abstract ideas.⁷⁹ Turning to the wherein clauses in the Prometheus patent on page ten *supra*, the Court dismissed the possibility that they could change an unpatentable concept into a patentable application by summarily stating that they “simply tell a doctor about the relevant natural laws”⁸⁰ Finally, the Court understood the determining step to instruct the doctor to “engage in well-understood, routine, conventional activity.”⁸¹ The Court ultimately determined that neither the administering, determining, nor wherein limitations standing alone or in combination “[were] sufficient to transform unpatentable natural correlations into patentable applications of those regularities.”⁸²

The Court suggested additional justifications for its conclusion that Prometheus’s patents were drawn to ineligible subject matter from two cases dealing with the patent eligibility of processes using mathematical formulas which, like laws of nature, are not patentable standing alone.⁸³ First, the Court stated that Prometheus’s claims “present[] a case for patentability that is weaker than *Diehr*’s patent-eligible claim and no stronger than *Flook*’s unpatentable one.”⁸⁴ While *Diehr* and *Flook* have proven difficult to reconcile,⁸⁵ developing a complete

⁷⁸ *Id.*

⁷⁹ *See id.* at 1291 (citing *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)).

⁸⁰ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1291 (2012).

⁸¹ *Id.* at 1298 (stating that this “activity” involves determining levels of thiopurine metabolites, but does not restrict the method researchers did not know of the precise correlation between thiopurine metabolite levels and the efficacy or toxicity of the drugs, they knew of the relationship).

⁸² *See id.*

⁸³ *See Mayo Collaborative Servs.*, 132 S. Ct. at 1292.

⁸⁴ *Id.*

⁸⁵ *See* Horacio E. Gutiérrez, *Peering Through the Cloud: The Future of Intellectual Property and Computing*, 20 FED. CIR. B.J. 589 (2011) (noting that *Diehr* and *Flook* had “very similar facts” with opposite results); Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253 (2011) (noting that the claims in *Diehr* and *Flook* are “exactly parallel”); Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program Related Inventions*, 39 EMORY L.J. 1025, 1104 (“[P]ost-Benson case law is replete with awkward distinctions and results that are often difficult to reconcile.”).

understanding of the Court’s rationale for its holding in *Mayo* requires a closer examination of these cases.

In *Parker v. Flook*, the Court considered the validity of a patent directed to a method for updating alarm limits for a catalytic chemical conversion of hydrocarbons in which the only point of novelty over prior, well known methods for changing alarm limits⁸⁶ was the inventor’s employment of a mathematical formula.⁸⁷ The entire process consisted of essentially three steps including “an initial step which merely measures the present value of the process variable (*e.g.*, the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value.”⁸⁸ The Court noted that the plain language of section 101 does not instruct on whether the claimed method—characterized only by the novel use of a mathematical formula—was patent-eligible subject matter.⁸⁹ It also acknowledged that “[t]he line between a patentable process and an unpatentable principle is not always clear.”⁹⁰ The Court stated that because mathematical formulas are not eligible for patenting by themselves,⁹¹ the question in this case was whether “post-solution *applications* of . . . a formula makes [a] method eligible for patent protection.”⁹² Ultimately, the Court answered its own question in the negative, characterizing the claimed process as accomplishing nothing more than “provid[ing] a[n unpatentable] formula for computing an updated alarm limit.”⁹³

⁸⁶ See *Parker v. Flook*, 437 U.S. 584, 585 (1978) (offering an explanation of an alarm limit as a predetermined number that, when exceeded by certain process variables such as pressure and temperature during the process of catalytic conversion, signals either irregularities in the process or the presence of potential dangers).

⁸⁷ See *id.* at 586–87.

⁸⁸ *Id.* at 585.

⁸⁹ *Id.* at 588.

⁹⁰ *Id.* at 589 (internal quotation marks omitted).

⁹¹ *Id.* at 585 (“In *Gottschalk v. Benson*, 409 U.S. 63, 93 S. Ct. 253, 34 L.Ed.2d 273, we held that the discovery of a novel and useful mathematical formula may not be patented.”).

⁹² *Id.* (emphasis added).

⁹³ *Parker*, 437 U.S. at 586.

Three years after the Court decided *Flook*, it was again tasked with determining the patent eligibility of a process which employed a mathematical equation.⁹⁴ The claimed process was a method for curing rubber which involved instruments that continuously monitored the temperature inside a mold cavity, transmitted the information to a digital computer which employed the Arrhenius equation⁹⁵ and made continuous adjustments to the cure time, and sent signals to open the mold at the appropriate time.⁹⁶ Unlike in *Flook*, the *Diehr* patent did not attempt to claim a well-known equation itself, nor did it seek to preempt further use of that equation. Rather, the applicants sought only “to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”⁹⁷ The Court held that the claimed process was patent-eligible, stating that it did “not view [the] claims as an attempt to patent a mathematical formula, but rather to [claim] an industrial process for the molding of rubber products”⁹⁸ In sum, the Court stated that its opinions in *Flook* and *Diehr* were consistent with the Court’s general position that “simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”⁹⁹

As a final justification for its holding in *Mayo*, the Court recognized that its subject matter eligibility jurisprudence has “repeatedly emphasized . . . a concern that patent law not

⁹⁴ See *Diamond v. Diehr*, 450 U.S. 175 (1981).

⁹⁵ *Id.* at 177 n.2 (indicating that the Arrhenius equation can be expressed as $\ln v = CZ + x$ where $\ln v$ is the natural log of the total required cure time, v ; C is the activation constant, Z is the temperature in the mold, and x is a constant dependent on the geometry of the mold in the press).

⁹⁶ *Id.* at 177–79.

⁹⁷ *Id.* at 187.

⁹⁸ *Id.* at 192–93.

⁹⁹ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1300 (2012) (citing *O’Reilly v. Morse*, 56 U.S. 62 (1853); *Gottschalk v. Benson*, 409 U.S. 63, 64, 65, 67, 93 (1972); and *Bilski v. Kappos*, 130 S. Ct. 3218, 3230 (2010) in support of the Court’s general view that appending conventional steps to laws of nature does not make those ideas patent-eligible).

inhibit further discovery by improperly tying up the future use of laws of nature and the like.”¹⁰⁰ The Court was concerned that “because [natural] laws and principles are ‘the basic tools of scientific and technological work,’ there is a danger that granting patents that tie up their use will inhibit future innovation”¹⁰¹ Prometheus’s claims implicated this concern because “telling a doctor to measure metabolite levels and to consider the resulting measurements in light of the correlations they describe . . . tie[s] up his subsequent treatment decision regardless of whether he changes his dosage in the light of the inference he draws using the correlations.”¹⁰² The Court clearly expressed a concern that declaring Prometheus’s claims eligible for patenting would impede the development of subsequent treatment methods that combine Prometheus’s claimed correlations with other discoveries.¹⁰³ Therefore, importantly, the Supreme Court’s holding in *Mayo* is founded on considerations external to the minimal requirements enumerated in section 101. *Mayo* provides that courts seeking to make a determination regarding patent eligibility should not only consider the invention in light of section 101 and cases that have interpreted the statute, but they should also engage in a separate analysis whereby they weigh considerations of the harm that could stem from tying up the use of natural laws and inhibiting discovery in a field into the calculus for determining whether certain subject matter is patent-eligible.

III. ASSOCIATION FOR MOLECULAR PATHOLOGY AND THE FEDERAL CIRCUIT’S INTERPRETATION OF *MAYO*

Mayo has already proven impactful—and likely stands to play an even greater role in the near future—as courts struggle to develop consistent standards in the subject matter eligibility

¹⁰⁰ See *Mayo Collaborative Servs.*, 132 S. Ct. at 1301.

¹⁰¹ *Id.* at 1292 (quoting *Gottshalk v. Benson*, 409 U.S. 63, 67 (1972)).

¹⁰² *Id.* at 1292.

¹⁰³ See *id.* at 1292.

arena. Its influence was felt, although minimally, in *Association for Molecular Pathology*—a highly publicized¹⁰⁴ case and the latest chapter in the gene patent debate.

In the mid-1990s, researchers confirmed that mutations in the BRCA1/2 genes¹⁰⁵ correlated with an increased risk of developing breast and ovarian cancer.¹⁰⁶ Women who inherit these genetic mutations face up to an eighty five percent risk of breast cancer—the second leading cause of cancer related death among women in the United States—and up to a fifty percent risk of ovarian cancer.¹⁰⁷ BRCA1 mutations have also been linked with cancers of the cervix, uterus, pancreas, and colon while BRCA2 mutations have been observed to increase the risk of developing pancreatic and stomach cancer as well as melanoma.¹⁰⁸ Male carriers of the BRCA1/2 mutation face an increased risk of breast and prostate cancer.¹⁰⁹ Determining the existence of BRCA1/2 mutations is a critically important diagnostic and preventative tool.¹¹⁰ Aside from the benefits that stem from an individual’s ability to make informed decisions relating to aspects of their life ranging from daily activities to family planning, knowledge of BRCA1/2 mutations enables doctors to tailor the most effective treatment regimens for each individual patient—selecting from minimally intrusive options such as increased surveillance and monitoring, to more aggressive forms of treatment like chemotherapy.¹¹¹

¹⁰⁴ See, e.g., Brent Kendall, *Court Rules Biotech Firm Can Patent Human Genes*, WALL ST. J. (Aug. 16, 2012), <http://online.wsj.com/article/SB10000872396390443324404577593251249665074.html>; Jonathan Stempel, *Myriad Wins Gene Patent Ruling from US Appeals Court*, REUTERS, Aug. 16, 2012, available at <http://www.reuters.com/article/2012/08/16/us-myriad-patent-idUSBRE87F12K20120816>.

¹⁰⁵ See *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L CANCER INST., <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA#r5> (last updated May 29, 2009) (stating that the names BRCA1 and BRCA2 stand for breast cancer susceptibility gene 1 and 2, respectively and explaining that tumor suppressor genes normally function to maintain the stability of a cell’s genetic material (DNA) and help to prevent uncontrolled cell growth).

¹⁰⁶ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181, 203 (S.D.N.Y. 2010).

¹⁰⁷ *Id.*

¹⁰⁸ *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, *supra* note 104.

¹⁰⁹ See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d. at 203.

¹¹⁰ See *Ass’n for Molecular Pathology*, 653 F.3d 1329, 1339 (Fed. Cir. 2011).

¹¹¹ *Id.*

In September 1994, Myriad Genetics, Inc. (Myriad)—based on its work in conjunction with researchers at the National Institute for Environmental Health Sciences, the University of Utah, McGill University, and Eli Lilly Co.—sequenced the BRCA1 gene and sought to patent it.¹¹² By the end of 1995, Myriad filed for patents on the BRCA2 gene following its work with scientists in Canada and at the University of Pennsylvania.¹¹³ As the sole licensee¹¹⁴ of the patents related to the BRCA1/2 genes, Myriad controls all research and testing on or associated with the genes¹¹⁵ and, as the benefactor of a limited monopoly, charges inflated prices for the test.¹¹⁶ In addition, Myriad has aggressively prohibited other labs from performing its patented test¹¹⁷ and generally refuses to grant licenses for second opinion diagnostic testing.¹¹⁸ Studies indicate that this exclusivity impedes research and hinders the development of improvements to testing.¹¹⁹

Myriad’s seven patents contained a total of fifteen composition and method claims.¹²⁰ The composition claims are directed to three different types of isolated DNA molecules

¹¹² *Id.* at 202.

¹¹³ *Id.*

¹¹⁴ *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1324 (Fed. Cir. 2012) (stating that the University of Utah is the owner of the patents in suit).

¹¹⁵ See ACLU, <http://www.aclu.org/free-speech/brca-faqs> (last visited Apr. 23, 2013).

¹¹⁶ See *Genetic Testing Facilities and Cost*, BREASTCANCER.ORG, http://www.breastcancer.org/symptoms/testing/genetic/facility_cost (last visited Nov. 9, 2012).

¹¹⁷ See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 205 (referring to cease and desist letters concerning BRCA1/2 genetic testing sent to Dr. Kazazian, the University of Pennsylvania, and the director of the Yale DNA Diagnostics Lab).

¹¹⁸ Kevin E. Noonan, *USPTO Holds First Hearing on “Second Opinion” Genetic Testing*, PATENT DOCS (Feb. 16, 2012), <http://www.patentdocs.org/2012/02/uspto-holds-hearing-on-second-opinion-genetic-testing.html> (reporting on the status of two planned hearings aimed at implementing a provision of the Leahy-Smith America Invents Act requiring the USPTO to study the advisability of permitting “second opinions” for patented genetic diagnostic tests without patent infringement liability stating that Myriad generally prevented other testing labs from performing its patented test).

¹¹⁹ See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d. at 206–07; Olga Bogard, *Patenting the Human Body: The Constitutionality of Gene Patents and Suggested Remedies for Reform*, 63 SMU L. REV. 1319, 1326 (2010) (stating that Myriad took an “unprecedented [path] in the field of genetic testing” by departing from the general practice of willingly granting licenses to labs to improve access to diagnostic testing and second opinions, and to encourage price reductions and acceptance among insurance carriers, by strictly enforcing their rights to exclude others from using their invention).

¹²⁰ See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 211.

including: (1) isolated DNA sequences—identical to naturally occurring sequences—encompassing the full length gene sequence; (2) shorter isolated sequences of DNA—measuring as short as fifteen nucleotides; and (3) cDNA molecules which are distinct from the naturally occurring sequences in that their non-coding segments have been removed and they are complimentary to naturally occurring DNA.¹²¹ Claims 1 and 5 in Patent 5,747,282 are representative of the composition claims at issue in this case and recite: “1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 . . . 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1”¹²² Isolated DNA is often an essential element in many procedures to diagnose diseases and detect genetic disorders.¹²³

In response to the restrictive licensing and high costs of obtaining BRCA1/2 tests, The American Civil Liberties Union (ACLU), The Association for Molecular Pathology, several non-profit women’s organizations, research scientists, and individuals initiated a lawsuit in 2010 challenging the validity of Myriad’s patents in the Southern District of New York.¹²⁴ In a departure from what was the common practice of upholding gene patents, Judge Sweet—emphasizing the similarity between the function of isolated genes and native DNA as carriers of information¹²⁵—determined that Myriad’s composition and method claims impermissibly sought to patent ineligible products of nature under 35 U.S.C. § 101.¹²⁶ Judge Sweet, in an effort to differentiate isolated DNA from other chemical compounds that were the subjects of previous

¹²¹ See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1364 (Fed. Cir. 2011).

¹²² U.S. Patent No. 5,747,282 (filed June 7, 1995).

¹²³ See George Rice, *DNA Extraction*, http://serc.carleton.edu/microbelife/research_methods/genomics/dnaext.html

¹²⁴ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010).

¹²⁵ See *id.* at 228.

¹²⁶ See *id.* at 238.

patents,¹²⁷ pointed to the dual nature of DNA—acknowledging that it is both a chemical compound, but also a physical carrier of genetic information.¹²⁸ Judge Sweet further declared that Myriad’s diagnostic method claims were invalid because they claimed a comparison—an unpatentable mental process—of genetic sequences to determine if differences existed.¹²⁹

Myriad appealed to the Federal Circuit, which issued its first ruling in the case on July 29, 2011.¹³⁰ Judge Lourie, in his majority opinion, looked to the framework for determining patent eligibility set out in *Funk Bros.* and *Chakrabarty*, which asked whether the subject matter at issue was “markedly different”¹³¹ from that which exists in nature.¹³² Judge Lourie—concluding that Myriad’s isolated DNA met this minimum standard and were patent-eligible—pointed to the unique chemical structure of isolated DNA.¹³³ He indicated that Judge Sweet erred in determining patent eligibility based on a comparison of the function of isolated and genomic DNA and instead urged that isolated DNA be considered a distinct chemical entity.¹³⁴ Judge Lourie also cautioned against departing from the USPTO’s current practice of awarding gene patents and advised that such a dramatic change in policy be initiated by the legislature and not the courts.¹³⁵

¹²⁷ See *Park-Davis & Co. v. Mulford & Co.*, 196 F. 496, 496 (2d Cir. 1912), *supra* note 18 (noting that chemical substances, like crystalline adrenaline, were patent-eligible).

¹²⁸ See *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 228.

¹²⁹ See *id.* at 233–37.

¹³⁰ See *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1333 (Fed. Cir. 2011).

¹³¹ *Id.* at 1351 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

¹³² See *id.* at 1351.

¹³³ See *id.* (contrasting isolated DNA with native DNA explaining that “[n]ative DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome, the DNA molecule is packaged around histone proteins into a structure called chromatin, which in turn is packaged into the chromosomal structure Isolated DNA, in contrast, is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule”).

¹³⁴ See *id.* at 1353.

¹³⁵ See *Ass’n for Molecular Pathology*, 653 F.3d at 1354–55.

In his concurring opinion, Judge Moore indicated that the difference in chemical structure between isolated DNA and genomic DNA was not enough, by itself, to render isolated DNA “markedly different” from genomic DNA and thus patentable per se.¹³⁶ Rather, Judge Moore engaged in a more searching inquiry, asking “whether these differences impart a new utility which makes [isolated DNA] markedly different from nature.”¹³⁷ He concluded that shorter isolated DNA segments were clearly patent-eligible given they are particularly well-suited to accomplish a number of tasks that genomic DNA could not accomplish.¹³⁸ Judge Moore conceded that larger isolated DNA fragments presented a more difficult question of patent eligibility¹³⁹ given that although they have the same chemical characteristics as shorter isolated fragments, they do not retain the same utility.¹⁴⁰ Nonetheless, Judge Moore concluded that because Congress has generally “authorized an expansive scope of patentable subject matter,” and the USPTO has allowed patents on isolated DNA for decades, these settled expectations of patent law “tip[ped] the scale in favor of patentability.”¹⁴¹

Judge Bryson’s dissent maintained that Myriad’s composition claims were categorically directed to unpatentable subject matter.¹⁴² In an approach similar to the one adopted by Judge Sweet in his district court opinion, Judge Bryson’s holding was based on an understanding that the chemical differences between isolated and genomic DNA were of secondary importance to

¹³⁶ See *id.* at 1364–65 (Moore, J., concurring in part).

¹³⁷ *Id.* at 1365.

¹³⁸ See *id.* at 1365 (explaining that while “[smaller isolated DNA] sequences can be used as primers in a diagnostic screening process to detect gene mutations . . . and as the basis for probes Naturally occurring DNA cannot be used to accomplish these same goals”).

¹³⁹ See *id.* at 1366 (defining “longer strand” as a piece of isolated DNA containing “most or all of the entire gene” and stating that “[l]onger strands of isolated DNA, in particular isolated strands which include most or all of the entire gene, are a much closer case.”).

¹⁴⁰ See *id.* (noting that longer isolated segments are unsuitable as primers which are typically only 100–1,000 bases in length).

¹⁴¹ *Ass’n for Molecular Pathology*, 653 F.3d at 1367.

¹⁴² See *id.* at 1373.

the actual function of isolated and genomic DNA—which both operate to transfer information.¹⁴³ Judge Bryson rebutted the majority’s reliance on USPTO precedent by pointing out that the USPTO’s guidelines are not entitled to significant weight, as indicated by the Supreme Court’s refusal to adhere to the guidelines—which stated that microorganisms were not patent-eligible—at the time they decided *Chakrabarty* and given that the Department of Justice—which speaks for the executive branch, to which the USPTO belongs—filed a brief taking the position that Myriad’s composition claims were not eligible for patenting.¹⁴⁴ Judge Bryson further raised policy arguments in support of his determination that isolated DNA should not be patent-eligible—including concerns about the preemptive force of Myriad’s broad claims on “the next generation of innovation in genetic medicine”¹⁴⁵

The Federal Circuit’s decision to uphold Myriad’s composition claims directed to isolated human DNA marked a victory not only for Myriad, but also for the entire biotechnology industry. Following the court’s decision, the ACLU petitioned the Federal Circuit to review the decision, arguing that the court “erred in failing to consider whether the DNA fragments claimed in these patents are products of nature.”¹⁴⁶ When the Federal Circuit declined to accept the petition for a rehearing, the ACLU filed a petition for writ of certiorari.¹⁴⁷ Less than a week after its decision in *Mayo* was announced, the Supreme Court granted the pending petition for a writ

¹⁴³ See *id.* at 1378.

¹⁴⁴ See *id.* at 1380–81; Brief for the United States as Amicus Curiae in Support of Neither Party, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), (2010 WL 4853320, at *10) (“[I]solated but otherwise unaltered genomic DNA is not patent-eligible subject matter under 35 U.S.C. § 101.”).

¹⁴⁵ *Id.* at 1380.

¹⁴⁶ Plaintiffs-Appellees’ Petition for Panel Rehearing at 1, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2011 WL 5057016, at *1.

¹⁴⁷ Petition for Writ of Certiorari, *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, No. 11-725, 2011 WL 6257250 (Dec. 7, 2011).

of certiorari.¹⁴⁸ The Court vacated the Federal Circuit’s judgment and remanded the case to that court for “further consideration in light of [*Mayo*].”¹⁴⁹

Although the Federal Circuit’s second *Association for Molecular Pathology* decision purports to evaluate the effect of *Mayo* on the patent eligibility of the isolated DNA at issue in *Association for Molecular Pathology*,¹⁵⁰ in fact, the Federal Circuit rather glancingly acknowledged the Supreme Court’s *Mayo* decision. Ultimately, the Federal Circuit reaffirmed its holding that “the composition claims covering isolated DNA sequences associated with predisposition to breast and ovarian cancers were directed to patent-eligible subject matter.”¹⁵¹

IV. THE FEDERAL CIRCUIT FAILED TO INCORPORATE *MAYO* INTO *ASSOCIATION FOR MOLECULAR PATHOLOGY*

The Federal Circuit’s primary rationale for its dismissive treatment of *Mayo* in evaluating the patent eligibility of Myriad’s composition claims on remand was summed up by the court as follows: “[t]he principal claims of the patents before us on remand relate to isolated DNA molecules. *Mayo* does not control the question of patent-eligibility of such claims.”¹⁵² In other words, the Federal Circuit largely disregarded *Mayo* because *Mayo* dealt with the patent eligibility of *method* claims while the claims at issue in *Association for Molecular Pathology* were directed to *compositions* of matter. Notably, as discussed *infra*, neither Supreme Court nor Federal Circuit precedent supports the Federal Circuit’s treatment of different types of claims as each having their own distinct set of concerns. In fact, the Court has indicated that, in the process of determining whether certain categories of claims are eligible for patenting, it is appropriate to draw upon concerns raised in dealing with one category of claim and consider

¹⁴⁸ See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

¹⁴⁹ *Id.*

¹⁵⁰ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1308 (Fed. Cir. 2012) (“Our decision on remand . . . both decides the issues that were before us in the original appeal and evaluates the effect of *Mayo* on those issues.”).

¹⁵¹ *Id.*

¹⁵² *Id.* at 1325.

their applicability in the context of another type of claim. The Supreme Court’s decisions in *Gottschalk v. Benson* and *Bilski v. Kappos* are illustrative of the Court’s practice of applying concerns across claim types.¹⁵³

The claimed invention in *Benson* was a “method for converting binary coded decimal (BCD) numerals into pure binary numerals.”¹⁵⁴ The claims professed to cover any use of the method in any apparatus or machine of any type.¹⁵⁵ While the claims were initially rejected by the USPTO—and then by the Board of Patent Appeals—they were upheld by the Court of Customs and Patent Appeals.¹⁵⁶ The Acting Commissioner of Patents then obtained certiorari.¹⁵⁷ In arriving at the conclusion that a computer program—without substantial practical application except in association with a computer—was not a patentable process, the Court repeated its frequently expressed concern that “phenomena of nature . . . mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”¹⁵⁸ The Court cautioned that “[upholding] the patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.”¹⁵⁹ The Court went on to quote its *Funk Bros.* decision stating, “[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.”¹⁶⁰ The Court continued, stating, “[w]e dealt [in *Funk Bros.*] with a product claim, while the present case deals with a process claim. But we think the same principle applies.”¹⁶¹

¹⁵³ See *Gottschalk v. Benson*, 409 U.S. 63 (1972).

¹⁵⁴ *Id.* at 64.

¹⁵⁵ See *id.*

¹⁵⁶ Application of *Benson*, 441 F.2d 682 (1971).

¹⁵⁷ See *Benson*, 409 U.S. at 63.

¹⁵⁸ *Id.* at 67.

¹⁵⁹ *Id.* at 72.

¹⁶⁰ *Id.* (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

¹⁶¹ *Id.* at 67–68.

The Court’s reasoning regarding the preemptive effect on the mathematical formula that would result from upholding the patent in *Benson* is analogous to the preemptive effect on the genetic code that would result from upholding Myriad’s composition claims. In the same way that upholding the patent on the mathematical formula in *Benson*—which “ha[d] no substantial practical application except in connection with a digital computer”—would have wholly preempted the use of the mathematical formula, upholding Myriad’s composition claims directed to genes—the only physical embodiments of the genetic code—would effectively preempt the use of the genetic code.¹⁶² Thus, *Benson* can be read to caution against upholding patents that would have broad preemptive effects in a field by allowing courts to impute concerns previously attributable only to a certain type of claim and to consider them in the context of different claim types.

Bilski, like *Benson*, illustrates the notion that concerns raised in the context of one type of claim are applicable to other claim types. In attempting to clarify the plurality opinion, Justice Stevens’s concurrence highlighted a number of perceived deficiencies in the Court’s analysis of subject matter eligibility.¹⁶³ Stevens placed the plurality’s suggestion that “the [subject matter eligibility] analysis turns on the category of patent involved” among those deficiencies.¹⁶⁴ Stevens, instead, maintained that “we have never in the past suggested that the [patent eligible subject matter] inquiry varies by subject matter.”¹⁶⁵

Finally—despite its departure from this concept in its *Association for Molecular Pathology* opinion on remand—even the Federal Circuit has explicitly recognized that the scope

¹⁶² *Id.* at 71.

¹⁶³ See *Bilski v. Kappos*, 130 S. Ct. 3218, 3234–36 (2010) (Stevens, J. concurring).

¹⁶⁴ *Id.* at 3236.

¹⁶⁵ *Id.*

of a 35 U.S.C. § 101 analysis should not be limited by the claim type.¹⁶⁶ In *AT&T Corp. v. Excel Communications, Inc.*, the court stated that “we consider the scope of § 101 to be the same regardless of the form—machine or process—in which a particular claim is drafted.”¹⁶⁷ The court acknowledged that “the Supreme Court’s decisions in *Diehr*, *Benson*, and *Flook* all of which involved method (i.e., process) claims, have provided and supported the principles which we apply to both machine-and process- type claims.”¹⁶⁸ The Federal Circuit went on to apply its reasoning from two cases dealing with composition claims to the method claims at issue in the case before it.¹⁶⁹

Therefore, *Benson*, *Bilski*, and *AT&T* can be read to contravene the Federal Circuit’s primary rationale for its dismissive treatment of *Mayo*—that *Mayo* dealt with method claims while *Association for Molecular Pathology* deals with composition claims. These cases provide clear examples of instances where courts recognized the universal applicability of the concerns raised in the context of one type of claim and considered the implications of those concerns in the context of another type of claim. Instead of recognizing that the concerns the Court raised in *Mayo* in the context of method claims were applicable to composition claims, the Federal Circuit ignored this instruction from precedent and chose to consider different claim types in isolation.

In arriving at its conclusion that Myriad’s isolated DNA molecules were patent-eligible, the Federal Circuit also erred in confining its analysis to *Funk Bros.* and *Chakrabarty*¹⁷⁰—from which the court gleaned the “markedly different” test for determining the patent eligibility of

¹⁶⁶ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1340 (Fed. Cir. 2012) (Judge Moore concurring) (acknowledging that “the *Prometheus* discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims). Myriad’s argument that *Prometheus* is constrained to methods is an untenable position”). Notably, Judge Moore did not modify her analysis to reflect this statement on remand and joined Judge Lourie in upholding Myriad’s patents. *Id.*

¹⁶⁷ *AT&T Corp. v. Excel Commc’ns Inc.*, 172 F.3d 1352, 1358 (Fed. Cir. 1999).

¹⁶⁸ See *id.*

¹⁶⁹ See *id.*

¹⁷⁰ See *Ass’n for Molecular Pathology*, 689 F.3d at 1326 (“*Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules.”).

compositions of matter.¹⁷¹ This error becomes apparent upon considering the Supreme Court's repeated disinclination to adhere to rigid tests developed by the Federal Circuit in favor of more nuanced and holistic analyses. The dynamic between the Supreme Court and the Federal Circuit in two cases is indicative of the common approach employed by the Court when faced with a decision of whether or not to adhere to a mechanical test proffered by the Federal Circuit.

For instance, as discussed earlier, the Court chose not to adopt the Federal Circuit's exclusive application of the M or T test to determine whether the subject matter at issue in Prometheus's patents was eligible for patenting.¹⁷² *KSR Intern. Co. v. Teleflex Inc.* is also representative of the Court's practice of declining to adhere to the rigid tests for deciding issues of patentability as applied by the Federal Circuit.¹⁷³ Although the issue presented in *KSR* concerned whether the claimed invention was obvious—another obstacle to patentability—the Federal Circuit has explicitly weighed considerations from the obviousness context into the calculus for determining patent eligibility under 35 U.S.C. § 101.¹⁷⁴ In *KSR*, the Supreme Court held that the Federal Circuit's application of the teaching, suggestion, or motivation (TSM) test for obviousness was overly rigid, and the Court urged that any approach to deciding issues of obviousness be flexible.¹⁷⁵ As applied by the Federal Circuit, the TSM test was the principal mechanism for determining whether a claimed invention was obvious by looking for a teaching, suggestion, or motivation to combine certain existing inventions in a manner that yielded the

¹⁷¹ See *Chakrabarty* *supra* note 22 and accompanying text.

¹⁷² See sources cited *supra* notes 57–103 and accompanying text.

¹⁷³ See *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

¹⁷⁴ See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329, 1351 (Fed. Cir. 2011) (citing *Funk Bros.*—a case decided on obviousness—in terms of 35 U.S.C. § 101 to serve as a comparison to the subject matter at issue in *Chakrabarty*).

¹⁷⁵ See *KSR Intern. Co.*, 550 U.S. at 419.

claimed invention.¹⁷⁶ If such a teaching, suggestion, or motivation was found, the invention would be obvious.¹⁷⁷

In holding that the Federal Circuit’s rigid application of the TSM test in *KSR* was in error, the Supreme Court stated that the Court’s precedent “set[s] forth an expansive and flexible approach [for determining obviousness that is] inconsistent with the way the [Federal Circuit] applied its TSM test here.”¹⁷⁸ The Court further characterized the TSM test as a “helpful insight,” but cautioned that “[h]elpful insights . . . need not become rigid and mandatory formulas.”¹⁷⁹ The Court then stated that “when a court transforms [a] general principle into a rigid rule that limits the obviousness inquiry, as the [Federal Circuit] did here, it errs.”¹⁸⁰

Thus, *Mayo* and *KSR* demonstrate the Federal Circuit’s commitment to advancing rigid frameworks and the Supreme Court’s repeated insistence that the tests proffered by the Federal Circuit not be dispositive on the issues of patent eligibility under 35 U.S.C. § 101 and obviousness, but rather that they occupy a small portion of the calculus towards reaching a workable conclusion. The Federal Circuit’s strict adherence to the “markedly different” test, which it gleaned from *Funk Bros.* and *Chakrabarty*, predictably provides the Supreme Court with yet another chance to reject the court’s narrow analysis in favor of a much more nuanced and fact specific determination. For instance, neither *Funk Bros.* nor *Chakrabarty* analyzed the impact of issuing a patent to the claimed invention on the public or the risk of tying up the use of natural laws.

In *Association for Molecular Pathology*, the Federal Circuit went to great lengths to divorce its decision from policy considerations. Before engaging in an analysis of whether

¹⁷⁶ See *id.* at 418.

¹⁷⁷ See *id.*

¹⁷⁸ See *id.* at 415.

¹⁷⁹ *Id.* at 419.

¹⁸⁰ *Id.*

Myriad’s composition claims directed to isolated DNA were patent-eligible, the Federal Circuit cautioned that “it is important to state what this appeal is not about.”¹⁸¹ The Federal Circuit contended that the *Association for Molecular Pathology* case was “not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion.”¹⁸² Nor was the case about “whether the . . . owner of the . . . patents, or Myriad, the exclusive licensee . . . acted improperly in its licensing or enforcement policies with respect to the patents.”¹⁸³ The court also contended that the appeal was not about “whether it is [sic] desirable for one company to hold a patent or license covering a test that may save people’s lives”¹⁸⁴ But in *Mayo*—which the Supreme Court intended to guide the Federal Circuit’s decision in *Association for Molecular Pathology* on remand—the Court did not consider the issue of patent eligibility in a vacuum. Rather, it examined the landscape of patent eligibility from a position that fully accounted for the policy implications of its decision, paying particular attention to its concern that awarding a patent may tie up the use of natural laws in an area.¹⁸⁵ This broad view of the question of subject matter eligibility was the essence of the Court’s holding in *Mayo*, and this marriage of precedent with policy is disturbingly absent from the Federal Circuit’s first and second *Association for Molecular Pathology* opinions.

Finally, the Federal Circuit’s reliance on the statement from *Chakrabarty* in support of an extraordinarily broad scope of patent-eligible subject matter—which indicates that, “[t]he Committee Reports accompanying the 1952 [Patent] Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man’”—is

¹⁸¹ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1324 (Fed. Cir. 2012).

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ See *supra* notes 100–103 and accompanying text.

misplaced.¹⁸⁶ The full quote from the Committee Reports teaches a far more limited understanding of the scope of patentable subject matter. The full quote instructs that, “[a] person may have ‘invented’ a machine or a manufacture, which *may* include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of [this] title are fulfilled.”¹⁸⁷ As the Supreme Court cautioned when it heard *Chakrabarty*, “[t]his [quote] is not to suggest that § 101 has no limits or that it embraces every discovery.”¹⁸⁸

Had the Federal Circuit not dismissed the concerns the Supreme Court expressed in *Mayo* as applicable only to method claims, and instead accounted for the implications of tying up the use of the natural laws in the calculus for determining patent eligibility, they would likely have concluded that Myriad’s claims to isolated DNA were not patent-eligible. The Federal Circuit would have had to look no further than to the district court’s *Association for Molecular Pathology* opinion to get a sense of the dramatic impact that awarding patents on the isolated DNA had among patients, researchers, and other groups.¹⁸⁹

Research has shown that gene patents have “persistent negative effects on subsequent scientific research.”¹⁹⁰ The possibility of obtaining patent protection for discoveries related to genetic research largely does not motivate scientists to conduct research and as a result, “patents

¹⁸⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess., 6 (1952)).

¹⁸⁷ See *Bilski v. Kappos*, 130 S. Ct 3218, 3249 (2010) (quoting S. REP. 1979, at 5; H.R. REP. 1923, at 6) (emphasis added).

¹⁸⁸ *Chakrabarty*, 447 U.S. at 309.

¹⁸⁹ See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d. 181, 186 (S.D.N.Y. 2010) (describing the effects of Myriad’s gene patents on researchers who stopped BRCA1/2 testing upon receiving cease-and-desist letters regarding the patents in suit, doctors who are unable to disseminate the results of patients’ BRCA1/2 tests, genetic counselors who are unable to send patient samples to laboratories other than Myriad for testing, and patients who are unable to pay the full the cost of BRCA1/2 tests out of pocket if the tests are not covered by insurance).

¹⁹⁰ See *id.* (quoting Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 27 Nat’l Bureau of Econ. Research, Working Paper No. 16213, (2010)).

are not needed for much of U.S.-based genetic research to occur.”¹⁹¹ One of the primary purposes of the U.S. patent system—full disclosure of a claimed invention—is already accomplished by “the norms of academic science” which encourage full disclosure of research results in peer reviewed journals.¹⁹² As much as forty six percent of labs conducting genetic research feel that gene patents either delayed or limited their research.¹⁹³ The exclusive rights conferred by gene patents do not result in faster genetic test development nor are they necessary for the development of genetic tests to detect rare genetic diseases.¹⁹⁴ In fact, the discovery of the BRCA1/2 genes was made possible by substantial funding from the National Institutes of Health and through the use of well-known sequencing techniques by teams of scientists—some of whom were resolutely opposed to patenting the BRCA1/2 genes.¹⁹⁵ Some researchers have characterized DNA patents as “difficult, if not impossible, to circumvent”¹⁹⁶ because the patents often foreclose research on both the effects of the DNA sequence and the naturally occurring gene.¹⁹⁷

Regarding the effects of gene patents on patients seeking patented therapies, research has indicated that “where patents and licensing practices have created a sole-provider of a genetic test, patient access to those tests has suffered in a number of ways.”¹⁹⁸ First, when a sole-

¹⁹¹ See U.S. DEP’T. OF HEALTH & HUMAN SERVS., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society* (2010), available at http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf.

¹⁹² *Id.*

¹⁹³ See Supplemental Brief for Appellees, Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2215682, at *10–11.

¹⁹⁴ U.S. DEP’T. OF HEALTH & HUMAN SERVS., *supra* note 190.

¹⁹⁵ See Corrected Brief of Amici Curiae, Information Society Project at Yale Law School Scholars in Support of Plaintiffs-Appellees, Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2885885, at *5–6.

¹⁹⁶ Isabelle Huys, et. al., *Legal Uncertainty in the Area of Genetic Diagnostic Testing*, 27 *Nature Biotechnology* 903, 907 (2009).

¹⁹⁷ See Brief for Knowledge Ecology International and Universities Allied for Essential Medicines as Amici Curiae in Support of Plaintiffs-Appellees, Supporting Affirmance, Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2885874, at *7.

¹⁹⁸ *Id.* at 3.

provider of a genetic test does not accept a patient's insurance, the cost of obtaining the test often proves prohibitive for large numbers of patients.¹⁹⁹ Second, in situations where gene patents have created a sole-provider, patients are unable to obtain an independent second opinion on test results.²⁰⁰ It has been recognized that “[c]onfirmatory testing by another laboratory is the laboratory equivalent to the time-honored practice of obtaining a second opinion from a clinician.”²⁰¹ Sole-providers of genetic tests that aggressively enforce their patents could cause additional access problems for patients.²⁰² In one instance, patients with familial long QT syndrome—a life-threatening condition—were unable to receive testing for the condition for an eighteen month period because the patent holder had not yet developed a commercial genetic test but sought to exclude others from infringing on its patent by providing a similar test.²⁰³ Although scientists identified targeted cancer therapies effective in treating those with BRCA mutations years ago, evidence suggests that BRCA1/2 gene patents have hindered the availability of treatments.²⁰⁴

¹⁹⁹ See *id.*

²⁰⁰ See *id.* at 44 (explaining that “[t]he legal complaint filed against Myriad names one plaintiff who would have liked a second opinion on her BRCA1/BRCA2 genetic test results but instead had to make major medical decisions based on the Myriad test results alone.”).

²⁰¹ Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2011 WL 585711, at *7 (describing one of the plaintiffs in *Ass’n for Molecular Pathology* who was unable to obtain a second opinion on the results of her BRCA1/2 tests results and was forced to make major medical decisions—such as whether to pursue the treatment options of a mastectomy or oophorectomy (ovary removal)—based on the results of a single test).

²⁰² See U.S. DEP’T. OF HEALTH & HUMAN SERVS., *supra* note 190.

²⁰³ *Id.* at 3–4, 40 (describing other instances where exclusive rights have been enforced as a means for preventing clinical laboratories from offering genetic testing including Myriad’s enforcement of its exclusive rights to BRCA1/2 genes to prevent other labs from conducting genetic testing for breast cancer, Athena Diagnostics’ use of its exclusive rights to hearing loss and Alzheimer’s genes to reduce the number of alternative providers, and Miami Children’s Hospital’s use of its patent on the Canavan disease gene to either prevent other labs from performing testing or require a royalty fee in order to continue testing).

²⁰⁴ See Supplemental Brief for Appellees, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2215682, at *10 (quoting Susan M. Domcheck et al., *Challenges to the Development of New Agents for Molecularly Defined Patient Subsets: Lessons from BRCA1/2 – Associated Breast Cancer*, 29 J. ON CLINICAL ONCOLOGY 4224 (2011)).

Finally, gene patents often have deteriorative effects on genetic test quality.²⁰⁵ A researcher opined that “[t]he most robust method for assuring quality in laboratory testing is through comparison of results obtained on samples shared between different labs.”²⁰⁶ Competition among multiple laboratories offering genetic testing for the same indication often acts as a catalyst for improvements in test quality and for the development of more thorough testing techniques.²⁰⁷ Sample sharing and competition often do not occur in environments where a sole-provider of a genetic test prevents others from providing testing.²⁰⁸ A 2006 study of 300 individuals who received negative test results from Myriad’s BRAC test, despite coming from families comprised of individuals with four or more members that had breast or ovarian cancer, concluded that “genetic testing does not provide all available information to women at risk . . . [since] 12% of those from high risk families with breast/ovarian cancer and with negative . . . commercial test results for [BRCA1/2] nonetheless carry cancer predisposing [mutations] in one of these genes.”²⁰⁹ The study went on to note that because of the expense and invasiveness of corrective procedures—such as a mastectomy—inaccurate BRCA1/2 test results coupled with a patient’s inability to secure a second opinion can have particularly negative consequences.²¹⁰

V. ESTABLISHING A WAY FORWARD

On November 30, 2012, the Supreme Court elected to grant certiorari in *Association for Molecular Pathology*, following the Federal Circuit’s cursory review of the impact of *Mayo* on

²⁰⁵ See *id.* at 4, 46.

²⁰⁶ *Id.* at 4.

²⁰⁷ See *id.*

²⁰⁸ *Id.*

²⁰⁹ Brief for AARP as Amicus Curiae in Support of Plaintiffs-Appellees and Arguing for Affirmance, Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2011 WL 585711, at *7 (quoting Tom Walsh et. al., *Spectrum of Mutations in BRCA1, BRCA2 CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS’N 1379 (2006)).

²¹⁰ See *id.* at 6.

the issues presented in *Association for Molecular Pathology*.²¹¹ In agreeing to hear the case, however, the Court chose not to review whether the Federal Circuit erred in finding *Mayo* and *Association for Molecular Pathology* irreconcilable, nor did the Court confine itself to addressing the issue of whether the petitioners lacked standing to challenge the validity of Myriad's patents.²¹² Rather, the Court elected to review the broadest of the three questions raised by the petitioner, namely, "[a]re human genes patentable?"²¹³ The fact that the question is before the Court suggests that the answer cannot be gleaned merely from the text of § 101. As such, the process of developing an answer to the extraordinarily broad question of whether human genes are patentable will likely entail an extra-statutory analysis of the issues. Happily, such an analysis should be fresh in the Court's mind after its decision in *Mayo*—where, as discussed *supra*, the Court carefully entertained a traditional § 101 analysis while simultaneously stepping away from the statute to account for the policy implications of its decision—and concluded that the Prometheus patents were not directed to patent-eligible subject matter.

Of particular concern to a unanimous Court in *Mayo* was the inhibitory effect that upholding the Prometheus patents would have on subsequent developments in the field of thiopurine administration.²¹⁴ The Court noted that the patents "threaten[ed] to inhibit the development of more refined treatment recommendations . . . that combine Prometheus's correlations with later discovered features of metabolites, human physiology or individual patient characteristics." This concern applies with equal or greater force to Myriad's BRCA1/2 patents because while the Court emphasized that Prometheus's patents *threatened* to inhibit the

²¹¹ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

²¹² *Petition for a Writ of Certiorari, Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, (No. 12-398), 2012 WL 4502947.

²¹³ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012); *Petition for a Writ of Certiorari, Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, (No. 12-398), 2012 WL 4502947.

²¹⁴ See *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 132 S. Ct 1289, 1302 (2012).

development of subsequent treatments, Myriad's patents have already had a substantial preemptive effect on further genetic research, genetic test development, and patient access to testing.²¹⁵

Of course, in order to use *Mayo* as authority permitting an extra-statutory analysis of whether certain subject matter is patent-eligible, the Court must be satisfied that the considerations it advanced in *Mayo* are not limited to method claims. Although the claims at issue in *Mayo* were directed to a method of administering thiopurines, the Court made no representations that the concerns it raised in *Mayo* were limited to the method claim context—contrary to the Federal Circuit's argument in *Association for Molecular Pathology* on remand.²¹⁶ Instead, it is likely that the Court's reasoning in *Mayo* resulted from a recognition that questions of subject matter eligibility are often extremely complex and in some cases, a more in depth consideration of the varied effects of upholding patents on certain subject matter is warranted. The Court—relying primarily on *Benson*, *Bilski*, and *AT&T*, which all support the notion that concerns raised in the context of one type of claim are applicable in the context of another—will likely find *Mayo* is particularly applicable to the issues in *Association for Molecular Pathology*. Such a finding will enable the Court to weigh the significant policy implications of affording human genes patent protection—including the substantial preemptive effect such protection would have on future studies of patented human genes—and will lead the Court to conclude that human genes are not patent-eligible.

²¹⁵ See sources cited *supra* notes 189–210 and accompanying text.

²¹⁶ See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1325 (Fed. Cir. 2012).

VI. ORAL ARGUMENT PROVIDES MORE ANALOGIES THAN ANSWERS

On April 13, 2013, the Supreme Court heard oral arguments in *Association for Molecular Pathology*.²¹⁷ Notably, the Justices struggled to determine just how far removed from nature certain subject matter has to be before it can be considered patent-eligible, using analogies to gold made into jewelry, drugs isolated from plants in the Amazon, baseball bats carved from trees, and eggs, flower, and salt used to make a cookie.²¹⁸ These analogies underscore the complexity of the issue before the Court.

Justices Scalia, Kennedy, Alito, and Kagan expressed some concern over whether companies like Myriad would have sufficient incentive to develop innovative new therapies without the possibility of securing patents on products isolated from nature.²¹⁹ Christopher Hansen, arguing on behalf of the ACLU, pointed to the “enormous recognition” that companies and innovators would receive for their discoveries.²²⁰ While Justices Scalia quipped “[w]ell, that’s lovely” at Hanson’s rationale, Justice Kagan indicated that she hoped Hanson was going to point to the possibility of securing method patents or use patents on technology incorporating unpatentable natural products as sufficient incentive to encourage continued innovation.²²¹

Some Justices indicated that they might be hesitant to reach the broad question of whether human genes constitute patent-eligible subject matter at all. Chief Justice Roberts observed that the Court might be asking the wrong patent question altogether and suggested that perhaps the issue was one of obviousness—whether Myriad’s patents should fail because the method of extracting human genes would have been obvious to any trained scientist in the

²¹⁷ Transcript of Oral Argument, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, (No. 12-398), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-398-amc7.pdf.

²¹⁸ *Id.* at 4–5, 41, 7, 35.

²¹⁹ *Id.* at 11–16.

²²⁰ *Id.* at 15.

²²¹ *Id.* at 13, 15.

field.²²² Similarly, Justice Alito, expressing reservations about attempting to decide the broad question of when manipulating a product of nature can transform that product into an item of human invention, asked “why should we jump in and decide the broadest possible question?”²²³

Encouragingly, the Justices seemed not to be convinced by Gregory Castanias’s suggestion on behalf of Myriad that the product of nature doctrine—which excludes products of nature from the scope of patentable subject matter—has lost its utility in modern science.²²⁴ Castanias argued that one of the goals of personalized medicine is to more closely replicate the natural actions of an individual’s body and that the product of nature doctrine, if read too broadly, threatens to impede progress in this developing area of medicine.²²⁵ Justice Kennedy indicated that merely isolating DNA does not impart additional utility into that segment absent the addition of chemicals and tags to make it a probe and only as a probe does isolated DNA become useful.²²⁶

Understanding that the Court’s questioning during oral argument is not always a reliable indication of how the Court will ultimately rule, the general tenor of the oral argument left the impression that the Justices may be hesitant to grant patent protection to isolated human genes. The Court’s decision is expected by the end of June 2013.²²⁷

²²² *Id.* at 26.

²²³ Transcript of Oral Argument at 28, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, (No. 12-398), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-398-amc7.pdf.

²²⁴ Lyle Denniston, *Argument recap: Analogies to the rescue*, SCOTUSBLOG (Apr. 15, 2013, 1:17 PM), <http://www.scotusblog.com/2013/04/argument-recap-analogies-to-the-rescue/>.

²²⁵ Transcript of Oral Argument at 46, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, (No. 12-398), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-398-amc7.pdf.

²²⁶ *Id.*

²²⁷ Mark A. Hearron, James J. Mullen, Matthew I. Kreeger, *After “Myriad” Oral Argument, Supreme Court Set to Decide Patentability of Isolated Human DNA Molecules*, MONDAQ (Apr. 22, 2013), <http://www.mondaq.com/unitedstates/x/234882/Patent/After+Myriad+Oral+Argument+Supreme+Court+Set+To+Decide+Patentability+Of+Isolated+Human+DNA+Molecules>.

VII. CONCLUSION

The Supreme Court's *Mayo* opinion makes clear that when the Court considers whether human genes are patentable, it will take a broad view of the implications of its decision and ultimately weigh the well-documented effects of tying up the use of natural laws in this area into the calculus for determining whether this unique subject matter is patent-eligible. The probability that the Court will adopt this broad approach is enhanced by the Court's explicit recognition in *Benson* and *Bilski* that the analysis of subject matter eligibility should not be narrowly confined to comparisons between identical claim types and by the Court's repudiation of the Federal Circuit's strict adherence to inflexible standards for patent eligibility and obviousness in *Mayo* and *KSR*, respectively. The Court is likely to conclude that human genes are not eligible for patenting, and thus, that Myriad's claims directed to isolated BRCA1/2 DNA are not patent-eligible. Declining to extend patent protection to human genes will positively impact genetic test quality, test development, and patient access to genetic tests. Importantly, it will also provide courts with a clearer picture of the appropriate subject matter eligibility analysis for human genes. This analysis undoubtedly requires courts to satisfy the threshold requirements set forth in section 101, but also requires courts to engage in forward-looking considerations of the preemptive effects of granting patent protection.