

2015

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Recommended Citation

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https://scholarship.shu.edu/student_scholarship/785

**The Public Policy Considerations After
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Samuel J. Berse

Introduction

“It is a chemical entity, but DNA’s importance flows from its ability to encode and transmit the instructions for creating humans. Life’s instructions ought not be controlled by legal monopolies created at the whim of Congress or the courts,” writes Dr. James Watson, one of the winners of the Nobel Prize in Physiology or Medicine in 1962 for the discovery of the structure of DNA.¹ Dr. Watson also proclaims, “[i]n years to come, with the right advances in genetic engineering, we may well be able to treat or rectify mental disabilities and physical diseases which today are deemed incurable. Such hope is all the more reason that scientific *research* on human genes *should not be impeded* by the existence of *unnecessary patents*.”² Indeed this viewpoint may be well-reasoned, but determining whether a patent is necessary or unnecessary is undoubtedly subjective.

Patents are fundamentally necessary for advancements in scientific research, and stating anything to the contrary would oppose the patent system’s purpose.³ Though, with the recent Supreme Court decision that largely abolished gene patentability and with the inaction of new laws, there are unresolved questions as to whether patents in the field of genetic testing will continue to exist in their current form, and with that, what the future will hold for the underlying

¹ Brief for James D. Watson as Amici Curiae Supporting Neither Party, Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303 (2012) (No. 2010-1406), *available at* https://www.aclu.org/files/assets/2012_06_15_-_james_d_watson_brief_on_remand.pdf; *James Watson – Biographical*, NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/medicine/laureates/1962/watson-bio.html (last visited Oct. 30, 2013).

² Brief for James D. Watson as Amici Curiae Supporting Neither Party, Association of Molecular Pathology v. USPTO, 689 F.3d 1303 (2012) (No. 2010-1406) (emphasis added).

³ Adrian Tombling, *Ban on Human Gene Patents is Baffling but it Won’t Impede Biotech Research*, THE GUARDIAN (June 18, 2013, 8:51 PM), <http://www.theguardian.com/science/blog/2013/jun/18/ban-human-gene-patents-biotech-research>).

research.⁴ Courts are in the process of addressing the whirlwind of litigation in this area, and the outcomes of each case are uncertain. This Note summarily addresses some of the consequences and the policy and practical implications of the Supreme Court holding that isolated genes are unpatentable.⁵

Specifically, this Note addresses how new patent law provisions, the Leahy-Smith America Invents Act (“AIA”), has changed the practice of patent law and considerations that courts need to be cognizant of when making future decisions. Part I addresses the fundamentals of patent law that pertain to the subsequent discussions. Part II addresses the background case law that led up to the recent monumental Supreme Court decision, *Myriad* and the guidance later issued by the USPTO.⁶ Part III discusses the AIA and how it changed the practice of patent law with respect to procedures for challenging the validity of patents through post grant proceedings. Part IV highlights some of the considerations of the new post grant proceedings in the AIA with respect to *Myriad*. Finally, this Note concludes that the current state of patent law practice in this very particular area is currently sensible, but it is at a very pivotal and delicate point. With crucial court decisions looming on the horizon, patent law needs to evolve in such a way to continue promoting research in the genetic testing industry, as opposed to hindering further developments. This will be accomplished by allowing genetic tests to qualify as patent eligible subject matter.

Part I: Patent Law Background

Pursuant to the Constitution, “[c]ongress shall have the power to . . . promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to [a]uthors and [i]nventors the

⁴ Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

⁵ *Id.*

⁶ *Id.*

exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”⁷ This provision gave rise to the United States Patent Act of 1790, and with that, the first patents were born. A patent is a “property right granted by the Government of the United States of America to an inventor []to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . for a limited time in exchange for public disclosure of the invention.”⁸ The United States Patent Act was refined by Thomas Jefferson in 1793, and remained unchanged until 1952 when the United States Patent and Trademark Office (“USPTO”) began classifying patents into three categories: utility patents, design patents, and plant patents.⁹ The general focus of the Note is on utility patents, which are granted for the invention of “a new and useful method, process, machine, device, manufactured item, or chemical compound” or any new and useful improvement.¹⁰

In practice, in order to receive a utility patent, an inventor publicly discloses his invention in exchange for the approximately twenty-year period of exclusivity to use and practice the invention from the date of filing the patent application with the USPTO.¹¹ Through the lengthy process of obtaining a patent, the inventor submits a patent application containing claims ideally and specifically identifying the proposed invention to the USPTO for review by a patent examiner (“examiner”), and the invention becomes publicly disclosed when the patent application is published by the USPTO eighteen months after it is filed.¹² The examiners communicate with the inventors by sending them office actions that include the examiner’s

⁷ U.S. CONST. art. 1, § 8, cl. 8.

⁸ USPTO, <http://www.uspto.gov/inventors/patents.jsp> (last visited April 19, 2014).

⁹ “A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.” General Information Concerning Patents, USPTO, http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp.

¹⁰ Mary Bellis, *Utility Patent*, ABOUT.COM, http://inventors.about.com/od/definations/g/Utility_Patent.htm.

¹¹ 35 U.S.C. § 154(a)(2).

¹² USPTO, <http://www.uspto.gov/patents/resources/types/utility.jsp> (last visited Apr. 19, 2014); 35 U.S.C. § 122 (patent applications are published eighteen months after filing and once published, patents are easily available on websites such as GOOGLE.COM/PATENTS or [HTTP://PORTAL.USPTO.GOV/PAIR/PUBLICPAIR](http://PORTAL.USPTO.GOV/PAIR/PUBLICPAIR)).

detailed analysis of the patent application, including the reasons the inventor cannot yet receive a patent for the particular invention.¹³ Examiners will only issue a notice of allowance, which will result in the granting of a patent provided that the inventor still wants the patent and pays the issue fee, for patent applications that adhere to all applicable provisions.¹⁴ The Supreme Court case regarding gene patentability, the focal point of this Note, deals primarily with one of those provisions for patentability.

Generally speaking, *Ass'n for Molecular Pathology v. Myriad Genetics*¹⁵ was about “patent-eligible” subject matter defined under 35 U.S.C. §101.¹⁶ This provision identifies four categories of patent-eligible subject matter: a process, a machine, a manufacture, and a composition of matter.¹⁷ All things within the scope of a utility patent must fall within at least one of these four categories.¹⁸ Genes, defined as the basic units of heredity that are responsible for all physical and inheritable characteristics of an organism, were claimed in the utility patents at issue in *Myriad* because genes are chemical compounds or a composition of matter.¹⁹ Examples of patent ineligible subject matter, or the so-called judicial exceptions, include: “laws of nature, physical or natural phenomenon, and abstract ideas.”²⁰ Once claims have been determined to be patent-eligible, whether by an examiner or in court, the patentability inquiry proceeds to other provisions that, for example, assess novelty and nonobviousness.²¹

¹³ 37 CFR § 1.104

¹⁴ 37 CFR § 1.311

¹⁵ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. at 2107.

¹⁶ 35 U.S.C §101.

¹⁷ *Id.*

¹⁸ *Id.*; Z. Peter Sawicki, Visala C. Goswitz & Amanda Prose, *Patenting Biologicals: Myriad Issues and Options in the Wake of Myriad*, BENCH & BAR OF MINNESOTA, Sept. 2013. at 24, 24. http://mmbenchbar-digital.com/mmbenchbar/september_2013#pg24.

¹⁹ DICTIONARY.COM, <http://dictionary.reference.com/browse/gene> (last visited Mar. 22, 2014); “A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.” General Information Concerning Patents, USPTO, http://www.uspto.gov/patents/resources/general_info_concerning_patents.jsp.

²⁰ *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

²¹ 35 U.S.C. §§ 102, 103.

As of *Myriad*, the USPTO had granted thousands of gene patents for over thirty years.²² The USPTO even reaffirmed those guidelines in 2001.²³ But, in *Myriad* the Court essentially held that patents can no longer be granted for the simple discovery that a particular human gene sequence corresponds to a specific inheritable trait.²⁴ Thus, without expressly acknowledging Dr. Watson's views, the Court nonetheless fundamentally agreed with him that genes should not be patentable, but not because they are unnecessary patents, but because the discovery of a gene is unpatentable.²⁵

Part II: *Myriad* and Patent Eligible Subject Matter

A: Recent Case Law

On June 16, 1980, the Supreme Court decided its first modern-day pivotal case in the area of patent eligible subject matter.²⁶ In *Chakrabarty*, the Court ruled that “[a] live, human-made micro-organism is patentable subject matter under § 101.”²⁷ Looking at the legislative history, the Court opined that “Congress contemplated that patent laws should be given wide scope . . . and broad construction. While laws of nature, physical phenomena, and abstract ideas are not patentable [the claims are] to composition of matter -- a product of human ingenuity ‘having a distinctive name, character [and] use.’”²⁸ This opinion was revolutionary for its time because the patent examiner had previously rejected the patent on the grounds that micro-organisms are products of nature and that living thing were unpatentable subject matter.²⁹ Yet, crucial to the court's holding in overcoming that analysis, the Court found the inventor produced

²² See Eric J. Rogers, Can You Patent Genes? Yes and No, 93 J. Pat. & Trademark Off. Soc'y 19 (2010).

²³ 66 Fed. Reg. 1092-94 (Jan. 5, 2001).

²⁴ See generally, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107.

²⁵ See generally, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107.

²⁶ See *Diamond v. Chakrabarty*, 447 U.S. 303, 305.

²⁷ *Id.*

²⁸ *Id.* (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615, *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127).

²⁹ *Id.* at 306.

a new bacterium that had markedly different characteristics from bacterium found in nature.³⁰ Those characteristics were further found to have the potential for significant utility, and thus, the bacterium was patent eligible subject matter.³¹ Importantly, the court explained that not all differences rise to the level of “marked differences.”³² “Marked differences” must be significant differences that are more than incidental or trivial differences.³³

Three decades later in *Bilski v. Kappos*,³⁴ the Court found that a claimed process at issue was unpatentable subject matter, and thus invalid, when it involved an abstract idea that broadly preempted its use in all fields.³⁵ Processes are patentable subject matter under 35 U.S.C. § 101, but in this case, the claimed process was found to be the abstract idea of hedging risk in the energy business, and the process was unpatentable because “[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.³⁶ The Court opined that the 1952 Patent Act did not expand the scope of patentable subject matter to include any series of steps as a process under 35 U.S.C. § 101, and that “[t]he patent application here can be rejected under our precedents on the unpatentability of abstract ideas.”³⁷

Two years after *Bilski*, in March 2012, the Supreme Court held in *Mayo Collab. Servs. v. Prometheus Labs.*³⁸ that Prometheus' medical test, which determined the proper dosage of a

³⁰ *Id.* at 311.

³¹ *Id.* at 310.

³² Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, for Patent Examining Corps (March 4, 2014), available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

³³ *Id.*

³⁴ See *Mayo Collab. Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1305 (2012); *Bilski v. Kappos*, 130 S. Ct. 3218.

³⁵ *Bilski v. Kappos*, 130 S. Ct. at 3231.

³⁶ 35 USC § 101; *Id.* (quoting *In Re Bilski*, 545 F.3d 943, 1013 (2008) (Rader, J., dissenting); see, e.g., D. Chorafas, Introduction to Derivative Financial Instruments 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, FINANCIAL ACCOUNTING: AN INTRODUCTION TO CONCEPTS, METHODS, AND USES, 581-82 (13th ed. 2010); S. Ross, R. Westerfield, & B. Jordan, FUNDAMENTALS OF CORPORATE FINANCE, 743-44 (8th ed. 2008).

³⁷ *Bilski v. Kappos*, 130 S. Ct. at 3231, 3249.

³⁸ *Mayo Collab. Servs. v. Prometheus Labs.*, 132 S. Ct. at 1305.

particular drug by measuring levels of the drug's metabolites in a patient's system, was not patentable.³⁹ The Court reasoned that the processes covered by Prometheus' patents do not transform otherwise unpatentable natural laws, in this case the correlation between the levels of the drug's metabolites in the patient's system with respect to the proper dosage the patient should be given, into patent-eligible applications in accordance with 35 U.S.C. § 101.⁴⁰ Laws of nature, in addition to abstract ideas, are expressly excluded from that definition.⁴¹ In the instance of Prometheus' medical test, in addition to finding that it involved an application of an unpatentable law of nature, the Court also found that the claims merely contained steps that involved "well-understood, routine, conventional activity previously engaged in by researchers in the field."⁴² Thus, the patents Prometheus had were invalid, especially in light of *Bilski*.

In the cases of *Bilski* and *Prometheus*, when a patent or claims therein are invalidated by the USPTO or courts, those respective sections become worthless. In a sense, invalidation is a way of saying a patent or claims therein should not have been granted by the examiners. Thus, invalid patents or claims are unenforceable against another entity for the purpose of an infringement lawsuit.⁴³ With that consideration in mind, the focus of this Note now turns to the keystone case-line involving Myriad Genetics, Inc. and their patents with claims presently being litigated in numerous district courts.

In 1996, Myriad Genetics located and sequenced two cancer susceptibility genes known as BRCA1 and BRCA2.⁴⁴ Myriad developed and patented a genetic test for mutations in these genes and threatened to sue doctors and institutions that were using the BRCA deoxyribonucleic

³⁹ *See Id.*

⁴⁰ *Id.*

⁴¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309, (1980).

⁴² *Mayo Collab. Servs. v. Prometheus Labs.*, 132 S. Ct. at 1305.

⁴³ Mary L. Miller & Richard P. Vitek, *Validity and Invalidity of Patent Claims*, TECH. TRANSFER PRAC. MANUAL, excerpt available at http://www.autm.net/AM/Template.cfm?Section=Volume_3_TOC&Template=/CM/ContentDisplay.cfm&ContentID=2207.

⁴⁴ Dorothy R. Auth, *Myriad Aftermath What Remains Patent Eligible?*, 250 N.Y. L.J. 6 (2013)

acid (“DNA”) sequences to test patients for genetic predisposition to breast, ovarian, and prostate cancer.⁴⁵ The American Civil Liberties Union (“ACLU”), the Association of Molecular Pathology (“AMP”) and several individual doctors, genetic counselors, scientific researchers, and patients challenged Myriad's patents and argued that human genes are not patent eligible and thus certain patent claims were invalid.⁴⁶ The district court ruled against Myriad and found that all of Myriad's asserted DNA claims were products of nature and therefore patent ineligible under 35 U.S.C. §101. The Federal Circuit reversed on appeal.⁴⁷ The Supreme Court granted certiorari, reaffirmed the district court's holding by vacating the judgment of the Federal Circuit, and remanded back to the Federal Circuit.⁴⁸

On remand, the Federal Circuit again held that genomic DNA and the synthetic DNA molecule known as complementary DNA (“cDNA”) are patent eligible.⁴⁹ The court reasoned that genomic DNA can be extracted from its cellular environment using a number of well-established laboratory techniques.⁵⁰ Thus, a particular segment of DNA, such as a gene, can then be excised or amplified from the DNA to obtain the isolated DNA segment of interest.⁵¹ Likewise, DNA molecules can also be synthesized in the laboratory.⁵² However, in several processes analogous to those that occur in cells, naturally occurring sequences of genetic information serve as the template to create cDNA, a molecule that does not naturally exist

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Ass'n for Molecular Pathology v. United States PTO*, 653 F.3d 1329 (Fed. Cir. 2011); *Ass'n for Molecular Pathology v. United States PTO*, 689 F.3d 1303 (Fed. Cir. 2012).

⁴⁸ *Auth*, *supra* note 44.

⁴⁹ *Id.*

⁵⁰ *Ass'n for Molecular Pathology v. United States PTO*, 689 F.3d at 1313.

⁵¹ *Id.*

⁵² *Id.*

because it is not a direct copy of the DNA sequence that it complements.⁵³ Resultantly, the judges maintained divergent opinions that raised questions about the precise contours of DNA's patent eligibility, especially with respect to cDNA's patent eligibility.⁵⁴

Judge Alan D. Lourie's majority opinion upheld Myriad's BRCA DNA claims on the grounds that the chemical differences generated during the isolation process between naturally-occurring and isolated DNA sequences created a non-naturally occurring molecule.⁵⁵ The claims at issue were from U.S. Patent 5,747, 282, and recited:

1. An isolated DNA coding for a BRCA1 polypep[ptide], said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.⁵⁶

“SEQ ID NO:1” and “SEQ ID NO:2” correspond to the BRCA1 DNA coding region and the BRCA1 protein, respectively, and in his opinion, the isolated DNA that is removed from its native cellular environment has been manipulated in such a way that it is markedly different from what exists inside the body.⁵⁷ Underscoring this notion was the idea that “courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.”⁵⁸

Judge Kimberly A. Moore joined the majority's judgment for cDNA sequences, and concurred in judgment with respect to the isolated DNA sequences, but wrote separately to

⁵³ Ass'n for Molecular Pathology v. United States PTO, 689 F.3d at 1313 (cDNA is generated from mRNA, and therefore only contain the coding regions of DNA known as exons. DNA itself contains both exons and non-coding regions known as introns).

⁵⁴ Auth, *supra* note 44.

⁵⁵ Ass'n for Molecular Pathology v. USPTO, 689 F.3d at 1326.

⁵⁶ U.S. Patent 5,747, 282; *Id.* at 1309.

⁵⁷ Ass'n for Molecular Pathology v. USPTO, 689 F.3d at 1328.

⁵⁸ *Id.* at 1333 (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997)); Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc).

explain her reasoning which was based on the USPTO's history of awarding gene patents and the reliance interest of patent holders.⁵⁹ She felt that "to the extent the majority rests its conclusion on the chemical differences between genomic and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims to human genes are directed to patentable subject matter."⁶⁰ If this case was decided on a blank canvas, Judge Moore may have concluded that isolated DNA are not patentable subject matter, and again she points to the same principle as the majority highlights that "we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved."⁶¹

Judge William C. Bryson, concurring in part and dissenting in part, argued the genetic similarities between naturally occurring and isolated BRCA DNA dwarfed any chemical differences between the two.⁶² Judge Bryson believed that although Myriad had valid claims to cDNA, Myriad did not have valid claims to the BRCA genes and associated gene fragments.⁶³ In his opinion, "Myriad's claims to the isolated BRCA genes seem to me to fall clearly on the 'unpatentable' side of the line the Court drew in *Chakrabarty*. Myriad is claiming the genes themselves, which appear in nature on the chromosomes of living human beings."⁶⁴ He concludes that "[t]here is no collective right of adverse possession to intellectual property, and we should not create one" and that "[o]ur role is to interpret the law that Congress has written in accordance with the governing precedents." Given that Judge Bryson would affirm the district court's rulings as to the BRCA gene and BRCA gene segment claims, which ruled that DNA is

⁵⁹ *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012).

⁶⁰ *Id.* at 1341.

⁶¹ *Id.* at 1343.

⁶² *Ass'n for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012).

⁶³ *Id.* at 1348.

⁶⁴ *Id.* at 1350.

patent ineligible subject matter, these divergent positions set the stage for a subsequent appeal to the Supreme Court.⁶⁵

In the most recent iteration of *Myriad*, when presented with the question of whether Myriad's patents and claims to isolated BRCA1 and BRCA2 gene gave Myriad the exclusive right to isolate an individual's BRCA1 and BRCA1 gene, the Supreme Court held that, "separating [a] gene from its surrounding genetic material is not an act of invention," and that genes isolated from human DNA claimed in Myriad's patents were not patentable because the "location and order" of the molecules in those genes "existed in nature before Myriad found them" even though the process of isolating nucleic acids, the building blocks of DNA, involves changing their structure by breaking chemical bonds.⁶⁶ Now, isolated genomic DNA is classified as a product of nature and therefore patent ineligible under 35 U.S.C. §101.⁶⁷ Though, cDNA is still patent eligible because it is not naturally occurring.⁶⁸ The Supreme Court's holding therefore upheld the patentability of cDNA, but reversed the Federal Circuit's determination of the patentability of isolated DNA.⁶⁹

For the first time the Court made it exceedingly clear that Myriad's mere discovery of the precise location and genetic sequence of BRCA1 and BRCA2 within chromosomes 17 and 13 did not amount to a patentable invention.⁷⁰ However, despite losing five of Myriad's 520 patent claims to BRCA1 and BRCA 2 DNA patents, notably including the three claims previously mentioned, Myriad maintained its claims to cDNA.⁷¹ The Court agreed that cDNA is patent

⁶⁵ *Id.* at 1358; Auth, *supra* note 44.

⁶⁶ Myriad Genetics, No. 12-398, slip op. at 12; Brian Resnick, *Why is Myriad Genetics Still Filing Patent Suits for Breast-Cancer Tests?*, NAT'L J. (2013).

⁶⁷ Auth, *supra* note 44.

⁶⁸ Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2109.

⁶⁹ Resnick, *supra* note 66.

⁷⁰ Dayrel S. Sewell, *Unanimous U.S. Supreme Court and Angelina Jolie: BRCA1 & BRCA2 Patentability*, INTELL. PROP. TODAY 24 (2013).

⁷¹ *Id.*

eligible because cDNA is synthesized in such a way that it is non-naturally occurring and is not simply isolated.⁷² Thus, cDNA evaded the law of nature exception to patent eligibility.⁷³

Just hours after the *Myriad* decision was released, the USPTO sent out a memorandum to all patent examiners.⁷⁴ The memo advised that, “[e]xaminers should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being ineligible subject matter under 35 U.S.C. § 101.”⁷⁵ Although that particular piece of guidance is directly in line with the *Myriad* decision, a later sentence highlights uncertainty for the future by stating that “[o]ther claims, *including method claims*, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in Manual of Patent Examining Procedure (“MPEP”) 2106, Patent Subject Matter Eligibility.”⁷⁶ “Method” claims are another word for “process” claims, and the USPTO statement here is a cause for substantial concern among patent practitioners and research institutions because the memorandum mentioned possible eligibility issues of method claims, despite the fact that the *Myriad* holding was expressly confined to non-method claims.⁷⁷ With this dichotomy, the memo concludes by stating: “[t]he USPTO is closely reviewing the decision in *Myriad* and will issue more comprehensive guidance on patent subject matter eligibility determinations, including the role isolation plays in those determinations.”⁷⁸ On March 4, 2014, the USPTO issued its guidance.⁷⁹

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, for Patent Examining Corps (June 13, 2013), *available at* http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf.

⁷⁵ *Id.*

⁷⁶ *Id.*

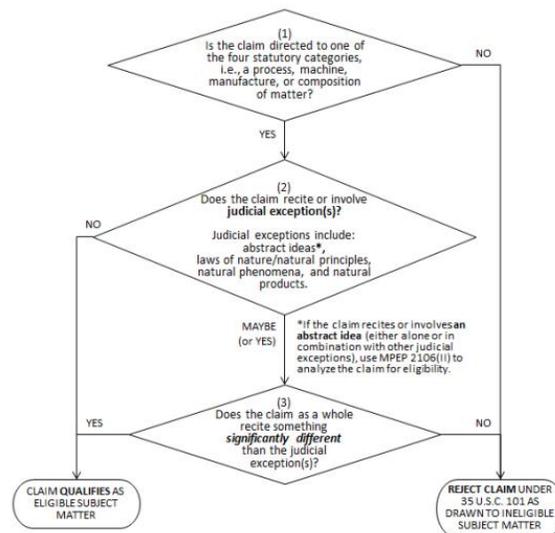
⁷⁷ *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. at 2119.

⁷⁸ Hirshfeld, *supra* note 74.

⁷⁹ Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, for Patent Examining Corps (March 4, 2014), *available at* http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf.

B: USPTO Guidance

In light of *Myriad*, the USPTO issued guidance for all claims reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products.⁸⁰ Notably, as this guidance memo, like all USPTO memorandum, is not binding law, either the legislature can enact superseding statutes or the court can release overruling opinions. *Myriad* is a prime example of that notion.⁸¹ The USPTO expressly stated that “while the holding in *Myriad* was limited to nucleic acids, *Myriad* is a reminder that claims reciting or involving natural products should be examined for a marked difference under *Chakrabarty*.”⁸² To do so, this flowchart should be followed by examiners.⁸³



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This chart illustrates a procedure that has streamlined this area of patent examination by clearly defining, in a test of sorts, what qualifies as eligible subject matter and what does not qualify as eligible subject matter.⁸⁵ It is no longer a subjective test with an open standard, but

⁸⁰ *Id.*

⁸¹ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. at 2119.

⁸² Hirshfeld, *supra* note 79.

⁸³ Hirshfeld, *supra* note 79.

⁸⁴ Hirshfeld, *supra* note 79.

⁸⁵ Hirshfeld, *supra* note 79.

rather an objective one that follows this precise analysis, even with respect to the weighing of twelve factors for ascertaining whether something is significantly different than a judicial exception.⁸⁶ Though, the USPTO did not create this protocol, and in fact, it appears that this analytical framework has been derived from Judge Robert W. Sweet from the Southern District of New York.⁸⁷ In the first opinion on the merits in the *Myriad* case-line, Judge Sweet held that fifteen of Myriad's claims spanning seven patents were invalid under 35 U.S.C. § 101, and issued a declaratory judgment against Myriad.⁸⁸ Judge Sweet's analysis of the claims followed the structure above.⁸⁹ Because the isolated DNA molecules were a composition of matter, yet also a judicial exception as a product of nature, Judge Sweet then turned his analysis to whether the isolated DNA was markedly different from native DNA.⁹⁰ Judge Sweet opined that the isolated DNA was not markedly different from native DNA, and could not be markedly different, because of the very nature of DNA.⁹¹ The claims to isolated BRCA1 and BRCA2 DNA, in order to serve any importance for genetic testing, must maintain the "defining characteristic of DNA in its native . . . form [and this] mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature."⁹²

In summation, the first question essentially asks if something is directed to patentable subject matter under 35 U.S.C. § 101, and if it is not then it cannot be patentable.⁹³ The second question asks if there is a judicial exception and if not then the subject matter is patent eligible.⁹⁴ The third question asks if the claim is significantly different from an unpatentable judicial

⁸⁶ Hirshfeld, *supra* note 79.

⁸⁷ See *Ass'n for Molecular Pathology v. United States PTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010)

⁸⁸ *Id.* at 211.

⁸⁹ *Id.* at 227-28.

⁹⁰ *Id.*

⁹¹ *Id.* at 229.

⁹² *Id.*

⁹³ Hirshfeld, *supra* note 79.

⁹⁴ Hirshfeld, *supra* note 79.

exception, and is therefore patent eligible subject matter.⁹⁵ To analyze whether something is significantly different, there are six factors that weigh in favor of eligibility and six factors that weigh against eligibility.⁹⁶

Factors that weigh toward eligibility (significantly different):

- a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.
- b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).
- c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).
- d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).
- e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).
- f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

- g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.
- h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.

⁹⁵ Hirshfeld, *supra* note 79.

⁹⁶ Hirshfeld, *supra* note 79.

- i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).
- j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.
- k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).
- l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.⁹⁷

In practice, these factors are applied in the same fashion as a judge would in a court of law. The USPTO even provided some examples for what examiners should find when required to analyze claims within this field.⁹⁸

Not surprisingly, the weighing of those twelve factors complements the *Myriad* decision. One factor weighing against eligibility is whether the “[c]laim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.”⁹⁹ Under this analysis, because isolated DNA is not markedly different from the chromosomal DNA, as its nucleotide sequence has not been changed, isolated DNA is unpatentable.¹⁰⁰ Although there is a resulting difference in the molecule’s structure, that does not rise to the level of a marked difference.¹⁰¹ Though, of absolute utmost importance is the analysis of cDNA under the twelve eligibility factors. Even though the process of making cDNA is routine in the biotechnology art, the USPTO reasons that cDNA nonetheless has a nucleotide

⁹⁷ Hirshfeld, *supra* note 79.

⁹⁸ Hirshfeld, *supra* note 79.

⁹⁹ Hirshfeld, *supra* note 79.

¹⁰⁰ Hirshfeld, *supra* note 79.

¹⁰¹ Hirshfeld, *supra* note 79.

sequence markedly different from naturally occurring DNA and is therefore patent eligible subject matter.¹⁰²

C: Myriad at Present and the Uncertain Future

Shortly after the Supreme Court decision, Myriad fired back and filed infringement suits against its competitors. Initially, Myriad filed suit against Ambry Genetics Corp. and Gene By Gene Ltd., who began offering BRCA1 and BRCA2 tests for \$2,280 and \$995 respectively, a price cheaper than the \$4,000 Myriad charges.¹⁰³ Since those two initial suits, Myriad also filed suit against BioReference Laboratories, Inc. (“BioReference”) in Utah federal court alleging that BioReference, through its genetic sequencing laboratory subsidiary, GeneDx, Inc., is infringing on Myriad’s intellectual property by offering OncoGeneDx, a comprehensive series of inherited cancer carrier testing, which includes testing for BRCA1 and BRCA2.¹⁰⁴ Myriad later sued Invitae claiming infringement of claims in eleven patents underlying Myriad's BRCAAnalysis test for hereditary breast and ovarian cancer risk.¹⁰⁵ Invitae responded by countersuing for a declaratory judgment of non-infringement.¹⁰⁶ Additionally, Quest Diagnostics (“Quest”) sought declaratory judgment that it would not be infringing on Myriad’s patents by selling tests for the BRCA genes, and Myriad filed suit against Quest, too.¹⁰⁷ Further, a sixth entity, Counsyl, is seeking a declaratory judgment, similar to Quest, that it is not infringing upon Myriad’s

¹⁰² Hirshfeld, *supra* note 79.

¹⁰³ Resnick, *supra* note 66.

¹⁰⁴ GLOBENEWSWIRE, <http://globenewswire.com/news-release/2013/10/22/582274/10053651/en/Bio-Reference-Laboratories-Inc-Sued-by-Myriad-Genetics-Confident-in-Its-Position.html> (last visited Mar. 22, 2014).

¹⁰⁵ GENOMEWEB, <http://www.genomeweb.com/clinical-genomics/invitae-countersues-myriad-northern-california-district-court> (last visited Mar. 22, 2014).

¹⁰⁶ *Id.*

¹⁰⁷ *Myriad Sues Quest Over BRCA1/2 Patents*, GENOMEWEB DAILY NEWS (Oct. 24, 2013), <http://www.genomeweb.com/clinical-genomics/myriad-sues-quest-over-brca12-patents>; *BioReference Laboratories, Inc. Sued by Myriad Genetics, Confident in its Position: Company Not Yet Served, but has Been Prepared for an Expected Action*; MARKETWATCH (Oct. 22, 2013, 8:13 AM) http://www.marketwatch.com/story/bioreference-laboratories-inc-sued-by-myriad-genetics-confident-in-its-position-2013-10-22?reflink=MW_news_stmp.

patents.¹⁰⁸ To date, only Ambry and Gene By Gene countersued Myriad claiming anti-trust violations.¹⁰⁹ However, Myriad and Gene By Gene have settled their suits with each other.¹¹⁰ As part of the terms, Gene By Gene cannot sell its genetic test for BRCA1 and BRCA2 alone, but can continue to sell its array that tests multiple genes including BRCA1 and BRCA2.¹¹¹

Fundamentally, Myriad believes they possess valid patent claims covering what they consider a new biomarker, new reagents and techniques for analyzing the biomarker, and new methods for determining a patient's risk of breast and ovarian cancer using these reagents and techniques.¹¹² Myriad argues the 515 valid claims it still holds relating to the BRCA1 and BRCA2 tests are sufficient for the issuance of a preliminary injunction.¹¹³ Importantly, the Supreme Court holding in *Myriad* only invalidated five of Myriad's original 520 claims spanning the many patents it holds on BRCA1 and BRCA2 genetic testing.¹¹⁴

Despite the fact that Myriad maintains it still has 515 valid and enforceable claims in twenty-four patents underlying its test, companies are fighting back. A spokesperson from Quest said the company expected Myriad's lawsuit and described it as "merely the latest in a pattern of behavior toward any test provider that introduces a new option in BRCA testing that can benefit patients."¹¹⁵ Quest is apparently confident that its genetic test does not violate any of Myriad's claims and will vigorously defend its product.¹¹⁶ Invitae alleges in its complaint that its

¹⁰⁸ *Counsyl Files for Declaratory Judgment That It's Not Infringing Myriad's BRCA Patent Claims*, GENOMEWEB DAILY NEWS (Sept. 27, 2013), <http://www.genomeweb.com/clinical-genomics/counsyl-files-declaratory-judgment-its-not-infringing-myriads-brca-patent-claims>.

¹⁰⁹ GENOMEWEB, *supra* note 105. Brief for Defendant, (No. 2:13-cv-00640-RJS) *Myriad v. Ambry* <http://cdn.arstechnica.net/wp-content/uploads/2013/08/Ambry-Myriad-Antitrust-docs1.pdf>.

¹¹⁰ MYRIAD, *BRCA Patent Owners and Gene by Gene, Ltd. Resolve Patent Suit*, <http://investor.myriad.com/release-detail.cfm?ReleaseID=824154> (last visited Mar. 22, 2014).

¹¹¹ *Id.*

¹¹² Resnick, *supra* note 66.

¹¹³ Brief for Plaintiff, (No. 2:13-cv-00640-RJS) *Myriad v. Ambry* <http://ia601800.us.archive.org/24/items/gov.uscourts.utd.89779/gov.uscourts.utd.89779.5.0.pdf>.

¹¹⁴ *Id.*

¹¹⁵ GENOMEWEB, *supra* note 107.

¹¹⁶ *Id.*

comprehensive test offers the sequencing of over 200 human genes for less than the single Myriad BRCA1/2 test.¹¹⁷ Invitae further asserts that its genetic test is not covered by any valid claim of a Myriad patent.¹¹⁸ Even more dramatic, based on the Federal Circuit's holding that was neither appealed to nor decided by the Supreme Court, Invitae alleges that approximately fifty additional claims in four of Myriad's patents should be invalidated under the grounds that they are invalid method claims.¹¹⁹ Time will tell who indeed is correct, and on what precise grounds, because a court's finding of either infringement or non-infringement necessarily implies a straightforward winner and loser, as opposed to the narrow ruling of the *Myriad* decision where the Supreme Court invalidated just five claims spanning all of Myriad's patents. Absent settlement, one party must prevail, and the future of the genetic testing industry could be forever changed. This outcome could be drastic for many reasons, one of which is rooted in the AIA and discussed below.

Part III: Post Grant Proceedings

A: Overview of the AIA's New Post Grant Proceedings

There are several ways that third parties can have patents or claims canceled by the USPTO. It is certainly advantageous to contest patents in the USPTO, as opposed to the federal courts, and even more so after the AIA. Before the AIA, patent cancellation options available to third parties through the USPTO included: third party prior art submissions, ex parte reexamination, and inter partes reexamination.¹²⁰ Third party prior art submissions allowed for

¹¹⁷ Complaint, *Invitae v. Myriad*, (N.D. Cal. 2013) (No. 3:13-cv-05495-1), *available at* <http://patentdocs.typepad.com/files/cand-3-13-cv-05495-1.pdf>.

¹¹⁸ *Id.* (for example: Myriad Patent No. 6,033,857, claim 4 (requiring "(e) amplifying all or part of the BRCA2 gene from said tissue sample using primers for a specific BRCA2 mutant allele") when Invitae's tests do not use any such DNA primers).

¹¹⁹ *Id.* (*see, e.g.*, claims 2, 3, 5, 8, 13-15, 17-20, 23, 30 and 33 of U.S. Patent No. 5,753,441; claims 3-8 of U.S. Patent No. 6,033,857; claims 32, 33 and 44 of U.S. Patent No. 6,051,379; and claims 1-18 of U.S. Patent No. 6,951,721).

¹²⁰ *See* 35 U.S.C. §§ 301-07, 311-19.

third parties to submit patents, published patent applications, or printed publications that may be relevant to the examination of a patent application.¹²¹ Ex parte reexamination allowed for third parties to challenge any unexpired patents on the basis of novelty, obviousness, and claim scope.¹²² Such challenges would be successful if there was a substantial new question of patentability.¹²³ Inter partes reexamination was very similar to ex parte reexamination, but it was a more extensive and costly proceeding that revolved around the petitioner prevailing upon proving the reasonable likelihood of success as to at least one claim.¹²⁴ However, the patent community criticized those options.¹²⁵ Third party prior art submissions were simply inadequate; ex parte reexamination was too narrow in scope and too lengthy in pendency; and inter partes reexamination was viewed as too risky in light of its estoppel provisions.¹²⁶ Also, under the old provisions, there were the ever present concerns about using the judicial system to resolve patent disputes in the United States, including, but not limited to: cost, nearly unlimited discovery, lay juries, and lengthy pendency.¹²⁷

With the rollout of the AIA, there have been some changes to these patent cancellation options. First, third party prior art submissions have been adapted to better serve their purpose of providing patent examiners with the best possible prior art references and are now known as pre-

¹²¹ Gene Quinn, *AIA Oddities: Third Party Submissions of Prior Art*, IPWATCHDOG, <http://www.ipwatchdog.com/2013/09/19/aia-oddities-third-party-submissions-of-prior-art/id=45118/> (Sept. 19, 2013, 8:25 AM); USPTO, http://www.uspto.gov/aia_implementation/faqs-preissuance-submissions.jsp (last visited April 19, 2014). See 35 U.S.C. § 122(e) and 37 CFR § 1.290.

¹²² RATNER PRESTIA, <http://www.rppostgrant.com/ComparisonCharts/post-grant-review-comparison.html> (last visited April 19, 2014).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ FINNEGAN, <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=5cfdc68b-8b4a-42c3-bf4b-750e0cf416f1> (last visited April 19, 2014).

¹²⁶ *Id.*

¹²⁷ Quinn, *supra* note 121.

issuance submissions.¹²⁸ Pre-issuance submissions now allow for third parties to accompany their submissions of patents, published patent applications, or printed publications with a concise written description of the relevance of those documents.¹²⁹ Second, ex parte reexamination is fundamentally still in place and is instituted under the same general standard of review, but there are some key changes. It has been renamed to post-grant review (“PGR”) and has been better adapted to serve its intended function of quasi-judicial administrative proceedings that will help relieve some of the burden of patent litigation from domestic federal courts.¹³⁰ Third, inter partes reexamination has been replaced by inter partes review (“IPR”) and is instituted under the same standard of review, but can only be initiated on the basis of novelty and nonobviousness concerns, as opposed to also enablement, which can be done in PGR, and arguably even patentability under 35 U.S.C. § 101, which is discussed below.¹³¹ Both IPR and PGR are statutorily designed to be resolved within one year of their institution, as opposed to the pre-AIA proceedings that would last either two or three years.¹³²

Also notably with IPR, although estoppel applies to the petitioner in an IPR, those provisions only apply to the petitioner, and that entity cannot request or maintain a subsequent proceeding before USPTO with respect to any challenged patent claim on any ground that was raised or reasonably could have been raised in the IPR.¹³³ This leaves open the door for other third parties to initiate a subsequent IPR.¹³⁴ Likewise, the petitioner may not assert in a

¹²⁸ BRINKS, GILSON & LIONE, *Proposed New Rules Under AIA to Affect Third-Party Submissions of Prior Art* http://www.brinksgilson.com/news_events/3406-proposed-new-rules-under-aia-affect-third-party-submissions-prior-art (last visited Mar. 22, 2014).

¹²⁹ Quinn, *supra* note 121.

¹³⁰ *Id.*

¹³¹ FISH & RICHARDSON, *Post-Grant: Inter Partes Review*, <http://fishpostgrant.com/inter-partes-review/> (last visited Mar. 22, 2014).

¹³² PRESTIA, *supra* note 122.

¹³³ THE UNITED STATES PATENT AND TRADEMARK OFFICE, (Dec. 11, 2013, 4:47 PM), http://www.uspto.gov/aia_implementation/faqs_post_grant_review.jsp.

¹³⁴ *Id.*

subsequent district court or action that a claim is invalid on any ground that was raised or reasonably could have been raised in the IPR.¹³⁵ Again, that provision only impacts the original petitioner.¹³⁶ These provisions are the extent of estoppel, and invalidity opinions will absolutely not carry over between patents.¹³⁷ Thus, it is more efficient to have a court ruling invalidating entire classes of patents instead of individual opinions collectively accomplishing the same result, and this naturally lends itself to the necessity of the courts subsequently deciding Myriad's unsettled litigation. The focus now turns to what precise effects that unsettled litigation will have on both PGR and IPR, respectively.

B: PGR

Congressional hearings held between 2001 and 2006 explored the creation of PGR proceedings where patents can be challenged early in life and on all validity grounds.¹³⁸ During that time, the core intellectual property professional organizations, and accompanying reports and studies, called for the establishment of such a proceeding.¹³⁹ At a 2004 House Intellectual Property Subcommittee hearing, the American Intellectual Property Law Association ("AIPLA") Executive Director, Michael Kirk, presented the main argument for authorizing post-grant

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ See generally *Perspectives on Patents: Post-Grant Review Procedures and other Litigation Reforms: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 109th Cong. (2006); *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. (2004) (hereinafter 2004 House hearing); *Patent Reexamination and Small Business Innovation: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 107th Cong. (2002); *Patents: Improving Quality and Curing Defects: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 107th Cong. (2001) (hereinafter 2001 House hearing).

¹³⁹ See 2004 House hearing, *supra* note 138, at 29-30 (statement of Michael Kirk, Executive Director, AIPLA) ("The call for an effective, efficient post-grant system to review patents has reached a crescendo. It is time to act."); *id.* at 10-11 (statement of James Toupin, General Counsel, USPTO); *id.* at 52 (Letter of Biotechnology Industry Organization) (listing reports and groups). For a history of the events leading to the enactment of inter partes reexamination in 1999, see 2001 House hearing, *supra* note 138, at 13 (statement of Michael Kirk, Executive Director, AIPLA); *id.* at 23-24 (statement of Jeffrey Kushan, Powell, Goldstein, Frazer, and Murphy).

review.¹⁴⁰ He believed that it is often prohibitively expensive or even impossible to test the validity of a newly-issued patent that is of dubious validity, and the continued existence of such a patent can disrupt product development in a field of technology for years.¹⁴¹ Invalid or overbroad patents both discourage follow-on innovation, thereby preventing competition, and also raise prices through unnecessary licensing and litigation.¹⁴² Yet another reason for authorizing PGR is because the “USPTO is a particularly appropriate venue for making validity determinations in a cost-effective and technically sophisticated environment.”¹⁴³ It stands to reason that PGR serves a significant and substantial purpose.¹⁴⁴

Section 6 of the AIA amended Chapter 31's authorization of inter partes proceedings and created the new PGR administrative proceedings.¹⁴⁵ The law now allows the Director of the USPTO to institute PGR proceedings if he finds that the information presented in the petition and any response “[show] that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.”¹⁴⁶

PGR, for petitions filed on or after March 19, 2013, costs \$12,000 plus a fee of \$250.00 for each claim in excess of 20 within the patent, and the post-institution fee is \$18,000 plus a fee of \$550.00 for each claim in excess of 15 within the patent.¹⁴⁷ Thus, for \$32,750, up to 20 claims in a single patent can be reviewed in PGR, with an additional cost of \$800 per claim reviewed in

¹⁴⁰ 2004 House hearing, *supra* note 138 at 29 (statement of Michael Kirk, Executive Director, AIPLA).

¹⁴¹ 2004 House hearing, *supra* note 138 at 29 (statement of Michael Kirk, Executive Director, AIPLA).

¹⁴² FTC.GOV, *Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition*, FED. TRADE COMM’N (March 2011), available at <http://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf>.

¹⁴³ *Perspectives on Patents: Harmonization and Other Matters: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 109th Cong. 77 (2005) (statement of Q. Todd Dickinson, Vice President and Chief Intellectual Property Counsel, General Electric Co., and former USPTO Director) (2005).

¹⁴⁴ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013). In Justice Scalia’s concurrence in part and concurrence in judgment, Justice Scalia stated that with respect to his own knowledge or belief that he cannot affirm the fine details of molecular biology.

¹⁴⁵ Leahy-Smith America Invents Act sec. 6(a), § 314(a), 125 Stat. at 300.

¹⁴⁶ *Id.*

¹⁴⁷ THE UNITED STATES PATENT AND TRADEMARK OFFICE, (Dec. 11, 2013, 4:47 PM), http://www.uspto.gov/aia_implementation/faqs_post_grant_review.jsp.

excess of 20. Post-institution fees represent fees that are paid upfront but are refunded in the event that the petitioner's request for PGR is denied.¹⁴⁸

In part, 35 U.S.C. § 321, the provision enacted for post-grant proceedings, states: “[a] petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim).”¹⁴⁹ Of particular relevance in the analysis is 35 U.S.C. § 321(b), which defines the grounds under 282(b).¹⁵⁰ 35 U.S.C. § 282(b) states:

- (b) Defenses.—The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:
 - (1) Noninfringement, absence of liability for infringement or unenforceability.
 - (2) Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability.
 - (3) Invalidity of the patent or any claim in suit for failure to comply with—
 - (A) any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or
 - (B) any requirement of section 251.
 - (4) Any other fact or act made a defense by this title.”¹⁵¹

Limiting the analysis to the specified paragraphs (2) and (3), post-grant proceedings can be brought up against patents for reasons including something that is “a condition for patentability” or violations of 35 U.S.C. §§ 112 or 251.¹⁵² For the purpose of this discussion, the primary concern is defining the phrase “a condition for patentability.”

It has long been understood, by some that the Patent Act sets out the conditions for patentability in three sections: §101, §102, and §103.¹⁵³ There is a plethora of additional

¹⁴⁸ FISH & RICHARDSON, Post-Grant Alert: New PTO Fees Effective March 19, 2013, (Mar. 22, 2013) <http://fishpostgrant.com/news/post-grant-alert-new-pto-fees-effective-march-19-2013/>.

¹⁴⁹ 35 U.S.C. §321 (2013).

¹⁵⁰ *Id.*

¹⁵¹ 35 U.S.C. §282(b) (2013).

¹⁵² *Id.*

¹⁵³ *See Graham v. John Deere*, 383 U.S. 1, 12 (1966) (“The [1952 Patent] Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness, the new statutory formulation, as set out in § 103.”).

precedent for that same notion.¹⁵⁴ In the eyes of the USPTO leadership, commentators incorrectly note that because 35 U.S.C. § 101 is not expressly stated within the text of 35 U.S.C. § 282(b)(3), it is therefore not a condition for patentability and cannot be grounds for PGR.¹⁵⁵ However, the USPTO leadership opines that commentators further incorrectly assert that because 35 U.S.C. § 101 is not included in 35 U.S.C. § 282(b)(2), even though 35 U.S.C. § 101 is included “in part II” of Title 35, 35 U.S.C. § 101 is not “specified in part II as a condition for patentability” when it is entitled “[i]nventions patentable,” as opposed to 35 U.S.C. §§ 102 and 103 that are both entitled “[c]onditions for patentability.”¹⁵⁶ Despite this seemingly valid statutory contention, the USPTO leadership does not find that argument persuasive and believes that for the purpose of PGR, 35 U.S.C. § 101 is considered a condition for patentability.¹⁵⁷

The Supreme Court previously held that 35 U.S.C. § 101 is absolutely a condition for patentability.¹⁵⁸ In *Graham v. John Deere Co. of Kansas City*,¹⁵⁹ the Supreme Court stated in dicta that the 1952 Patent Act “sets out the conditions of patentability in three sections,” citing 35 U.S.C. §§ 101, 102, and 103.¹⁶⁰ The Supreme Court also addressed invalidity under 35 U.S.C. § 101 when it was raised as a defense to an infringement claim under 35 U.S.C. § 282.¹⁶¹

¹⁵⁴ See *Aristocrat Tech. Australia Pty. Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008). In addition to allowing for post-grant review under 35 U.S.C. § 112, section 282(b) also allows for post-grant review on any ground specified in title 35 as “a condition for patentability.” While 35 U.S.C. §§ 102 and 103 are expressly titled “conditions for patentability,” 35 U.S.C. § 101 is generally also considered to be a condition for patentability, and thus, appears to be a ground under which a petitioner can assert invalidity in a post-grant review.

¹⁵⁵ David Kappos, *PTAB and Patentability Challenges*, DIRECTOR’S FORUM: A BLOG FROM USPTO’S LEADERSHIP (Sept. 24, 2012, 4:44 PM), http://www.uspto.gov/blog/director/entry/ptab_and_patentability_challenges.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 12 (1966), *Mayo Collab. Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

¹⁵⁹ *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 12 (1966).

¹⁶⁰ *Id.*

¹⁶¹ *Mayo Collab. Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305.

Additionally, the Federal Circuit expressly rejected the argument, raised by the dissenting judge in *Dealertrack, Inc. v. Huber*¹⁶² that 35 U.S.C. § 101 is not a “condition for patentability” under 35 U.S.C. § 282, stating that “the defenses provided in the statute, 35 U.S.C. § 282, include not only the conditions of patentability in 35 U.S.C. §§ 102 and 103, but also those in 35 U.S.C. § 101.”¹⁶³ The Federal Circuit in *Dealertrack* clarified that the use of the term “conditions for patentability” in the titles of 35 U.S.C. §§ 102 and 103, but not 35 U.S.C. § 101, did not change the result, relying on the Supreme Court’s pronouncement in *Pennsylvania Department of Corrections v. Yeskey*,¹⁶⁴ that a statute’s title “is of use only when it sheds light on some ambiguous word or phrase” in the statute and that it “cannot limit the plain meaning of the text.”¹⁶⁵

Though, in so-called additional considerations by the Chief Judge of the Federal Circuit, Chief Judge Rader posits that the Supreme Court long ago held that 35 U.S.C. § 101 is not a “condition of patentability.”¹⁶⁶ Chief Judge Rader acknowledges that the statute does not list 35 U.S.C. § 101 among invalidity defenses to infringement, but that with regards to 35 U.S.C. § 282, while invalidity for failing to meet a “condition of patentability” is among the authorized defenses, 35 U.S.C. § 101 is nonetheless not a “condition of patentability.”¹⁶⁷

However, contrary to the views expressed by some of the judges of the Federal Circuit, the legislative history of the AIA makes it clear that Congress instituted the Patent Trial and Appeal Board (PTAB) to consider challenges brought under 35 U.S.C. § 101 in post-grant

¹⁶² *Dealertrack v. Huber*, 674 F.3d 1315, 1330 n.3 (Fed. Cir. 2012).

¹⁶³ *Id.* (internal quotation marks omitted) (citing *Aristocrat Techs. Austl. PTY Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008)).

¹⁶⁴ *Pennsylvania Department of Corrections v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 528-29 (1947)).

¹⁶⁵ *Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 528-29 (1947)).

¹⁶⁶ *CLS Bank Int’l v. Alice Corp. Pty*, 717 F.3d 1269 (Fed. Cir. 2013) citing *Diehr*, 450 U.S. at 189-90 (citing *In re Bergy*, 596 F.2d 952, 963 (CCPA 1979) (Section 101 “was never intended to be a ‘standard of patentability,’ the standards, or conditions as the statute calls them, are in 102 and 103”)).

¹⁶⁷ *Id.*

reviews.¹⁶⁸ A House Committee Report states that “the post-grant review proceeding permits a challenge on any ground related to invalidity under section 282.”¹⁶⁹ Likewise, Arizona Senator Jon Kyl also included “section 101 invention issues” among those “that can be raised in post-grant review.”¹⁷⁰ Summarily, even though the opinions of some judges on the Federal Circuit are that 35 U.S.C § 101 is not a condition for patentability, in the view of the USPTO, the PTAB should consider patentability challenges brought under 35 U.S.C. § 101 in post-grant reviews.¹⁷¹ Unless the courts or Congress direct the USPTO otherwise, that is what the USPTO will continue to do.¹⁷²

This is significant because it means that patents or patent claims can be canceled by a third party for a fraction of the cost of litigation.¹⁷³ A 2005 study found that 4,382 of the 23,688 human genes in the National Center for Biotechnology Information's gene database are explicitly claimed as intellectual property.¹⁷⁴ Patents with claims to those 4,382 genes will be safe from PGR, because PGR can only be implemented on patents filed after March 16, 2013. But, future patents issued are now possibly at stake for being invalidated after *Myriad* through PGR.¹⁷⁵ PGR could be instituted for a patent on the basis that the twelve factors examiners consider when reviewing patent applications under 35 U.S.C. § 101 demonstrate that it is “more likely than not that at least one claim is unpatentable.”¹⁷⁶ So, simply showing that more factors weigh against patentability rather than for patentability should be enough to invalidate a patent via PGR.

¹⁶⁸ H.R. Rep. No.112-98, at 47 (2011).

¹⁶⁹ *Id.*

¹⁷⁰ 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011).

¹⁷¹ Kappos, *supra* note 155.

¹⁷² *Id.*

¹⁷³ FISH & RICHARDSON, *supra* note 148.

¹⁷⁴ See Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239-240 (October 14, 2005).

¹⁷⁵ 35 U.S.C. § 321.

¹⁷⁶ PRESTIA, *supra* note 122.

C: IPR

Amended by the AIA, 35 U.S.C. § 311 defines its scope as: “[a] petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.”¹⁷⁷ Therefore, an IPR cannot be directed to 35 U.S.C. § 101.¹⁷⁸ So, *Myriad* does not provide a basis for patent invalidation in an IPR because the holding that DNA sequences are nonpatentable subject matter, is not within the scope of an IPR. As a result, *Myriad* has no notable effect on IPR because the *Myriad* holding implicated changes to the scope of patentable subject matter with respect to 35 U.S.C. § 101, and none of the other conditions for patentability.¹⁷⁹

Presently, post-*Myriad*, the relevant considerations are how the new post-grant proceedings will impact existing and future patents. However, with the AIA, *Myriad* has a more profound effect on patents issued from applications filed after March, 16, 2013 because of PGR.¹⁸⁰ Though, this is expressly under the condition that a PGR must be requested on or prior to nine months after patent issuance.¹⁸¹ For newly issued patents, there is a nine-month window in which a PGR can be filed, and after that nine-month window, only an IPR can be filed.¹⁸² Resultantly, the terms of the statutes will only allow a 35 U.S.C. § 101 cause of action to be brought in a PGR, and not in an IPR.¹⁸³ Therefore, for IPR to be relevant for invalidating patents to genes or genetic testing, for example, case law would need to evolve such that something that was previously patentable is now unpatentable in light of either 35 U.S.C. §§ 102 or 103 for lack

¹⁷⁷ 35 U.S.C. § 311.

¹⁷⁸ *Id.*

¹⁷⁹ *See generally*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. at 2107.

¹⁸⁰ USPTO, http://www.uspto.gov/aia_implementation/faqs_post_grant_review.jsp (last visited Dec. 30, 2013).

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ 35 U.S.C. §§ 282, 311, 321.

of novelty or due to obviousness. The case law could feasibly evolve in that way, in some respects, but in the meantime, the future possibilities will be contemplated.

Part IV: The Future of Genetic Testing in a Post-Myriad World

A. If Myriad is Defeated in Subsequent Litigation

If Myriad is defeated in any of the now-pending litigations, and the courts hold that, for whatever reason, Myriad loses its monopoly over BRCA1 and BRCA2, the ramifications might be enormous. Myriad itself might not be terribly affected as its patents are expiring over the next several years and that would likely be before litigation even ends, but other patent holders with claims to genes could find those patents invalidated.¹⁸⁴ Myriad could lose if a future court holds, for example, that Myriad's genetic test is now considered obvious, in accordance with 35 U.S.C. § 103 and therefore unpatentable in light of the fact that DNA is no longer patentable subject matter under 35 U.S.C. § 101. Such a holding implies that a previously undiscovered genetic sequence cannot provide the basis for a previously known process utilizing the previously unknown genetic sequence. Because of this, the genetic testing industry would come to a grinding halt as companies' patents could be brought into PGR so long as they were issued within the past nine months. Resultantly, companies could freely use what was once patented by another company that may have invested substantial amounts of money and time. Also, at that point, companies would stop filing patents and stop investing in genetic testing research. This is precisely what Dr. Watson wanted to avoid, but it would ironically be the consequence of a dramatic court ruling.¹⁸⁵

¹⁸⁴ GENOMEWEB, <http://www.genomeweb.com/clinical-genomics/warning-would-be-competitors-myriad-and-brca-test-patent-holders-sue-ambry-gene> (last visited Mar. 22, 2014).

¹⁸⁵ Brief for James D. Watson as Amici Curiae Supporting Neither Party, Association of Molecular Pathology v. USPTO, 689 F.3d 1303 (2012) (No. 2010-1406).

Representatives of Myriad said that, “[t]o create tests for hereditary breast cancer and ovarian cancer, our company and its investors spent more than \$500 million over 17 years before we were able to recoup this investment.”¹⁸⁶ That is quite a staggering figure. A study in 2011 indicates that nine medical schools received that much money in the year 2011.¹⁸⁷ Likewise, only two universities attained that mark in 2008.¹⁸⁸ This money was to fund the entirety of those particular schools’ research in the biological sciences, and not merely one particular study or development.¹⁸⁹ The studies are quite clear, however, in pointing out that individual labs are generally funded with merely hundreds of thousands of dollars.¹⁹⁰ Even prestigious grants are a mere drop in the bucket compared to Myriad’s expenditure.¹⁹¹

B: Impact of Future Myriad Loss on Post Grant Proceedings

In the event Myriad again loses in subsequent litigation, any arguments asserted against their patents’ validity could then be used, generally, with respect to every seemingly applicable patent by way of post-grant proceedings, either IPR or PGR. Thus, a loss for Myriad means a loss for every other patent that could be invalidated for similar reasons.

The logic the Court used in *Prometheus* could realistically be applied by future courts to hold that certain genetic tests, specifically Myriad’s, are wholly unpatentable subject matter.¹⁹² In *Prometheus*, just as a natural correlation was found to be unpatentable subject matter when it

¹⁸⁶ Peter D. Meldrum, *Myriad Genetics: Patents Save Lives, Aid Innovation*, USA TODAY (Apr. 14, 2013 6:59 PM), <http://www.usatoday.com/story/opinion/2013/04/14/myriad-genetics-supreme-court-editorials-debates/2082553/>.

¹⁸⁷ Ronda Britt, *Universities Report Highest-Ever R&D Spending of \$65 Billion in FY 2011*, INFOBRIEF (Nov. 2012), <http://www.nsf.gov/statistics/infbrief/nsf13305/nsf13305.pdf>.

¹⁸⁸ NATIONAL CENTER FOR SCIENCE AND ENGINEERING STATISTICS, *Universities Report Highest-Ever R&D Spending of \$65 Billion in FY 2011* (Nov. 2012), available at <http://mup.asu.edu/research2010.pdf>.

¹⁸⁹ *Id.*

¹⁹⁰ Meredith Wadman, *Study Says Middle Sized Labs Do Best: A Comparison of Funding Level and Output has Captured Attention at the US National Institutes of Health*, NATURE (Nov. 16, 2010), available at <http://www.nature.com/news/2010/101116/full/468356a.html>.

¹⁹¹ See Yung S. Lie, *Damon Runyon Grants Prestigious Fellowship Awards to 17 Top Young Scientists* (July 9, 2013), http://www.eurekalert.org/pub_releases/2013-07/drcr-drg070913.php; Drew Menard, *Biology Professor Receives Prestigious Grant for Alzheimer’s Research* (Aug. 30, 2013), <http://www.liberty.edu/news/index.cfm?PID=18495&MID=97365>.

¹⁹² See *Mayo Collab. Servs. v. Prometheus Labs.*, 132 S. Ct. 1289.

was incorporated into a known diagnostic test, an analogous situation may very well exist where a future court decides that isolated human DNA, as unpatentable subject matter, cannot be used in conjunction with a known diagnostic test in order to ultimately create patentable subject matter.¹⁹³ As a result, any patents granted within the past nine months with claims to a similarly situated genetic test would be directly affected by the new changes to post-grant proceedings wherein PGR could be instituted under 35 U.S.C. § 101 grounds for invalidity.¹⁹⁴ However, a court could potentially invalidate Myriad's claims for other reasons. For example, a court could hold that using a procedurally known genetic test with what is now unpatentable isolated human DNA is actually obvious, and therefore unpatentable under 35 U.S.C. § 103.¹⁹⁵ As unpatentable under this section, IPR could then potentially be invoked. This therefore means that any patent analogous to Myriad's invalidated patents could be subject to post-grant review proceedings regardless of when they were issued.¹⁹⁶

Although that notion is contrary to the USPTO guidance, the ramifications of such a court holding would be disastrous as the results would cut against one of the main purposes of instituting reformed post-grant proceedings, and that was to avoid lengthy periods of litigation in the federal courts.¹⁹⁷ Undoubtedly this conclusion necessarily implies there would be a massive overload of the USPTO's post-grant proceeding infrastructure, but it is hard not to imagine such an occurrence. Given how lucrative genetic testing appears to be, especially considering Myriad is presently entangled in six suits, a competitor looking to enter the industry could simply file a substantially cheaper post-grant proceeding with the USPTO instead of having to file a

¹⁹³ See *Mayo Collab. Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1305.

¹⁹⁴ See 35 U.S.C. § 282

¹⁹⁵ 35 U.S.C. § 103

¹⁹⁶ 35 U.S.C. §§ 282, 311, 321

¹⁹⁷ Hirshfeld, *supra* note 74.

declaratory judgment invalidating a competitors' patent.¹⁹⁸ If the goal is to capture the market share by keeping prices down, companies such as Invitae and Counsyl would bring companies like Myriad into one of the options for post-grant proceedings, if given the chance.¹⁹⁹

C: Myriad is Victorious in Subsequent Litigation

If Myriad wins in subsequent litigation, then life continues as it has for as long as genetic tests have been patented. DNA tests were invented in the mid-1980s, so this is all relatively recent technology.²⁰⁰ Although Myriad's victory directly opposes Dr. Watson's ideology of research not being stymied by gene patents, this outcome actually indirectly supports the very same ideology.²⁰¹ Companies like Myriad would invest in research only because of the promise of the twenty-years of exclusivity granted by patents.²⁰² Thus, keeping the status quo in check may very well be the ideal ending. It seems patently unfair for companies to have invested potentially hundreds of millions of dollars and accomplished something extraordinary that no one else has been able to do or would have been able to do otherwise, and then discover they cannot actually enjoy the fruits of their labor.

Surely the public directly benefits from being able to obtain diagnostic medicine at a cheaper price, but it is also the public that is indirectly harmed.²⁰³ As previously explained, universities cannot conduct research of the same magnitude and expense as private corporations, therefore, research in the field of genetic testing may cease to exist in its current form.²⁰⁴ Thus, it seems practical for companies that have invested tremendous amounts of money in scientific breakthroughs to be able to recoup those expenditures. For centuries, the primary way that has

¹⁹⁸ GENOMEWEB, *supra* note 105; GENOMEWEB, *supra* note 108.

¹⁹⁹ USPTO, *supra* note 147.

²⁰⁰ Randy James, *A Brief History of DNA Testing*, TIME (June 19, 2009), <http://content.time.com/time/nation/article/0,8599,1905706,00.html>.

²⁰¹ *See supra* note 2.

²⁰² 35 U.S.C. § 154.

²⁰³ Resnick, *supra* note 66.

²⁰⁴ NATIONAL CENTER FOR SCIENCE AND ENGINEERING STATISTICS, *supra* note 188.

been accomplished has been through patents necessarily promoting inventions and innovations.²⁰⁵ For their bottom lines, companies need a reason to invest in something in particular, and taking away those incentives, patents in the case of genetic testing, could be devastating for any potential future developments.

D: Broad Interpretation of *Myriad* Impacting Future Patent Law Practice

Myriad can impact the pharmaceutical industry in other ways besides genetic testing. Just as the Court held in *Myriad* that DNA is not patentable solely because it was isolated, precedent could come down either from the courts or from the USPTO that proteins, for example, are no longer patentable in a form currently claimed in patents because they are naturally occurring and are merely isolated.²⁰⁶

Though, as a whole, one thing the Supreme Court made clear in *Myriad* is that it will not show deference to existing patent law practice and it may render holdings contrary to the desires of the USPTO or even the Federal Circuit.²⁰⁷ As an example, when presently considering patent eligibility of a small molecule or protein isolated or purified from a natural source, the latest edition of the USPTO's MPEP instructs that "[p]urer forms of known products may be patentable" and that "[p]ure materials are novel vis-à-vis less pure or impure materials because there is a difference between pure and impure materials," suggesting potential patent eligibility of purified substances from natural sources.²⁰⁸ To the extent that these guidelines support patentability of a small molecule or protein isolated or purified from a natural source, and to the

²⁰⁵ U.S. CONST. art. 1, § 8, cl. 8.

²⁰⁶ Samuel B. Adams & Carl A. Morales, *Myriad's Possible Impact on Patent Eligibility of Isolated non-DNA Chemical Substances* (June 19, 2013), available at <http://www.lexology.com/library/detail.aspx?g=bd44bfc3-2349-4c4d-bd23-d1d80d1467f0>.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

extent that the USPTO has previously granted claims to such substances, *Myriad* suggests that these current and past practices by the agency may not be entitled to deference.²⁰⁹

Conclusion

Moving forward as a society, it is imperative for companies investing time and money into the development of genetic tests to be able to obtain patents for these tremendous inventions. Should that cease to be the case, it is imaginable that most biotechnology companies will move on to other, more profitable areas of research. When that happens, nothing short of legislative action could fill the void left behind of billions of dollars of research funding. Fortunately, this grim outcome can be avoided in two respects. First, courts adjudicating the future *Myriad* cases could feasibly issue narrow holdings against *Myriad* that will not have a broad-sweeping effect on the rest of the industry. These holdings could be limited to the facts in the case as it relates to comparing *Myriad*'s genetic tests with those genetics tests of its competitors for determinations of patent validity or invalidity or patent infringement or non-infringement on a case-by-case basis. Second, as justice so requires, courts could rule for *Myriad*. If *Myriad* is found, despite any previous rulings, to in fact have invented new genetic tests that meet all of the statutory requirements of patentability, then *Myriad* should also be found to possess valid patents that can be enforceable against other entities, as applicable. Post-grant proceedings fit into the broader picture because they present cheaper and quicker options for invalidating another's, perhaps a competitor's, patent and courts need to tread carefully and be mindful of those proceedings when issuing future decisions in the *Myriad* case line. In short, the status quo can be maintained if *Myriad* either "wins" or "loses" in subsequent actions, even in light of the fact that *Myriad* already lost their claims to genes. If *Myriad* "loses" again, what will then matter the most is the way in which they lost and the reasoning behind the courts' holdings.

²⁰⁹ *Id.*