

**THE PRACTICAL IMPLICATIONS OF  
ASSOCIATION OF MOLECULAR PATHOLOGY V.  
MYRIAD GENETICS, INC.  
AND  
BRCA1- & BRCA2-BASED HEREDITARY CANCER TEST  
PATENT LITIG. V. AMBRY GENETICS CORP.  
ON THE BIOTECHNOLOGY INDUSTRY**

*Samuel J. Berse\**

I.	INTRODUCTION.....	418
II.	PATENT LAW BACKGROUND .....	420
III.	MYRIAD AND PATENT-ELIGIBLE SUBJECT MATTER .....	423
	A. Recent Case Law .....	423
	B. USPTO Guidance—March 4, 2014.....	430
	C. USPTO Guidance—December 16, 2014.....	434
	D. Myriad at Present and the Uncertain Future.....	436
IV.	POST-GRANT PROCEEDINGS.....	439
	A. Overview of the AIA’s New Post-Grant Proceedings.....	439
	B. PGR .....	442
	C. IPR.....	447
V.	THE FUTURE OF GENETIC TESTING IN A POST- MYRIAD WORLD.....	448
	A. Myriad Defeat in Ambry .....	448
	B. Impact of Future Myriad Loss on Post-Grant Proceedings.....	450
VI.	CONCLUSION .....	451

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\*J.D. Candidate, 2015, Seton Hall University School of Law; M.A. in Biomedical Sciences, Rutgers Graduate School of Biomedical Sciences 2012. Special thanks to Professor Jordan K. Paradise for her exceptionally insightful remarks from this Note’s conception through publication.

## I. 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,” wrote Dr. James Watson, one of the Physiology or Medicine Nobel Prize winners in 1962 for the discovery of the structure of DNA.<sup>1</sup> Dr. Watson also proclaimed, “[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*.”<sup>2</sup> Indeed this viewpoint may be well-reasoned, but determining whether a patent is necessary or unnecessary is far too subjective to be reasonably practical.

Patents are fundamentally necessary for advancements in scientific research; stating anything to the contrary opposes both reality and the patent system’s purpose.<sup>3</sup> However, after the Supreme Court decision that largely abolished gene patentability, the recent Federal Circuit decision, and new patent laws there are unresolved questions as to the extent patents in the field of genetic testing will continue to exist and what the future holds for the underlying research.<sup>4</sup> The biotechnology industry has been shaken to its core numerous times over the past several years, and there is mounting pressure for stability, which is likely only obtainable through a legislative solution.<sup>5</sup> While this Note does not

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<sup>1</sup> Brief for James D. Watson as Amici Curiae Supporting Neither Party at 2, *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](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](http://www.nobelprize.org/nobel_prizes/medicine/laureates/1962/watson-bio.html) (last visited Oct. 30, 2013).

<sup>2</sup> Brief for James D. Watson, *supra* note 1, at 6 (emphasis added).

<sup>3</sup> 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>.

<sup>4</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambray Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*1 (Fed. Cir. Dec. 17, 2014).

<sup>5</sup> Austin Donohue, *USPTO Issues New Myriad Guidance*, BIOTECHNOW (Feb. 4, 2015), <http://www.biotech-now.org/public-policy/patently-biotech/2015/02/bio-deputy-general-counsel-remarks-on-revised-eligibility-guidance> (“If anything, this decision . . . is a reminder that the PTO’s efforts to bring stability to this area of the law could easily be undone by the

propose such legislation, this Note nonetheless addresses several practical implications affecting the industry and patent-holders as a result of the Supreme Court holding that isolated genes are unpatentable and the Federal Circuit holding that part of *Myriad's* patent-eligible subject matter did not add enough to wholly make the genetic testing claims patent-eligible.<sup>6</sup>

Specifically, this Note addresses how new provisions in the Leahy-Smith America Invents Act (“AIA”) changed the practice of patent law and considerations that courts need to be cognizant of when issuing future rulings. Part II delves into the fundamentals of patent law that pertain to the subsequent discussion and sets the stage for the notion that obtaining a patent does not unequivocally grant absolute rights. Part III addresses the background case law that led to the recent monumental Supreme Court decision, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>7</sup> the series of guidance issued by the United States Patent and Trademark Office (“USPTO”), and the most recent authority from the Federal Circuit in *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*<sup>8</sup> Part IV discusses the AIA and how it altered the practice of patent law with respect to procedures for challenging the validity of patents within the USPTO itself through post-grant proceedings. Part V highlights that these new post-grant proceedings alongside *Myriad* lead to less obvious, but still significant trouble for the industry’s leading patent-holders. Finally, this Note concludes that the practice of patent law is at a very pivotal and delicate point and that it must evolve to continue promoting research generally, and specifically in the genetic testing industry. This will be accomplished if genetic tests, as so-called methods, remain patent-eligible subject matter despite the fact that genes are now unpatentable.

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next Federal Circuit decision, or the one after that. We are afraid that we will be prosecuting applications on a shifting slate for some time to come. We need a more stable solution going forward.”).

<sup>6</sup> *Myriad Genetics, Inc.*, 133 S. Ct. at 2107; *Ambry Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*20.

<sup>7</sup> *Myriad Genetics, Inc.*, 133 S. Ct. at 2107.

<sup>8</sup> *Ambry Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*1; Memorandum from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, for Patent Examining Corps (Mar. 4, 2014), available at [http://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf).

## II. PATENT LAW BACKGROUND

Pursuant to the Constitution, “Congress 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 exclusive [r]ight to their respective [w]ritings and [d]iscoveries.”<sup>9</sup> This provision gave rise to the United States Patent Act of 1790, from which the first patents were born.<sup>10</sup> A patent is defined as 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.”<sup>11</sup> The United States Patent Act was largely unchanged until 1952 when the USPTO began classifying patents into three categories: utility patents, design patents, and plant patents.<sup>12</sup> The general focus of this 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 thereof.<sup>13</sup> In modern times, courts categorize chemical compounds as compositions of matter and define them as tangible items comprising two or more substances.<sup>14</sup> On the other hand, a patented method consists of a series of steps that is only infringed upon if each and every step is performed.

In order to receive a utility patent, an inventor publicly discloses his invention in exchange for a twenty-year period of exclusivity to use and practice the invention from the date that the patent application is filed with the USPTO.<sup>15</sup> Through the lengthy process of obtaining a patent, the inventor submits to the USPTO a patent application ideally containing claims that specifically identify the proposed invention. At the USPTO,

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<sup>9</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>10</sup> Press Release, USPTO, The U.S. Patent System Celebrates 212 Years, #02-26 (Apr. 9, 2002), available at <http://www.uspto.gov/news/pr/2002/02-26.jsp>.

<sup>11</sup> *Patent FAQs*, USPTO, <http://www.uspto.gov/inventors/patents.jsp> (last visited Apr. 19, 2014).

<sup>12</sup> “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 (Oct. 2014), <http://www.uspto.gov/patents-getting-started/general-information-concerning-patents>.

<sup>13</sup> Mary Bellis, *Utility Patent*, ABOUT.COM, [http://inventors.about.com/od/definations/g/Utility\\_Patent.htm](http://inventors.about.com/od/definations/g/Utility_Patent.htm) (last visited May 13, 2015).

<sup>14</sup> 35 U.S.C. § 101 (2012); Andrew Chadeayne, *Composition of Matter Claims*, INVENTING PATENTS (Sept. 17, 2013), <http://inventingpatents.com/composition-matter-claims/>.

<sup>15</sup> 35 U.S.C. § 154(a)(2) (2012).

a patent examiner (“examiner”) reviews the patent application, and the invention is publicly disclosed when the USPTO publishes the patent application eighteen months after it is filed.<sup>16</sup> The examiners communicate with inventors by sending office actions that include the examiner’s detailed analysis of the patent application, including reasons the inventor cannot yet receive a patent for the particular invention.<sup>17</sup> For patent applications that adhere to all applicable provisions, examiners will issue a notice of allowance resulting in the grant of a patent, provided that the inventor pays the issue fee.<sup>18</sup> The Supreme Court case *Myriad*, a focal point of this Note, deals primarily with one of those provisions for patentability—whether the subject matter itself is patentable.

Generally speaking, *Myriad* pertains to “patent-eligible” subject matter defined under 35 U.S.C. § 101.<sup>19</sup> This provision identifies four categories of patent-eligible subject matter: a process, a machine, a manufacture, and a composition of matter.<sup>20</sup> Everything within the scope of a utility patent must fall within at least one of these four categories.<sup>21</sup> Genes, chemical compounds or compositions of matter, defined as the basic units of heredity responsible for all physical and inheritable characteristics of an organism, were therefore claimed in utility patents.<sup>22</sup> Examples of patent ineligible subject matter, or the so-called judicial exceptions, include: “laws of nature, physical or natural phenomenon, and abstract ideas.”<sup>23</sup> Once an examiner or a court finds that claims are patent-eligible, the patentability inquiry proceeds to other provisions that,

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<sup>16</sup> *Id.* § 122(b)(1) (explaining that patent applications are published eighteen months after filing and once published they are easily accessible on websites such as GOOGLE.COM/PATENTS or HTTP://PORTAL.USPTO.GOV/PAIR/PUBLICPAIR); *Nonprovisional (Utility) Patent Application Filing Guide*, USPTO (Jan. 2014), <http://www.uspto.gov/patents/resources/types/utility.jsp>.

<sup>17</sup> 37 C.F.R. § 1.104 (2014).

<sup>18</sup> *Id.* § 1.311 (2014).

<sup>19</sup> 35 U.S.C. § 101 (2012); Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

<sup>20</sup> 35 U.S.C. § 101.

<sup>21</sup> *Id.*; Z. Peter Sawicki, Visala C. Goswitz & Amanda Prose, *Patenting Biologicals: Myriad Issues and Options in the Wake of Myriad*, BENCH & B. OF MINN., 24 (Sept. 2013), available at [http://mnbenchbar-digital.com/mnbenchbar/september\\_2013?pg=24#pg24](http://mnbenchbar-digital.com/mnbenchbar/september_2013?pg=24#pg24).

<sup>22</sup> *Gene*, DICTIONARY.COM, <http://dictionary.reference.com/browse/gene> (last visited Mar. 22, 2014); *General Information Concerning Patents*, *supra* note 12 (“A patent for an invention is the grant of a property right to the inventor, issued by the United States Patent and Trademark Office.”).

<sup>23</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

for instance, assess novelty and nonobviousness.<sup>24</sup>

For over thirty years before *Myriad*, the USPTO granted thousands of gene patents as compositions of matter.<sup>25</sup> The USPTO even reaffirmed the issuance of such patents in 2001.<sup>26</sup> But in *Myriad*, the Court essentially held that patents may no longer be granted for the simple discovery that a particular human gene sequence corresponds to a specific inheritable trait.<sup>27</sup> Thus, without expressly acknowledging Dr. Watson's views, the Court fundamentally agreed with him that genes should not be patentable, not because patents on genes are unnecessary, but because the discovery of a gene is unpatentable.<sup>28</sup> However, courts have yet to abolish the patentability of genetic tests.<sup>29</sup> The unresolved debate, then, is over whether the patentability of genetic tests has been implicitly abolished under certain circumstances.<sup>30</sup> *Myriad* put forth a tremendous effort trying to maintain its foothold in this industry, but it seems these battles are ones that *Myriad* will not win.<sup>31</sup>

Settlements of some disputes, along with the USPTO guidance and *Ambry*, leave the industry in a greater state of uncertainty in early 2015 than on June 13, 2013 when *Myriad* was decided.<sup>32</sup> *Ambry* signals early signs of trouble for the genetic testing industry because it shows courts will not hesitate to extend the unpatentability of genes to the also previously patentable methods that use those genes.<sup>33</sup> As such, *Ambry* demonstrates how crucial the underlying patentability of genes was for the patentability of genetic tests of those genes.<sup>34</sup> It may now be just a

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<sup>24</sup> 35 U.S.C. §§ 102, 103 (2012).

<sup>25</sup> Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 19 (2010).

<sup>26</sup> 66 Fed. Reg. 1092, 1092-94 (Jan. 5, 2001).

<sup>27</sup> Ass'n for Molecular Pathology v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>28</sup> *Id.*

<sup>29</sup> *Intellectual Property and Genomics*, NAT'L GENOME HUMAN RESEARCH INST., <http://www.genome.gov/19016590> (last updated Oct. 30, 2014).

<sup>30</sup> Leila Gray, *U.S. Supreme Court Decision to Bar Gene Patents Opens Genetic Test Options*, UW TODAY (June 20, 2013), <http://www.washington.edu/news/2013/06/20/u-s-supreme-court-decision-opens-genetic-test-options/>.

<sup>31</sup> Andrew Pollack, *Myriad Genetics Ending Patent Dispute on Breast Cancer Risk Testing*, N.Y. TIMES (Jan. 27, 2015), [http://www.nytimes.com/2015/01/28/business/myriad-genetics-ending-patent-dispute-on-breast-cancer-risk-testing.html?\\_r=0](http://www.nytimes.com/2015/01/28/business/myriad-genetics-ending-patent-dispute-on-breast-cancer-risk-testing.html?_r=0).

<sup>32</sup> *Id.*

<sup>33</sup> *Myriad Genetics, Inc.*, 133 S. Ct. at 2107; *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*1 (Fed. Cir. Dec. 17, 2014).

<sup>34</sup> *Id.*

matter of time before genetic tests are unpatentable solely because genes themselves are unpatentable.

### III. 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.<sup>35</sup> In *Diamond v. Chakrabarty*,<sup>36</sup> the Court ruled “[a] live, human-made micro-organism is patentable subject matter under § 101.”<sup>37</sup> Reviewing 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 here are to a] composition of matter — a product of human ingenuity ‘having a distinctive name, character[, and] use.’”<sup>38</sup> This opinion was revolutionary for its time because a patent examiner previously rejected this patent application on the grounds that microorganisms are products of nature and that living things, such as microorganisms, are unpatentable subject matter.<sup>39</sup> Yet, central to the Court rejecting that analysis, the inventor produced a new bacterium that had “markedly different characteristics” from bacteria found in nature.<sup>40</sup> The Court classified the bacterium as patent-eligible subject matter because those characteristics have the potential for significant utility.<sup>41</sup> Importantly, the Court explained that not all differences between something that is produced and something that is found in nature give rise to the level of “marked differences.”<sup>42</sup> “Marked differences” must be “significant differences,” which are more than merely incidental or trivial.<sup>43</sup>

Three decades later, in *Bilski v. Kappos*,<sup>44</sup> the Court found that a claimed process to hedge risk in the energy business was unpatentable subject matter, and thus invalid, when it involved an abstract idea that

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<sup>35</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.* at 305, 310.

<sup>38</sup> *Id.* (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

<sup>39</sup> *Id.* at 306.

<sup>40</sup> *Id.* at 310–11.

<sup>41</sup> *Diamond*, 447 U.S. at 310–11.

<sup>42</sup> Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8.

<sup>43</sup> *Id.*

<sup>44</sup> 130 S. Ct. 3218, 3231 (2010).

broadly preempted its use in all fields.<sup>45</sup> Processes are patentable subject matter under 35 U.S.C. § 101, but in this case, 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.”<sup>46</sup> 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.”<sup>47</sup>

Two years after *Bilski*, the Supreme Court held in *Mayo Collaborative Services v. Prometheus Laboratories*,<sup>48</sup> that Prometheus’ medical test, which determined the proper dosage of a particular drug by measuring levels of the drug’s metabolites in a patient’s system, was not patentable.<sup>49</sup> The Court reasoned that the processes covered by Prometheus’ patents did 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 complying with 35 U.S.C. § 101.<sup>50</sup> Laws of nature, in addition to abstract ideas, are expressly excluded from that definition.<sup>51</sup> In the instance of Prometheus’ medical test, 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.”<sup>52</sup> As a result, Prometheus’ patents were invalid, especially in light of *Bilski*.

In a sense, invalidation is a way of stating that the examiners should not have granted either an entire patent or some claims therein; invalid claims are unenforceable against another entity for the purpose of an

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<sup>45</sup> See *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1305 (2012).

<sup>46</sup> 35 USC § 101 (2012); *Bilski*, 130 S. Ct. at 3231 (Rader, J., dissenting) (quoting *In re Bilski*, 545 F.3d 943, 1013 (2008)) (citing DIMITRIS N. CHORAFAS, INTRODUCTION TO DERIVATIVE FINANCIAL INSTRUMENTS 75–94 (2008); S. ROSS, R. WESTERFIELD, & B. JORDAN, FUNDAMENTALS OF CORPORATE FINANCE, 743–44 (8th ed. 2008); C. STICKNEY, R. WEIL, K. SCHIPPER, & J. FRANCIS, FINANCIAL ACCOUNTING: AN INTRODUCTION TO CONCEPTS, METHODS, AND USES, 581–82 (13th ed. 2010)).

<sup>47</sup> *Bilski*, 130 S. Ct. at 3231, 3249.

<sup>48</sup> 132 S. Ct. 1289 (2012).

<sup>49</sup> *Id.* at 1294.

<sup>50</sup> *Id.*

<sup>51</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

<sup>52</sup> *Mayo*, 132 S. Ct. at 1305.

infringement lawsuit.<sup>53</sup> For example, according to *Bilski* and *Prometheus*, when the USPTO or courts invalidate a patent or some of its claims, the invalidated portions become worthless. With that consideration in mind, the focus of this Note now turns to the keystone case-line involving Myriad Genetics, Inc. and its patents containing claims that are being litigated in numerous district courts.

In 1996, Myriad Genetics located and sequenced two cancer susceptibility genes known as BRCA1 and BRCA2.<sup>54</sup> 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 acid (“DNA”) sequences to test patients for genetic predisposition to breast, ovarian, and prostate cancer.<sup>55</sup> The American Civil Liberties Union, the Association of Molecular Pathology, and several individual doctors, genetic counselors, scientific researchers, and patients challenged Myriad’s patents, arguing that human genes are not patent-eligible and that certain patent claims were invalid.<sup>56</sup> Finding that all of Myriad’s asserted DNA claims were products of nature and therefore patent ineligible under 35 U.S.C. § 101, the district court ruled against Myriad, but the Federal Circuit reversed on appeal.<sup>57</sup> The Supreme Court granted certiorari, reaffirmed the district court’s holding by vacating the judgment of the Federal Circuit, and remanded the case to the Federal Circuit for further consideration in light of *Prometheus*.<sup>58</sup>

On remand, a three-judge panel for the Federal Circuit again held that genomic DNA and the synthetic DNA molecule known as complementary DNA (“cDNA”) are both patent-eligible.<sup>59</sup> The judges reasoned that genomic DNA can be extracted from its cellular environment using a number of well-established laboratory techniques, and a particular segment of DNA, such as a gene, can be excised or

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<sup>53</sup> Mary L. Miller & Richard P. Vitek, *Validity and Invalidity of Patent Claims*, TECH. TRANSFER PRAC. MANUAL, available at [http://www.autm.net/AM/Template.cfm?Section=Volume\\_3\\_TOC&Template=/CM/ContentDisplay.cfm&ContentID=2207](http://www.autm.net/AM/Template.cfm?Section=Volume_3_TOC&Template=/CM/ContentDisplay.cfm&ContentID=2207).

<sup>54</sup> Dorothy R. Auth, *‘Myriad’ Aftermath: What Remains Patent Eligible?*, 250 N.Y. L.J. 6 (2013).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012); *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

<sup>58</sup> *Ass’n for Molecular Pathology v. USPTO*, 132 S. Ct. 1794, 1794 (2012).

<sup>59</sup> *Ass’n for Molecular Pathology*, 689 F.3d at 1326.

amplified from the DNA to obtain the isolated DNA segment of interest.<sup>60</sup> Likewise, DNA molecules can also be synthesized in a laboratory.<sup>61</sup> 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 because it is not a direct copy of the DNA sequence that it complements.<sup>62</sup> As a result, the judges issued divergent opinions that raised questions about the precise contours of DNA's patent eligibility, especially with respect to cDNA's patent eligibility.<sup>63</sup>

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.<sup>64</sup> The claims at issue were from U.S. Patent 5,747,282, and recited:

1. An isolated DNA coding for a BRCA1 polypep[tide, 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.<sup>65</sup>

"SEQ ID NO:1" and "SEQ ID NO:2" correspond to the BRCA1 DNA coding region and the BRCA1 protein, respectively, and in Judge Lourie's opinion the isolated DNA removed from its native cellular environment was manipulated in such a way that it was markedly different from what exists inside the body.<sup>66</sup> Underscoring this notion was the idea that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community."<sup>67</sup>

Judge Kimberly A. Moore joined the majority's opinion for cDNA sequences, and concurred in judgment with respect to isolated DNA sequences, but wrote separately to explain her reasoning based on the USPTO's history of awarding gene patents and the reliance interest of

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<sup>60</sup> *Id.* at 1313.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 1313–14 (explaining that cDNA is generated from mRNA, and therefore only contains the coding regions of DNA known as exons, while DNA itself contains both exons and non-coding regions known as introns).

<sup>63</sup> Auth, *supra* note 54.

<sup>64</sup> *Ass'n for Molecular Pathology*, 689 F.3d at 1336.

<sup>65</sup> *Id.* at 1309; U.S. Patent No. 5,747,282 col. 153 (filed June 7, 1995).

<sup>66</sup> *Ass'n for Molecular Pathology*, 689 F.3d at 1328.

<sup>67</sup> *Id.* at 1333 (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)); *see also* *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc).

2015]

## THE PRACTICAL IMPLICATION

427

patent holders.<sup>68</sup> Judge Moore opined 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.”<sup>69</sup> If this case were decided on a blank canvas, Judge Moore may have concluded that isolated DNA is not patentable subject matter, and yet again she echoes the majority’s sentiment 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.”<sup>70</sup>

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.<sup>71</sup> 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.<sup>72</sup> In Judge Bryson’s opinion, “Myriad’s claims to the isolated BRCA genes seem . . . 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.”<sup>73</sup> Judge Bryson concluded that “[o]ur role is to interpret the law that Congress has written in accordance with the governing precedents” and that “[t]here is no collective right of adverse possession to intellectual property, and we should not create one.”<sup>74</sup> 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 patent ineligible subject matter, these divergent positions set the stage for a subsequent appeal to the Supreme Court.<sup>75</sup>

In the most recent iteration of *Myriad*, the Supreme Court addressed the question of whether Myriad’s patents and claims to isolated BRCA1 and BRCA2 genes gave Myriad the exclusive right to isolate an individual’s BRCA genes.<sup>76</sup> The Court held that “separating [a] gene

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<sup>68</sup> *Ass’n for Molecular Pathology*, 689 F.3d at 1337.

<sup>69</sup> *Id.* at 1341.

<sup>70</sup> *Id.* at 1343.

<sup>71</sup> *Id.* at 1355.

<sup>72</sup> *Id.* at 1348.

<sup>73</sup> *Id.* at 1350.

<sup>74</sup> *Ass’n for Molecular Pathology*, 689 F.3d at 1350, 1358.

<sup>75</sup> *Id.*; Auth, *supra* note 54.

<sup>76</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013).

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.<sup>77</sup> Now, isolated genomic DNA is classified as a patent ineligible product of nature under 35 U.S.C. § 101.<sup>78</sup> However, cDNA is still patent-eligible because it is not naturally occurring.<sup>79</sup> The Supreme Court’s holding therefore upheld the patentability of cDNA, but reversed the Federal Circuit’s determination of the patentability of isolated DNA.<sup>80</sup>

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.<sup>81</sup> Myriad nonetheless maintained its claims to cDNA despite losing five of its 520 patent claims to BRCA1 and BRCA2 DNA, including the three claims previously discussed.<sup>82</sup> The Court agreed that cDNA is patent-eligible because cDNA is synthesized in such a way that it is non-naturally occurring and is not simply isolated.<sup>83</sup> Thus, cDNA evaded the law of nature exception to patent eligibility.<sup>84</sup>

Through *Myriad*, the Supreme Court clarified that it will not eagerly defer to existing patent law practice and that it may render opinions contrary to the desires of the USPTO or even the Federal Circuit.<sup>85</sup> As an example, when considering the 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

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<sup>77</sup> *Id.*; see Brian Resnick, *Why is Myriad Genetics Still Filing Patent Suits for Breast-Cancer Tests?*, NAT’L J. (Aug. 8, 2013), <http://www.nationaljournal.com/healthcare/why-is-myriad-genetics-still-filing-patent-suits-for-breast-cancer-tests-20130808>.

<sup>78</sup> Auth, *supra* note 54.

<sup>79</sup> *Myriad Genetics, Inc.*, 133 S. Ct. at 2107, 2109.

<sup>80</sup> Resnick, *supra* note 77.

<sup>81</sup> Dayrel S. Sewell, *Unanimous U.S. Supreme Court and Angelina Jolie: BRCA1 & BRCA2 Patentability*, INTELL. PROP. TODAY 24 (July 2013).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> *Id.*

<sup>85</sup> Samuel B. Adams & Carl A. Morales, *Myriad’s Possible Impact on Patent Eligibility of Isolated non-DNA Chemical Substances* (June 19, 2013), <http://www.lexology.com/library/detail.aspx?g=bdf4bfc3-2349-4c4d-bd23-d1d80d1467f0>.

impure materials because there is a difference between pure and impure materials,” suggesting purified substances from natural sources may be patent-eligible.<sup>86</sup> To the extent these guidelines support patentability of a small molecule or protein isolated or purified from a natural source, and to the 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.<sup>87</sup>

Just hours after the *Myriad* decision was released, the USPTO circulated a memorandum to all patent examiners.<sup>88</sup> The memorandum 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.”<sup>89</sup> Although that particular piece of guidance is directly in line with the *Myriad* decision, a later sentence highlights uncertainty for the future as the guidelines recite, “[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.”<sup>90</sup> “Method” claims are another word for “process” claims, and the USPTO’s statement here concerns patent practitioners and research institutions because the memorandum mentioned possible eligibility issues for method claims, despite the fact that the *Myriad* holding was expressly limited to non-method claims.<sup>91</sup> With this dichotomy, the USPTO memorandum 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.”<sup>92</sup> On March 4, 2014, the USPTO issued its first guidance on this issue since *Myriad*, and issued additional, revised guidance on December 16, 2014.<sup>93</sup>

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<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> 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](http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf).

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* (emphasis added).

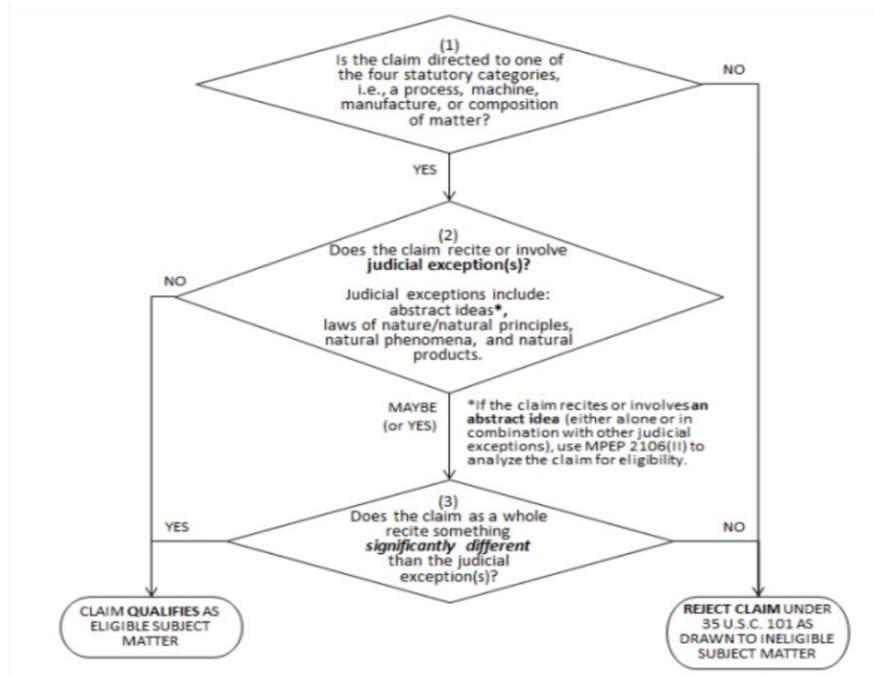
<sup>91</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013).

<sup>92</sup> Memorandum from Andrew H. Hirshfeld (June 13, 2013), *supra* note 88.

<sup>93</sup> 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618, 74619

*B. USPTO Guidance—March 4, 2014*

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.<sup>94</sup> Notably, like all USPTO memoranda, this is not binding law and either the legislature can enact superseding statutes or courts can issue overriding opinions.<sup>95</sup> 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*.”<sup>96</sup> To do so, examiners should refer to the following flowchart:<sup>97</sup>



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(Dec. 16, 2014), available at <http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29414.pdf> [hereinafter 2014 Interim Guidance]; Memorandum from Andrew H. Hirshfeld (June 13, 2013), *supra* note 88.

<sup>94</sup> Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8.

<sup>95</sup> See, e.g., *Myriad Genetics, Inc.*, 133 S. Ct. at 2107.

<sup>96</sup> Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8.

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* at 3.

This chart illustrates a streamlined patent examination procedure by clearly defining what does and does not qualify as patent-eligible subject matter.<sup>99</sup> It is no longer a subjective test with an open standard, but rather an objective one that follows a precise analysis, even with weighing twelve factors for ascertaining whether something is significantly different than a judicial exception.<sup>100</sup> Interestingly, but perhaps unsurprisingly, the USPTO did not create this protocol, and in fact it appears that this analytical framework was derived from Judge Robert W. Sweet from the Southern District of New York.<sup>101</sup> 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.<sup>102</sup> Judge Sweet's analysis of the claims followed the above structure.<sup>103</sup>

Because the isolated DNA molecules were considered a composition of matter, and fell under the judicial exceptions as a product of nature, Judge Sweet analyzed whether the isolated DNA was markedly different from native DNA.<sup>104</sup> 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.<sup>105</sup> 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."<sup>106</sup>

To summarize the flowchart, the first question asks whether a claimed invention is directed to patentable subject matter under 35 U.S.C. § 101, and if it is not, then it cannot be patentable.<sup>107</sup> The second question asks if there is a judicial exception, and if not, then the subject matter is patent eligible.<sup>108</sup> The third question asks if the claim is significantly different from an unpatentable judicial exception, and thus qualifies as

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<sup>99</sup> *See id.* at 3–4.

<sup>100</sup> *Id.* at 4–5.

<sup>101</sup> *See Ass'n for Molecular Pathology v. USPTO*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

<sup>102</sup> *Id.* at 211.

<sup>103</sup> *Id.* at 227–28.

<sup>104</sup> *Id.*

<sup>105</sup> *Id.* at 229.

<sup>106</sup> *Id.*

<sup>107</sup> Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8, at 2.

<sup>108</sup> *Id.* at 3.

patent-eligible subject matter.<sup>109</sup> To analyze whether a claimed invention is significantly different, there are six factors that weigh in favor of eligibility and six factors that weigh against eligibility.<sup>110</sup>

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.
- 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.<sup>111</sup>

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<sup>109</sup> *Id.* at 3.

<sup>110</sup> *Id.* at 4–5.

<sup>111</sup> *Id.*

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*THE PRACTICAL IMPLICATION*

433

For practical purposes, the USPTO also provides several examples of the steps examiners should take and conclusions they should reach when analyzing claim eligibility.<sup>112</sup>

Not surprisingly, the multi-factor test compliments 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.”<sup>113</sup> Under this analysis, isolated DNA is not patentable because it is not markedly different from the chromosomal DNA, as both forms of DNA have identical nucleotide sequences.<sup>114</sup> Although there is a resulting difference in the molecule’s structure, that difference does not rise to the level of a marked difference.<sup>115</sup> Here, the analysis of cDNA under the twelve eligibility factors is of utmost importance. Even though the process of making cDNA may very well be routine in the biotechnology art, the USPTO reasons that cDNA nonetheless has a nucleotide sequence markedly different from naturally occurring DNA and is therefore patent-eligible subject matter.<sup>116</sup>

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<sup>112</sup> *Id.* at 11–13.

<sup>113</sup> Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8, at 4.

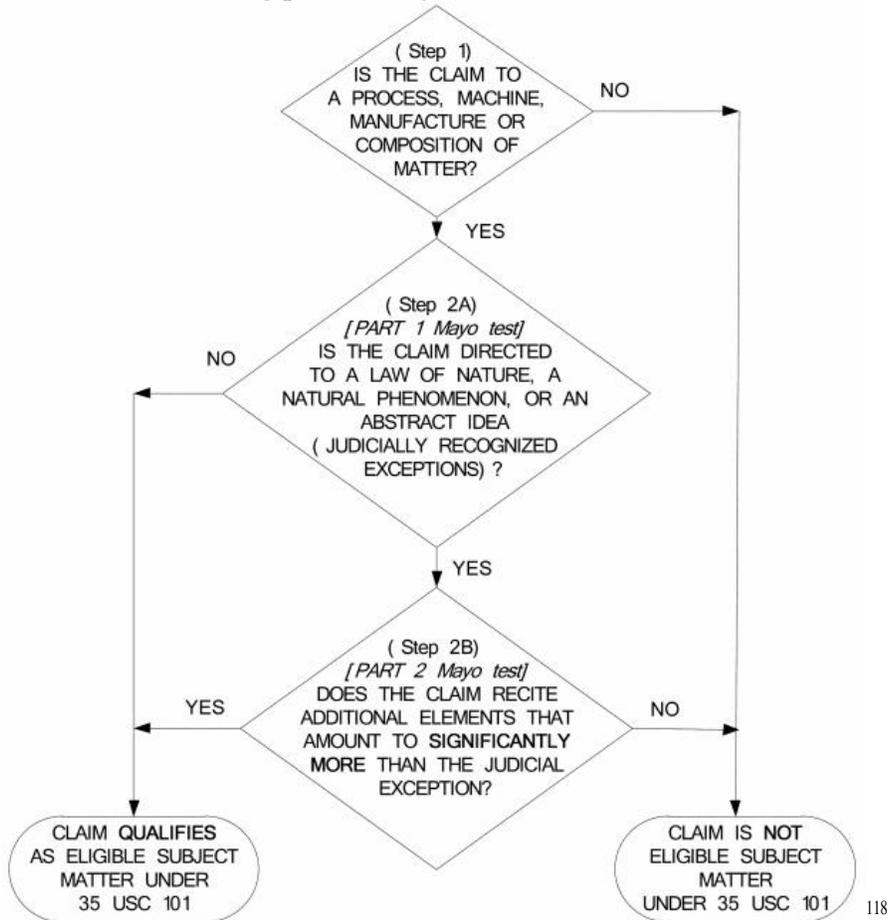
<sup>114</sup> *Id.* at 5.

<sup>115</sup> *Id.*

<sup>116</sup> *Id.* at 5.

C. *USPTO Guidance—December 16, 2014*

In response to public feedback from the USPTO's March 2014 guidance, the USPTO issued renewed guidance on December 16, 2014.<sup>117</sup> This renewed guidance includes a new flowchart examiners should follow when assessing patentability claims:



<sup>117</sup> Austin Donohue, *USPTO Issues New Myriad Guidance*, BIOTECHNOW (Dec. 17, 2014), <http://www.biotech-now.org/public-policy/patently-biotech/2014/12/uspto-issues-new-myriad-guidance#>; see 2014 Interim Guidance, *supra* note 93, at 74618.

<sup>118</sup> 2014 Interim Guidance, *supra* note 93, at 74621.

As the USPTO points out, there are two notable changes between this flowchart and the previous flowchart:

- All claims (product and process) with a judicial exception (any type) are subject to the same steps.
- Claims including a nature-based product are analyzed in Step 2A to identify whether the claim is directed to (recites) a “product of nature” exception. This analysis compares the nature-based product in the claim to its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/or properties. The analysis proceeds to Step 2B only when the claim is directed to an exception (when no markedly different characteristics are shown).<sup>119</sup>

In other words, the test now inquires in Step 2B as to whether the additional elements amount to “significantly more” than a judicial exception as opposed to the prior language of the claim as a whole reciting something “significantly different” than the judicial exception.<sup>120</sup> While Step 2A appears to remain unchanged textually, an examiner should apply it to nature-based products by determining whether a nature-based product limitation in a claim needs to be evaluated using a markedly different characteristic analysis, and performing that analysis if necessary.<sup>121</sup> “This revised analysis represents a change from prior guidance, because now changes in functional characteristics and other non-structural properties can evidence markedly different characteristics, whereas in the [March 2014 guidance] only structural changes were sufficient to show a marked difference.”<sup>122</sup> Importantly,

a product that is purified or isolated, for example, will be eligible when there is a resultant change in characteristics sufficient to show a marked difference from the product’s naturally occurring counterpart. If the claim recites a nature-based product limitation that does not exhibit markedly different characteristics, the claim is directed to a “product of nature” exception (a law of nature or naturally occurring phenomenon), and the claim will require further analysis to determine eligibility based on whether additional elements add significantly more to the exception.<sup>123</sup>

From a patentability standpoint, although inquiring “whether additional elements add significantly more to the exception” is a positive development that will likely maintain the patentability of genetic tests, “it

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<sup>119</sup> Compare *id.*, with Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8, at 2.

<sup>120</sup> Compare 2014 Interim Guidance, *supra* note 93, with Memorandum from Andrew H. Hirshfeld (Mar. 4, 2014), *supra* note 8, at 2.

<sup>121</sup> Donald Zuhn, *USPTO Issues Interim Guidance on Subject Matter Eligibility*, PATENT DOCS (Dec. 16, 2014), <http://www.patentdocs.org/2014/12/uspto-issues-interim-guidance-on-subject-matter-eligibility.html>.

<sup>122</sup> 2014 Interim Guidance, *supra* note 93, at 74623 n.27.

<sup>123</sup> *Id.*

will be a long time before we see more stability in this area of patent law.”<sup>124</sup> Just one day after issuing this guidance, the Court of Appeals for the Federal Circuit issued another decision in the *Myriad* line, discussed below.<sup>125</sup>

*D. 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 lawsuits 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 \$4,300 Myriad charges.<sup>126</sup> Since those two suits, Myriad also sued BioReference Laboratories, Inc. (“BioReference”) in Utah federal court alleging that BioReference, through its genetic sequencing laboratory subsidiary, GeneDx, Inc., infringed Myriad’s intellectual property by offering OncoGeneDx, a comprehensive series of inherited cancer carrier testing, which includes testing for BRCA1 and BRCA2.<sup>127</sup> Myriad later sued Invitae claiming infringement of claims in eleven patents underlying Myriad’s BRCAAnalysis test for hereditary breast and ovarian cancer risk.<sup>128</sup> In response, Invitae countersued for a declaratory judgment of non-infringement.<sup>129</sup> Additionally, Quest Diagnostics (“Quest”) sought a declaratory judgment that it would not be infringing on Myriad’s patents by selling tests for the BRCA genes; two weeks later Myriad filed suit against Quest, too.<sup>130</sup> Further, a sixth entity, Counsyl, is currently seeking

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<sup>124</sup> *Id.* at 74623; Donohue, *supra* note 117.

<sup>125</sup> BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 2014 U.S. App. LEXIS 23692, at \*1 (Fed. Cir. Dec. 17, 2014).

<sup>126</sup> Resnick, *supra* note 77.

<sup>127</sup> *BioReference Laboratories, Inc. Sued by Myriad Genetics, Confident in Its Position*, GLOBENEWSWIRE (Oct. 22, 2013), <http://globenewswire.com/news-release/2013/10/22/582274/10053651/en/BioReference-Laboratories-Inc-Sued-by-Myriad-Genetics-Confident-in-Its-Position.html>.

<sup>128</sup> *InVitae Countersues Myriad in Northern California District Court*, GENOMEWEB (Dec. 2, 2013), <http://www.genomeweb.com/clinical-genomics/invitae-countersues-myriad-northern-california-district-court>.

<sup>129</sup> *Id.*

<sup>130</sup> *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](http://www.marketwatch.com/story/bioreference-laboratories-inc-sued-by-myriad-genetics-confident-in-its-position-2013-10-22?reflink=MW_news_stmp); *Myriad Sues Quest Over BRCA1/2 Patents*, GENOMEWEB (Oct. 24, 2013),

a declaratory judgment, similar to Quest, that it is not infringing Myriad's patents.<sup>131</sup> To date, only Ambry and Gene By Gene countersued Myriad for antitrust violations.<sup>132</sup> However, Myriad and Gene By Gene have since settled their disputes.<sup>133</sup> As part of the settlement 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.<sup>134</sup>

Fundamentally, Myriad executives believe that the company possesses 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.<sup>135</sup> Myriad argues that the 515 valid claims it still holds relating to the BRCA1 and BRCA2 tests are sufficient for the issuance of the preliminary injunctions it is seeking against its competitors.<sup>136</sup> To recapitulate, 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.<sup>137</sup>

Despite the fact that Myriad maintains it still holds 515 valid and enforceable claims in twenty-four patents, its competitors are clearly fighting back. A spokesperson from Quest stated that the company expected Myriad's lawsuit and described it as "merely the latest in a

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<http://www.genomeweb.com/clinical-genomics/myriad-sues-quest-over-brca12-patents>.

<sup>131</sup> *Counsyl Files for Declaratory Judgment That It's Not Infringing Myriad's BRCA Patent Claims*, GENOMEWEB (Sept. 27, 2013), <http://www.genomeweb.com/clinical-genomics/counsyl-files-declaratory-judgment-its-not-infringing-myriads-brca-patent-claims>.

<sup>132</sup> Brief for Defendant, Univ. of Utah Research Found. v. Ambry Genetics Corp., No. 2:13-cv-00640-RJS (*In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.), 3 F. Supp. 3d 1213 (D. Utah 2014), available at <http://cdn.arstechnica.net/wp-content/uploads/2013/08/Ambry-Myriad-Antitrust-docs1.pdf>; *Gene by Gene Joins Ambry in Countersuit against Myriad Alleging Antitrust Violations*, GENOMEWEB (Aug. 15, 2013), <https://www.genomeweb.com/sequencing/gene-gene-joins-ambry-countersuit-against-myriad-alleging-antitrust-violations>.

<sup>133</sup> *BRCA Patent Owners and Gene by Gene, Ltd. Resolve Patent Suit*, MYRIAD (Feb. 7, 2013), <http://investor.myriad.com/releasedetail.cfm?ReleaseID=824154>.

<sup>134</sup> *Id.*

<sup>135</sup> Resnick, *supra* note 77.

<sup>136</sup> Brief for Plaintiff, Univ. of Utah Research Found. v. Ambry Genetics Corp., No. 2:13-cv-00640-RJS (*In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.), 3 F. Supp. 3d 1213 (D. Utah 2014), available at <http://ia601800.us.archive.org/24/items/gov.uscourts.utd.89779/gov.uscourts.utd.89779.5.0.pdf> [hereinafter Brief for Plaintiff Ambry].

<sup>137</sup> *Id.*

pattern of behavior toward any test provider that introduces a new option in BRCA testing that can benefit patients.”<sup>138</sup> Quest is apparently confident that its genetic test does not violate any of Myriad’s claims and plans to vigorously defend its product.<sup>139</sup> Similarly, Invitae asserts that its genetic test is not covered by any valid claim of a Myriad patent.<sup>140</sup> Invitae also alleges that its comprehensive test offers the sequencing of over 200 human genes for less than the single Myriad BRCA1/2 test.<sup>141</sup> Even more dramatic, Invitae alleges that approximately fifty additional claims in four of Myriad’s patents should be invalidated because they are invalid method claims.<sup>142</sup> Time will tell which party is indeed correct, and on what precise grounds. A court’s finding of either infringement or non-infringement necessarily implies a straightforward winner and loser, unlike the ruling in *Myriad* where the Supreme Court invalidated just five claims spanning all of Myriad’s patents, and did not completely divest Myriad of its patent exclusivity.<sup>143</sup> Absent a settlement, one party must prevail, and the future of the genetic testing industry might be forever changed. A defeat for Myriad could devastate the industry for many reasons, one of which is rooted in the AIA and discussed below. But now, the latest authority on this matter is the Court of Appeals for the Federal Circuit’s opinion in *Ambry*.<sup>144</sup>

Myriad appealed the District Court of Utah’s March 10, 2014 decision denying Myriad’s request for preliminary injunction to halt Ambry’s sale of BRCA1 and BRCA2 genetic tests.<sup>145</sup> The District

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<sup>138</sup> *Myriad Sues Quest Over BRCA1/2 Patents*, *supra* note 130.

<sup>139</sup> *InVitae Countersues Myriad in Northern California District Court*, GENOMEWEB, *supra* note 130.

<sup>140</sup> Brief for Plaintiff Ambry, *supra* note 136 (citing 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).

<sup>141</sup> Complaint at 2, *Invitae Corp. v. Myriad Genetics, Inc.*, No. 3:13-cv-05495-1 (N.D. Cal. 2013), available at <http://patentdocs.typepad.com/files/cand-3-13-cv-05495-1.pdf>.

<sup>142</sup> *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. Invitae based its allegations on the Federal Circuit’s holding that was neither appealed to nor decided by the Supreme Court.

<sup>143</sup> *See Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013).

<sup>144</sup> *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*1 (Fed. Cir. Dec. 17, 2014).

<sup>145</sup> *Univ. of Utah Research Found. v. Ambry Genetics Corp. (In re BRCA1- & BRCA2-*

Court's ruling was affirmed on appeal because the claims at issue were directed to invalid subject matter.<sup>146</sup> Myriad asserted six claims spanning three patents and importantly included two that involved screening patients covering the method of performing a genetic test.<sup>147</sup> The court first found that parts of those two claims were invalid because they were directed to the patent-ineligible abstract idea of comparing BRCA sequences.<sup>148</sup>

Turning to the remaining parts of those claims, the court found that the “non-patent-ineligible elements do not add ‘enough’ to make the claims as a whole patent-eligible.”<sup>149</sup> In so finding, the court reasoned the claimed elements “set forth well-understood, routine, and conventional activity engaged in by scientists at the time of Myriad’s patent applications.”<sup>150</sup> Simply put, the non-patent-ineligible elements of the two claims did nothing more than spell out what practitioners already knew, which was how to compare gene sequences using routine, ordinary techniques.<sup>151</sup> However, the court left open the possibility that Myriad could have been successful if it instead sought an injunction on one of its claims that was directed towards a method of detecting alterations where the alterations were specifically the genetic mutations that Myriad discovered.<sup>152</sup> With the overall patentability of genetic tests still at issue, the focus now shifts to the ways in which patents can be challenged by means other than lawsuits in federal courts.

#### IV. POST-GRANT PROCEEDINGS

##### A. Overview of the AIA’s New Post-Grant Proceedings

There are several ways third parties can persuade the USPTO to cancel others’ patents or claims. 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

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Based Hereditary Cancer Test Patent Litig.), 3 F. Supp. 3d 1213, 1277 (D. Utah 2014).

<sup>146</sup> *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 U.S. App. LEXIS 23692, at \*1.

<sup>147</sup> *Id.* at \*11–13.

<sup>148</sup> *Id.* at \*16–17.

<sup>149</sup> *Id.* at \*20.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 2014 U.S. App. LEXIS 23692, at \*21–22.

third parties through the USPTO included: (1) third party prior art submissions; (2) ex parte reexamination; and (3) inter partes reexamination.<sup>153</sup> Third party prior art submissions allowed for third parties to submit patents, published patent applications, or printed publications that may have been relevant to the examination of a patent application.<sup>154</sup> Ex parte reexamination allowed for third parties to challenge any unexpired patents on the basis of novelty, obviousness, and claim scope.<sup>155</sup> Such challenges were successful upon finding a substantial new question of patentability.<sup>156</sup> Inter partes reexamination was very similar to ex parte reexamination, but was a more extensive and costly proceeding whereby the petitioner prevailed upon proving a reasonable likelihood of success as to at least one claim, a much lower burden required for raising a substantial new question of patentability.<sup>157</sup> However, the patent community criticized those options.<sup>158</sup> 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.<sup>159</sup> Also, under the old provisions, there were growing 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.<sup>160</sup>

The rollout of the AIA drastically changed these patent cancellation options. First, third party prior art submissions, now known as pre-issuance submissions, have been adapted to better provide patent

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<sup>153</sup> See Prior Art Citations to Office and Ex Parte Reexamination of Patents, 35 U.S.C. §§ 301–07 (2012); Inter Partes Review, 35 U.S.C. §§ 311–19 (2012).

<sup>154</sup> Gene Quinn, *AIA Oddities: Third Party Submissions of Prior Art*, IPWATCHDOG (Sept. 19, 2013, 8:25 AM), <http://www.ipwatchdog.com/2013/09/19/aia-oddities-third-party-submissions-of-prior-art/id=45118/>; *Preissuance Submissions*, USPTO, [http://www.uspto.gov/aia\\_implementation/faqs-preissuance-submissions.jsp](http://www.uspto.gov/aia_implementation/faqs-preissuance-submissions.jsp) (last visited Apr. 19, 2014); see 35 U.S.C. § 122(e) (2012); 37 CFR § 1.290 (2014).

<sup>155</sup> *Comparison of Post-Grant Proceedings*, RATNER PRESTIA, <http://www.rppostgrant.com/ComparisonCharts/post-grant-review-comparison.html> (last visited Apr. 19, 2014).

<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

<sup>158</sup> See Filipe De Corte, et al., *AIA Post-Grant Review and European Oppositions: Will They Work in Tandem, or Rather Pass Like Ships in the Night?*, 14 N.C. J.L. & TECH. 93 (2012).

<sup>159</sup> *Id.* at 96.

<sup>160</sup> Quinn, *supra* note 154.

examiners with the best possible prior art references.<sup>161</sup> Pre-issuance submissions 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.<sup>162</sup> Second, ex parte reexamination, renamed post-grant review (“PGR”), is fundamentally still in place and is instituted under the same general standard of review.<sup>163</sup> But, there are some key changes that make PGR better adapted to serve as a quasi-judicial administrative proceeding to help relieve some of the burden of patent litigation from domestic federal courts.<sup>164</sup> Third, inter partes reexamination has been replaced by inter partes review (“IPR”).<sup>165</sup> Although IPR’s standard of review is unchanged, IPR can only be initiated on the basis of novelty and nonobviousness concerns, as opposed to enablement and arguably even patentability under 35 U.S.C. § 101, which can be raised in PGR.<sup>166</sup> 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 two to three years.<sup>167</sup>

Though estoppel applies to the petitioner in an IPR, only 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.<sup>168</sup> This leaves open the door for other third parties to initiate a subsequent IPR.<sup>169</sup> Likewise, the petitioner may not assert in a subsequent action that a claim is invalid on any ground that was raised or reasonably could have been raised in the IPR.<sup>170</sup> Again, that

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<sup>161</sup> *Proposed New Rules Under AIA to Affect Third-Party Submissions of Prior Art*, BRINKS, GILSON & LIONE (May 31, 2012), [http://www.brinksgilson.com/news\\_events/3406-proposed-new-rules-under-aia-affect-third-party-submissions-prior-art](http://www.brinksgilson.com/news_events/3406-proposed-new-rules-under-aia-affect-third-party-submissions-prior-art).

<sup>162</sup> Quinn, *supra* note 154.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

<sup>165</sup> *Post-Grant: Inter Partes Review*, FISH & RICHARDSON, <http://fishpostgrant.com/inter-partes-review/> (last visited Mar. 22, 2014).

<sup>166</sup> *Id.*

<sup>167</sup> *Comparison of Post-Grant Proceedings*, *supra* note 155.

<sup>168</sup> *America Invents Act (AIA) Frequently Asked Questions*, USPTO, <http://www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/america-invents-act-aia-frequently-asked> (last visited May 13, 2015).

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

provision only impacts the original petitioner.<sup>171</sup> These provisions are the extent of estoppel, and invalidity opinions will absolutely not carry over between patents. So at least in theory, it is more efficient for a single court to rule on the invalidity of entire classes of patents than for the USPTO to issue opinions through post-grant proceedings that collectively accomplish the same result; thus, it is necessary for the courts to subsequently decide Myriad's unsettled litigation.<sup>172</sup> The focus now turns to the precise effects that unsettled litigation will have on both PGR and IPR.

### B. PGR

Congressional hearings between 2001 and 2006 explored the creation of PGR proceedings where patents are challenged early in life and on all validity grounds.<sup>173</sup> Such a request was called for by the core intellectual property professional organizations and accompanying reports and studies.<sup>174</sup> At a 2004 House Intellectual Property Subcommittee hearing, the American Intellectual Property Law Association ("AIPLA") Executive Director, Michael Kirk, argued to authorize post-grant review.<sup>175</sup> He believed that testing the validity of a newly issued patent that is of dubious validity is often prohibitively expensive or impossible, and the continued existence of such a patent can

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<sup>171</sup> *Id.*

<sup>172</sup> *Id.*

<sup>173</sup> 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*].

<sup>174</sup> See *2004 House hearing*, *supra* note 173, at 13–16 (statement of James Toupin, General Counsel, USPTO), 38 (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.”), 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 173, at 38 (statement of Michael Kirk, Executive Director, AIPLA), 46 (statement of Jeffrey Kushan, Powell, Goldstein, Frazer, and Murphy).

<sup>175</sup> *2004 House hearing*, *supra* note 173, at 32 (statement of Michael Kirk, Executive Director, AIPLA).

disrupt product development in a field of technology for years.<sup>176</sup> Invalid or overbroad patents both discourage follow-on innovation, preventing competition, and also raise prices through unnecessary licensing and litigation.<sup>177</sup> Additionally, the “USPTO is a particularly appropriate venue for making validity determinations in a cost-effective and technically sophisticated environment.”<sup>178</sup> It stands to reason that PGR serves a significant and substantial purpose.<sup>179</sup>

Section 6 of the AIA amended Chapter 31’s authorization of inter partes proceedings and created the new PGR administrative proceedings.<sup>180</sup> 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 “[shows] that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.”<sup>181</sup>

For petitions filed on or after March 19, 2013, PGR costs \$12,000 plus a \$250.00 fee for each claim in excess of twenty within the patent; the post-institution fee is \$18,000 plus a \$550.00 fee for each claim in excess of fifteen within the patent.<sup>182</sup> Thus, for \$32,750, up to twenty claims in a single patent can be reviewed in PGR, with an additional cost of \$800 per claim reviewed in excess of twenty. Post-institution fees represent fees that are paid up front but refunded in the event that the petitioner’s request for PGR is denied.<sup>183</sup>

The provision enacted for post-grant proceedings, 35 U.S.C. § 321, states in part: “[a] petitioner in a post-grant review may request to cancel

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<sup>176</sup> *Id.* at 29 (statement of Michael Kirk, Executive Director, AIPLA).

<sup>177</sup> *Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition*, FTC.GOV (Mar. 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>.

<sup>178</sup> *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).

<sup>179</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013).

<sup>180</sup> Leahy-Smith America Invents Act, § 314(a), Pub. L. No. 112–29, Sec. 6(a), 125 Stat. 284, 300 (codified as amended in scattered sections of 35 U.S.C.).

<sup>181</sup> *Id.*

<sup>182</sup> *America Invents Act (AIA) Frequently Asked Questions*, *supra* note 168.

<sup>183</sup> *Post-Grant Alert: New PTO Fees Effective March 19, 2013*, FISH & RICHARDSON (Mar. 22, 2013), <http://fishpostgrant.com/news/post-grant-alert-new-pto-fees-effective-march-19-2013/>.

as unpatentable [one] 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).”<sup>184</sup> Of particular relevance in the analysis is 35 U.S.C. § 321(b), which defines the grounds under 282(b).<sup>185</sup>

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.<sup>186</sup>

Limiting the analysis to the specified paragraphs (2) and (3), post-grant proceedings can be brought up against patents for reasons including “condition[s] for patentability” or violations of 35 U.S.C. § 112 or § 251.<sup>187</sup> For the purpose of this discussion, the primary concern is defining the phrase “a condition for patentability.”

In one prominent view, the Patent Act sets out the conditions for patentability in sections § 101, § 102, and § 103.<sup>188</sup> Much additional precedent supports this notion.<sup>189</sup> In the eyes of the USPTO leadership, commentators incorrectly state that 35 U.S.C. § 101 is not a condition for patentability and cannot be grounds for PGR because it is not expressly stated within the text of 35 U.S.C. § 282(b)(3).<sup>190</sup> The USPTO leadership

<sup>184</sup> 35 U.S.C. § 321 (2012).

<sup>185</sup> *Id.*

<sup>186</sup> *Id.* § 282(b).

<sup>187</sup> *Id.*

<sup>188</sup> See *Graham v. John Deere Co. of Kan. City*, 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.”).

<sup>189</sup> See *Aristocrat Techs. Austl. 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.” *Id.* 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. *Id.*

<sup>190</sup> David Kappos, *PTAB and Patentability Challenges*, DIRECTOR’S FORUM: A BLOG FROM USPTO’S LEADERSHIP (Sept. 24, 2012, 4:44 PM),

further opines that commentators incorrectly assert that because 35 U.S.C. § 101 is not included in § 282(b)(2), it is not “specified in part II as a condition for patentability” although § 101 is entitled “[i]nventions patentable,” unlike § 102 and § 103 that are both entitled “[c]onditions for patentability.”<sup>191</sup> This assertion is made even though § 101 is included “in part II” of Title 35.<sup>192</sup> However, 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.<sup>193</sup>

The Supreme Court previously held that 35 U.S.C. § 101 is a condition for patentability.<sup>194</sup> In *Graham v. John Deere Co. of Kansas City*,<sup>195</sup> 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.<sup>196</sup> 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.<sup>197</sup>

Additionally, the Federal Circuit expressly rejected the argument raised by the dissent in *Dealertrack, Inc. v. Huber*<sup>198</sup> 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.”<sup>199</sup> The Federal Circuit in *Dealertrack* clarified that the use of the phrase “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; here, the court relied on the Supreme Court’s pronouncement in *Pennsylvania Department of Corrections v. Yeskey*,<sup>200</sup> that a statute’s title “is of use only when it sheds light on some ambiguous word or phrase”

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[http://www.uspto.gov/blog/director/entry/ptab\\_and\\_patentability\\_challenges](http://www.uspto.gov/blog/director/entry/ptab_and_patentability_challenges).

<sup>191</sup> *Id.*

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012); *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 12 (1966).

<sup>195</sup> *Graham*, 383 U.S. at 12.

<sup>196</sup> *Id.*

<sup>197</sup> *Mayo*, 132 S. Ct. at 1305.

<sup>198</sup> *Dealertrack v. Huber*, 674 F.3d 1315, 1330 n.3 (Fed. Cir. 2012) (Plager, J., dissenting).

<sup>199</sup> *Id.* (internal quotation marks omitted) (citing *Aristocrat Tech. Austl. Pty Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008)).

<sup>200</sup> *Pa. Dep’t of Corrs. v. Yeskey*, 524 U.S. 206, 212 (1998) (quoting *Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. 519, 528–29 (1947)).

in the statute and that it “cannot limit the plain meaning of the text.”<sup>201</sup>

In additional reflections by the now-retired Chief Judge Rader, he posited that the Supreme Court long ago held that 35 U.S.C. § 101 is not a “condition of patentability.”<sup>202</sup> Chief Judge Rader acknowledged that the statute does not list 35 U.S.C. § 101 among the invalidity defenses to infringement, but instead under 35 U.S.C. § 282.<sup>203</sup> As such, while invalidity for failing to meet a “condition of patentability” is among the authorized defenses, 35 U.S.C. § 101 is arguably not a “condition of patentability.”<sup>204</sup>

Contrary to the views expressed by several 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 reviews.<sup>205</sup> A House Committee Report provides that “the post-grant review proceeding permits a challenge on any ground related to invalidity under section 282.”<sup>206</sup> Likewise, Arizona Senator Jon Kyl included “section 101 invention issues” among those “that can be raised in post-grant review.”<sup>207</sup> To summarize, despite the opinions 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.<sup>208</sup> Unless the courts or Congress direct the USPTO otherwise, the USPTO will continue to do exactly that.<sup>209</sup>

Such a conclusion implies that patents or patent claims can be canceled by a third party through the USPTO on 35 U.S.C. § 101 grounds for a fraction of the cost of litigation.<sup>210</sup> 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

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<sup>201</sup> *Trainmen v. Baltimore & Ohio R.R. Co.*, 331 U.S. at 528–29.

<sup>202</sup> *CLS Bank Int’l v. Alice Corp. Pty.*, 717 F.3d 1269, 1335 (Fed. Cir. 2013) (citing *Diamond v. Diehr*, 450 U.S. 175, 189–90 (1981); *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”)).

<sup>203</sup> *CLS Bank Int’l*, 717 F.3d at 1335.

<sup>204</sup> *Id.*

<sup>205</sup> H.R. REP. NO. 112-98, at 47 (2011).

<sup>206</sup> *Id.*

<sup>207</sup> 112 CONG. REC. S157, 1375 (daily ed. Mar. 8, 2011).

<sup>208</sup> *Kappos*, *supra* note 190.

<sup>209</sup> *Id.*

<sup>210</sup> *Post-Grant Alert: New PTO Fees Effective March 19, 2013*, *supra* note 183.

property.<sup>211</sup> 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. However, future patents issued are now possibly at risk for being invalidated through PGR after *Myriad*.<sup>212</sup> PGR could be instituted for a patent if 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.”<sup>213</sup> Therefore, a third party showing that a greater number of factors weigh against patentability rather than for patentability is sufficient to invalidate a patent via PGR.<sup>214</sup>

### C. IPR

Amended by the AIA, 35 U.S.C. § 311 defines IPR’s 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.”<sup>215</sup> Therefore, IPR cannot be directed to 35 U.S.C. § 101.<sup>216</sup> As such, *Myriad* does not provide a basis for patent invalidation in an IPR because the holding that DNA sequences are unpatentable 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.<sup>217</sup>

Presently, post-*Myriad*, relevant considerations include 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.<sup>218</sup> But, this is expressly under the condition that a PGR must be requested on or prior

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<sup>211</sup> See Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 Sci. 239–40 (Oct. 14, 2005).

<sup>212</sup> 35 U.S.C. § 321 (2012).

<sup>213</sup> *Comparison of Post-Grant Proceedings*, *supra* note 155.

<sup>214</sup> *Id.*

<sup>215</sup> 35 U.S.C. § 311 (2012).

<sup>216</sup> *Id.*

<sup>217</sup> See generally *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

<sup>218</sup> *America Invents Act (AIA) Frequently Asked Questions*, *supra* note 168.

to nine months after patent issuance.<sup>219</sup> 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.<sup>220</sup> As a result, 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.<sup>221</sup> Therefore, for IPR to invalidate patents to genes or genetic testing, for example, case law would need to evolve such that something previously patentable is now unpatentable in light of either 35 U.S.C. §§ 102 or 103 for lack of novelty or obviousness. The case law could feasibly evolve in that way, and the post-*Myriad* future is discussed below.

## V. THE FUTURE OF GENETIC TESTING IN A POST-MYRIAD WORLD

### A. *Myriad Defeat in Ambry*

In addition to the landmark *Myriad* decision finding that patent claims to genes covered ineligible subject matter, the Federal Circuit took that one step further and held that DNA primers, as compositions of matter, were not patentable.<sup>222</sup> Although cDNA is patentable on the grounds that a lab technician “unquestionably creates something new,” the court found primers unpatentable despite the fact they are non-naturally occurring.<sup>223</sup> The court distinguished the two cases by explaining, “separating [DNA] from its surrounding genetic material is not an act of invention.”<sup>224</sup>

*Myriad* was defeated in a second respect, here, because the Court also deemed its methods of screening to be unpatentable.<sup>225</sup> Comparing a patient’s BRCA1 sequence with that of a wild-type, or normal, non-mutated sequence, and identifying any differences between the two was considered a “patent-ineligible abstract idea.”<sup>226</sup> Although the patented method required additional steps such as hybridizing the gene probe and amplifying and sequencing it, the court viewed these techniques as “well-

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<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> 35 U.S.C. §§ 282, 311, 321 (2012).

<sup>222</sup> BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 2014 U.S. App. LEXIS 23692, at \*8 (Fed. Cir. 2014).

<sup>223</sup> *Id.* at \*8 (quoting Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013)).

<sup>224</sup> *Id.* at \*7 (quoting *Myriad Genetics, Inc.*, 133 S. Ct. at 2117).

<sup>225</sup> *Id.* at \*17.

<sup>226</sup> *Id.* at \*17.

understood, routine, and conventional techniques” that a scientist would have contemplated “when instructed to compare two gene sequences.”<sup>227</sup> Therein lies the turning point that may make some fearful of the future.

While Myriad itself might not be terribly affected as its patents expire over the next several years, courts could invalidate patents of other patent holders with claims to genetic tests for reasons similar to those in *Ambry*, likely before the *Myriad* litigation even ends and potentially before settlements are reached.<sup>228</sup> For example, as the court found that at least part of Myriad’s genetic test is unpatentable in accordance with 35 U.S.C. § 101, it might not be that great of a stretch for a court, or the USPTO, to find that another genetic test is rendered obvious and unpatentable under 35 U.S.C. § 103.<sup>229</sup> Such a holding implies that a previously undiscovered genetic sequence cannot provide the basis for a previously known process using the previously unknown genetic sequence. Because of this, it is possible that 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.

Amendments to patents both during and after the PGR proceedings are severely restricted and although a PTAB ruling is appealable to the Federal Circuit, a final decision to reject some or all patent claims does not mean that patent prosecution is reopened.<sup>230</sup> As a result, a patent owner’s lack of a second chance to secure patentability over what was once patent-eligible subject matter means that anyone can freely use subject matter that was once patented by the company, which devoted substantial amounts of money and time to an invention, simply because patent law evolved after patents were obtained.<sup>231</sup> By experiencing such an occurrence, or even facing the mere threat of it, companies could stop

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<sup>227</sup> *Id.* at \*21.

<sup>228</sup> Turna Ray, *In Warning to Would-be Competitors, Myriad and BRCA Test Patent Holders Sue Ambry, Gene by Gene*, GENOMEWEB (July 10, 2013), <http://www.genomeweb.com/clinical-genomics/warning-would-be-competitors-myriad-and-brca-test-patent-holders-sue-ambry-gene>.

<sup>229</sup> 35 U.S.C. §§ 101, 103 (2012); *Ambry Genetics Corp.*, 2014 U.S. App. LEXIS 23692, at \*8.

<sup>230</sup> See MANUAL OF PATENT EXAMINING PROCEDURE § 1216.01 (9th ed. 2014); Lawrence Stahl & Donald Heckenberg, *The Limited Ability of a Patent Owner to Amend Claims and Present New Claims in Post-Grant and Inter Partes Reviews*, FITZPATRICK, CELLA, HARPER & SCINTO, [http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Fitz\\_PTO\\_1\\_5\\_8.pdf](http://www.fitzpatrickcella.com/DB6EDC/assets/files/News/Fitz_PTO_1_5_8.pdf) (last visited Mar. 1, 2015).

<sup>231</sup> See Ray, *supra* note 228.

filing patents for genetic tests. More importantly, companies could stop investing in research for the development of new genetic tests. Although hindering research is precisely what Dr. Watson wanted to avoid, it is ironically the consequence of a dramatic court ruling that invalidates arguably necessary patents.<sup>232</sup>

Representatives of Myriad adamantly declared, “[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.”<sup>233</sup> While it is unclear how much of that money was used to develop the various aspects of Myriad’s BRCA analysis test, one can safely assume that Myriad would not have invested such a sum if it could not have recouped its investment, and ultimately profited, by virtue of the exclusive rights granted by patents.<sup>234</sup>

*B. Impact of Future Myriad Loss on Post-Grant Proceedings*

In the event Myriad again loses in subsequent litigation, any arguments asserted against its patents’ validity could then be used, generally, with respect to every seemingly applicable patent through 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 of the Court in *Prometheus* could realistically be applied by future courts to hold that certain genetic tests, specifically Myriad’s, are wholly unpatentable subject matter.<sup>235</sup> In *Prometheus*, just as a natural correlation was found to be unpatentable subject matter when it was incorporated into a generally known or routine diagnostic test, an analogous situation may very well exist where a future court decides that isolated human DNA, as unpatentable subject matter, could not be used in conjunction with a known diagnostic test to ultimately create patentable subject matter.<sup>236</sup> As a result, any patents granted within the past nine months containing claims to a similarly situated genetic test

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<sup>232</sup> Brief for James D. Watson as Amici Curiae Supporting Neither Party, Ass’n of Molecular Pathology v. USPTO, No. 2010-1406, 689 F.3d 1303 (2012).

<sup>233</sup> 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/>.

<sup>234</sup> See 35 U.S.C. § 154(a)(2) (2012).

<sup>235</sup> See *Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289 (2012).

<sup>236</sup> See *id.* at 1305.

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.<sup>237</sup> However, a court may invalidate Myriad's claims for other reasons. For instance, a court could hold, falling in line with *Ambry*, 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.<sup>238</sup> Since the test would be considered unpatentable under this section, IPR could then potentially be invoked. Therefore, any patent or claim analogous to what would hypothetically comprise any of Myriad's future invalidated patents or claims, could be subject to post-grant review proceedings regardless of when they were actually issued.<sup>239</sup>

## VI. CONCLUSION

Going forward, it is imperative for companies investing time and money into the development of genetic tests to be able to obtain patents for their tremendous inventions. Should that cease to be the case, it is imaginable that most biotechnology companies will move into other more profitable areas of research and innovation. When that happens, nothing short of legislative action could fill the void left behind of billions of dollars of research funding that has been invested or that will be invested in producing currently patentable inventions.

Fortunately, this grim outcome can be avoided. Courts adjudicating future cases stemming from the *Myriad* case-line could feasibly issue narrow holdings that will not have a broad-sweeping effect on the rest of the industry. These holdings could be more limited to the facts in the respective cases and could avoid redefining the law. Hopefully the industry and the USPTO approach the legislature, or the legislature intervenes on its own accord, sooner rather than later, so a solution can be reached before it is too late. At this point, all relevant parties involved in clarifying and defining the law are seemingly diverging on these issues, further diminishing the hope of a swift resolution.

Post-grant proceedings fit into the broader picture because they present cheaper and quicker options for invalidating another's patent, and courts must tread carefully and be mindful of those proceedings when

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<sup>237</sup> See 35 U.S.C. § 282 (2012).

<sup>238</sup> *Id.* § 103; BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 2014 U.S. App. LEXIS 23692, at \*1 (Fed. Cir. Dec. 17, 2014).

<sup>239</sup> 35 U.S.C. §§ 282, 311, 321 (2012).

issuing decisions along the *Myriad* case-line. For better or worse, such court rulings override the views and the guidance provided by the USPTO leadership. When the Federal Circuit or the Supreme Court deems once seemingly patentable subject matter to be patent-ineligible, the USPTO's hands are tied and it is bound to harmonize its patent granting practices with that court's decision. Until the time when the laws are changed, courts have the final say, and unfortunately opinions are not always as predictable as everyone would expect. Although it was largely expected that the Court in *Myriad* would find DNA is unpatentable subject matter, the *Ambry* decision coming out merely one day after the USPTO's second interim guidance was a shocking blow that demonstrates the extraordinary volatility of patent law practice. With the ever-present uncertainty after these most unfortuitous events unfolded, *Ambry* must not foreshadow a future wherein the patentability of method claims hinges on the patentability of the underlying elements as compositions of matter.