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# Patenting the Human Body: Myriad, Prometheus, and the Future of Patentable Subject Matter in the United States

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PATENTING THE HUMAN BODY: MYRIAD, PROMETHEUS, AND THE FUTURE OF PATENTABLE  
SUBJECT MATTER IN THE UNITED STATES

I. INTRODUCTION

In 1990, the U.S. Human Genome Project officially began efforts to map the entire human genome.<sup>1</sup> The international project lasted thirteen years and cost approximately \$2.7 billion.<sup>2</sup> In addition to gaining valuable insight about the human genetic code, researchers are working to develop disease diagnostic tests and treatments using Deoxyribonucleic Acid (DNA) analysis.<sup>3</sup> Diagnostic testing for genetic disorders has increased steadily over the past two decades.<sup>4</sup> Over 350 biotechnology products are currently in clinical trials; many of these are based on genetic research.<sup>5</sup> A 2005 study found that nearly 20% of human genes are explicitly claimed in U.S. patents.<sup>6</sup> Many of these patents cover genes associated with numerous diseases, such as Alzheimer's disease,<sup>7</sup> cystic fibrosis,<sup>8</sup> Canavan disease,<sup>9</sup> and asthma.<sup>10</sup>

Researchers seek patents for gene sequences in order to provide incentives that are critical to downstream investment, which will, in turn, lead to further discoveries on which

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<sup>1</sup> U.S. Dep't. of Energy Office of Sci., *About the Human Genome Project*, Genomics.energy.gov., [http://www.ornl.gov/sci/techresources/Human\\_Genome/project/about.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/project/about.shtml) (last updated Sept. 19, 2011).

<sup>2</sup> See Nat'l Human Genome Research Inst., Nat'l Institutes of Health, *The Human Genome Project Completion: Frequently Asked Questions*, <http://www.genome.gov/11006943> (last updated Oct. 30, 2010).

<sup>3</sup> *Id.* ("Individualized analysis based on each person's genome will lead to a very powerful form of preventive medicine... Then, through our understanding at the molecular level of how things like diabetes or heart disease or schizophrenia come about, we should see a whole new generation of interventions, many of which will be drugs that are much more effective and precise than those available today.").

<sup>4</sup> Gert Matthijs & Gert-Jan B. Van Ommen, *Gene Patents: From Discovery to Invention. A Geneticist's View*, in GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 311, 316 (Geertrui Van Overwalle ed., Cambridge University Press 2009).

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

<sup>6</sup> Gloria Bevan & Kyle Jensen, *Intellectual Property Landscape of the Human Genome*, 310 SCI., 239-40, 239 (2005).

<sup>7</sup> Ronald Kotulak, *Taking License With Your Genes: Biotech Firms Say They Need More Protection*, CHI. TRIB., Sept. 12, 1999, [http://articles.chicagotribune.com/1999-09-12/news/9909120225\\_1\\_gene-patents-patent-office-molecular-pathology-laboratory](http://articles.chicagotribune.com/1999-09-12/news/9909120225_1_gene-patents-patent-office-molecular-pathology-laboratory).

<sup>8</sup> *Id.*

<sup>9</sup> Arthur Allen, *Who Owns My Disease?*, 26 MOTHER JONES 52-59 (2001).

<sup>10</sup> U.S. Patent No. 6,037,149 (filed Mar. 14, 2000).

genetic tests are based.<sup>11</sup> In the pharmaceutical and diagnostic healthcare industry, patent protection is viewed as crucial in aiding the recouping of substantial costs associated with the discovery and development of new therapies.<sup>12</sup> Patent-holders claim that without patent protection, there would be little motivation to make the discoveries in the first place, or to publish them.<sup>13</sup> The corporation Myriad Genetics has argued that if gene patents are no longer allowed, future developments in genetic diagnostic testing and therapies will slow or cease, or will not be disclosed in order to maintain trade-secret protection.<sup>14</sup>

There is a great deal of controversy surrounding gene patents.<sup>15</sup> Famous author Michael Crichton expressed the fears of many researchers, doctors, and patients when he wrote the following in a New York Times opinion editorial: “[y]ou, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it’s only too real.”<sup>16</sup> A 2005 survey of laboratory directors in the United States sought to quantify the impact of gene patents on the ability of doctors to perform research and provide clinical genetic testing services.<sup>17</sup> The study found that 53% of respondents decided not to develop or perform a test or service for clinical or research purposes because of a patent,<sup>18</sup> and

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<sup>11</sup> Beyan & Jensen, *supra* note 6; Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3,4 (2003), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1907368/pdf/0108.pdf>.

<sup>12</sup> Cho, *supra* note 11 at 3 (“In this industry particularly, patents are seen as necessary to enhance an inventor’s ability to recoup the substantial investments of many ears and hundreds of millions of dollars necessary to bring a new drug or device to market.”); Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F.Supp.2d 181, 210-11 (S.D.N.Y. 2010).

<sup>13</sup> Kotulak, *supra* note 7.

<sup>14</sup> Brief for Appellant at 4 Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329, 1350 (Fed. Cir. 2011) (No. 2010-1406).

<sup>15</sup> Jordan Paradise, *European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 133 (2004).

<sup>16</sup> Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, <http://www.nytimes.com/2007/02/13/opinion/13crichton.html>.

<sup>17</sup> Cho, *supra* note 11, at 3.

<sup>18</sup> *Id.* at 5.

67% reported a decreased ability to conduct research.<sup>19</sup> The American Society of Human Genetics found similar results in a separate survey, where 46% of respondents felt that patents had limited or delayed their research.<sup>20</sup>

Along with gene patents, diagnostic method patents have been the source of recent controversy.<sup>21</sup> Since 2006 three cases involving diagnostic method patents have reached the Supreme Court of the United States<sup>22</sup> with the potential for another case in the near future.<sup>23</sup> These cases are similar in that the diagnostic method patent in question involves a transformative or quantitative element originating within the human body: amino acid levels in a patient's blood,<sup>24</sup> drug metabolite concentrations,<sup>25</sup> patent immunization on a determined schedule,<sup>26</sup> or cancer cell growth rates in the presence of potential therapeutics.<sup>27</sup>

This Comment will discuss the judicial precedent surrounding diagnostic method claims utilizing scientific breakthroughs in genetic research, with an emphasis on the recent and publicized *Association for Molecular Pathology v. U.S. Patent and Trademark Office* (“*Myriad*”).<sup>28</sup> It will argue that under current patent law, *Myriad* was correctly decided, yet due to critical public policy concerns, the time may have arrived for a reinterpretation of what is considered patent-eligible subject matter. Part II is a brief overview what is considered

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<sup>19</sup> *Id.* at 7.

<sup>20</sup> Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 702 F.Supp.2d 181, 208 (S.D.N.Y. 2010).

<sup>21</sup> Asher Hodes, Note, *Diagnosing Patentable Subject Matter*, 26 BERKELEY TECH. L.J. 225, 230.

<sup>22</sup> Lab. Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 125 (2006) (dismissing writ of certiorari as improvidently granted); Prometheus Laboratories, Inc. v. Mayo Collaborative Services, 581 F.3d 1336 (Fed. Cir. 2009), *vacated*, 130 S.Ct. 3543 (2010), *rev'd*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*, 131 S.Ct. 3027 (U.S. Jun 20, 2011) (No. 10–1150); Classen Immunotherapies, Inc. v. Biogen IDEC, 130 S.Ct. 3541 (2010) (vacating judgment and remanding for further consideration in light of *Bilski v. Kappos*, 130 S.Ct. 3218 (2010)), *aff'd in part, rev'd in part, vacated in part*, 659 F.3d 1057 (Fed. Cir. 2011).

<sup>23</sup> Hodes, *supra* note 21 at 225; Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed*.

<sup>24</sup> *Metabolite Laboratories, Inc.*, 548 U.S. 125 (2006).

<sup>25</sup> *Prometheus*, 581 F.3d at 1347.

<sup>26</sup> Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011).

<sup>27</sup> Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011).

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

patentable under U.S. patent law. Parts III and IV discuss the patentability of DNA and method claims, respectively. Part V is dedicated to a study of the *Myriad* case, which represents the intersection of diagnostic method patents and gene patenting. Part VI analyzes the impact of the *Myriad* decision and the future of diagnostic method patenting.

## II. UNITED STATES PATENT LAW – PATENT ELIGIBLE SUBJECT MATTER

A United States patent confers upon the patentee an exclusive right to the patented invention for twenty years after the date the patent application was filed with the United States Patent and Trademark Office (USPTO).<sup>29</sup> In exchange for this right to exclude, the inventor must publicly disclose the invention through the specification.<sup>30</sup> In order to be patent eligible, the invention must meet several statutory requirements: it must concern patent-eligible subject matter,<sup>31</sup> it must be novel,<sup>32</sup> and it must be non-obvious.<sup>33</sup>

Patent-eligible subject matter is defined by Section 101 of the Patent Act of 1952 as: “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . .”<sup>34</sup> Under Section 100(b) of the Patent Act, “[t]he term ‘process’

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<sup>29</sup> 35 U.S.C. § 154(a)(2) (2011). The patent grants the patent holder “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process. . . .” 35 U.S.C. § 154 (a)(1) (2011).

<sup>30</sup> 35 U.S.C. § 112 (2011). “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” The first and second paragraphs of §112 (above) provide the distinct disclosure requirements for patent protection. This written information is collectively known as the patent specification. *Accord* F. SCOTT KEFF ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 154-55 (Robert C. Clark et al. eds., 5th ed. 2011).

<sup>31</sup> 35 U.S.C. § 101 (2011).

<sup>32</sup> 35 U.S.C. § 102 (2011).

<sup>33</sup> 35 U.S.C. § 103(a) (2011). “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.”

<sup>34</sup> 35 U.S.C. § 101 (2011).

means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”<sup>35</sup> The Supreme Court has interpreted the definition of patent-eligible subject matter as describing “four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter.”<sup>36</sup> The Court has also recognized that Congress intended that the scope of patentable subject matter should be given a broad interpretation.<sup>37</sup> Indeed, one may describe patent-eligible subject matter as “includ[ing] anything under the sun that is made by man.”<sup>38</sup>

There are limitations, however, to what may be considered patent-eligible subject matter. Supreme Court precedent “provides three specific exceptions to § 101’s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’”<sup>39</sup> As the number of patents covering pioneering technologies increases, the courts have struggled to develop a clear framework for determining patent eligibility under § 101, especially when the claimed invention does not produce tangible results, or when public policy concerns call for limiting patentability.<sup>40</sup>

### III. PATENTABILITY OF DNA

The 1980 Supreme Court case *Diamond v. Chakrabarty*<sup>41</sup> held that a live, man-made microorganism was patentable under § 101 as a “manufacture” or “composition of matter.”<sup>42</sup> This proved to be a seminal decision on patentable subject matter, as thousands of patents relating to genes and genetic material have been awarded since this case was decided.<sup>43</sup> In 1983,

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<sup>35</sup> 35 U.S.C. § 100(b) (2011).

<sup>36</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

<sup>37</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (“In choosing such expansive terms . . . modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”).

<sup>38</sup> *Id.* at 309 (quoting the language of the Congressional Committee Reports accompanying the 1952 Patent Act).

<sup>39</sup> *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 309).

<sup>40</sup> Stephen W. Chen, et al., *Patent Protection in Medicine and Biotechnology: An Overview*, 4 J. HEALTH & LIFE SCI. L. 106, 132 (2011).

<sup>41</sup> 447 U.S. 303 (1980).

<sup>42</sup> *Chakrabarty*, 447 U.S. at 303.

<sup>43</sup> Jordan Paradise, *European Opposition to Exclusive Control over Predictive Breast Cancer Testing and the*

the USPTO expanded the scope of patent protection available for genetic material by issuing the first patents relating to “isolated DNA.”<sup>44</sup> In 1991, the CAFC held that claims for a “purified and isolated DNA sequence” were valid and enforceable.<sup>45</sup> The USPTO has adopted this policy regarding the patentability of isolated and purified DNA, acknowledging it as patent eligible because “(1) an excised gene. . . does not occur in that isolated form in nature, or (2) . . . their purified state is different from the naturally occurring compound.”<sup>46</sup>

The Supreme Court has not yet definitively ruled on the patentability of DNA.<sup>47</sup> The closest the Court has come to addressing this issue was in *Laboratory Corp of America Holdings v. Metabolite Laboratories, Inc.* (“LabCorp”).<sup>48</sup> Metabolite Laboratories was the licensee of a patent that claimed methods for detecting vitamin B and folic acid deficiencies in patients.<sup>49</sup> Metabolite sued LabCorp for patent infringement when LabCorp began using a similar test developed by another company and discontinued royalty payments to Metabolite.<sup>50</sup> Specifically, the disputed claim was for a method of “detecting vitamin B deficiencies by measuring amino acid levels in a patient’s blood and then correlating those amino acid levels with vitamin B levels.”<sup>51</sup> LabCorp argued that this claim (claim 13 of Metabolite’s patent) was invalid for a variety of reasons,<sup>52</sup> but did not raise the issue of invalidity under § 101 until their appeal to the

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*Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics’ BRCA Patent Controversy.* 59 FOOD & DRUG L.J. 133, 133 (2004) (“Between 1980 and 2001, the U.S. Patent and Trademark Office (USPTO) awarded over 8,000 patents on genes and genetic material, including at least 1,500 claiming sequences of human genetic material.”).

<sup>44</sup> See U.S. Patent No. 4,680,264 claim 27 (filed July 1, 1983) (claiming a recombinant vector rather than genomic DNA).

<sup>45</sup> Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1219 (Fed. Cir. 1991).

<sup>46</sup> USPTO Examination Guidelines <http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf> (2001).

<sup>47</sup> Petition for Writ of Certiorari, *Ass’n for Molecular Pathology*, 16 (2011).

<sup>48</sup> Lab. Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 125 (2006) (Breyer, JJ., dissenting).

<sup>49</sup> Metabolite Laboratories, Inc. v. Lab. Corp. of America Holdings, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004).

<sup>50</sup> *Metabolite Laboratories, Inc.*, 370 F.3d at 1359.

<sup>51</sup> Hodes, *supra* note 21 at 230; *accord* U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

<sup>52</sup> *Metabolite Laboratories, Inc.*, 370 F.3d at 1365 (“LabCorp argues that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness.”).

Supreme Court.<sup>53</sup> The Supreme Court initially granted certiorari, yet later dismissed it as improvidently granted,<sup>54</sup> perhaps because the lower courts had not yet had an opportunity to rule on that issue. Consequently, the CAFC holding that the disputed claim is valid<sup>55</sup> and that LabCorp infringed the claim<sup>56</sup> is still valid.

#### IV. PATENTABILITY OF METHOD CLAIMS

The Supreme Court has held that a valid process claim cannot claim “laws of nature, natural phenomena, [or] abstract ideas.”<sup>57</sup> For example, an abstract mathematical formula cannot be patented.<sup>58</sup> The Court implemented these restrictions in order to discourage patentees from attempting to claim abstract subject matter by limiting the formula to a specific technology.<sup>59</sup> These restrictions exist in order to prevent preemption, wherein a patent bars all application of a fundamental principle.<sup>60</sup>

##### *A. The Development and Application of the Machine-or-Transformation Test*

In *Gottschalk v. Benson*<sup>61</sup> the Court recognized that the “[t]ransformation and reduction of an article ‘to a different thing’ is the clue to the patentability of a process claim that does not include particular machines.”<sup>62</sup> The Court of Appeals for the Federal Circuit (“CAFC”) later

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<sup>53</sup> Brief for the United States as Amicus Curiae at 15-19, *Lab. Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (No. 04-607), 2005 WL 3533248; *see also Metabolite Laboratories, Inc.*, 548 U.S. at 132 (“Question Three of the petition asks ‘[w]hether a method patent . . . directing a party simply to correlat[e] test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.’”) (citation omitted).

<sup>54</sup> *Metabolite Laboratories, Inc.*, 548 U.S. at 125-26.

<sup>55</sup> *Metabolite Laboratories, Inc.*, 370 F.3d at 1368.

<sup>56</sup> *Id.* at 1365.

<sup>57</sup> *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

<sup>58</sup> *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

<sup>59</sup> *Diehr*, 450 U.S. at 192-93 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula. . . . A mathematical formula as such is not accorded the protection of our patent laws . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.” (citations omitted)).

<sup>60</sup> Tiana Leia Russell, *Unlocking the Genome: The Legal Case Against Genetic Diagnostic Patents*, 16 MARQ. INTELL. PROP. L. REV. 81, 91 (2012).

<sup>61</sup> 409 U.S. 63 (1972).

<sup>62</sup> *Benson*, 409 U.S. at 70.



cited this standard as “a definitive test” for determining patent eligibility of a process claim in *In re Bilski*.<sup>63</sup> The Supreme Court held that the mathematical algorithm was not a “process” but an abstract idea and therefore unpatentable.<sup>64</sup> The Court explained that to hold otherwise “would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”<sup>65</sup>

In *Parker v. Flook*,<sup>66</sup> the Court established “that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable.”<sup>67</sup> However, the Court explained in *Diamond v. Diehr* that claims containing mathematical formulas which are tied to a valid application of a natural phenomenon or abstract idea may be patentable as a whole.<sup>68</sup> Under *Diehr*, when a claim contains a fundamental principle (such as a mathematical formula, natural phenomenon, or scientific principle), “an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract.”<sup>69</sup> In other words, although the entire claim must be considered when determining patentability, “the inventive concept cannot derive solely from the fundamental principle.”<sup>70</sup>

In *Bilski v. Kappos*<sup>71</sup> the CAFC drew on Supreme Court case law to articulate a two-prong “definitive test” for determining process patent eligibility. The court determined that “[a]

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<sup>63</sup> *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (“The Supreme Court, however, has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”).

<sup>64</sup> *Benson*, 409 U.S. at 71.

<sup>65</sup> *Id.* at 72.

<sup>66</sup> 437 U.S. 584 (1978).

<sup>67</sup> *Bilski*, 130 S. Ct. at 3231.

<sup>68</sup> *Diehr*, 450 U.S. at 192 (“[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e. g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101.”).

<sup>69</sup> *Id.* 450 U.S. at 191.

<sup>70</sup> Russell, *supra* note 60 at 81.

<sup>71</sup> 130 S. Ct. 3218 (2010).

claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”<sup>72</sup> A patentee need only show the process claim satisfies one of the two prongs to patent-eligible.<sup>73</sup> Following the analysis of *Benson*, *Flook*, and *Diehr*, the CAFC explained that “the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope to impart patent-eligibility,” and “the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.”<sup>74</sup> Essentially, the purpose of the claimed process must be the transformation of the article.<sup>75</sup>

The claimed invention at issue in *Bilski v. Kappos* involved a method of protecting buyers and sellers of commodities in the energy market against the risk of price changes.<sup>76</sup> The CAFC framed the issue as determining what “process” means as defined in § 101, and how to establish whether a particular claim is a “new and useful process.”<sup>77</sup> The CAFC concluded that the “machine-or-transformation test” was “the sole test for governing § 101 analyses”<sup>78</sup> and thus was the “test for determining patent eligibility of a process under § 101.”<sup>79</sup> Applying the machine-or-transformation test, the CAFC held the application at issue was not patentable as it satisfied neither the machine<sup>80</sup> nor transformation<sup>81</sup> prong of the test.

The Supreme Court granted certiorari to clarify the proper use of the machine-or-transformation test. According to the Court, the CAFC “incorrectly concluded that this Court

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<sup>72</sup> In re *Bilski*, 545 F.3d 943, 953 (Fed. Cir. 2008).

<sup>73</sup> *Id.* at 961.

<sup>74</sup> *Id.* at 961-62 (citations omitted).

<sup>75</sup> *Id.* at 962.

<sup>76</sup> *Bilski*, 130 S. Ct. at 3223.

<sup>77</sup> In re *Bilski*, 545 F.3d 943, 951 (Fed. Cir. 2008).

<sup>78</sup> *Id.* at 955.

<sup>79</sup> *Id.* at 956.

<sup>80</sup> *Id.* at 962 (“As to machine implementation, Applicants themselves admit that the language of claim 1 does not limit any process step to any specific machine or apparatus.”).

<sup>81</sup> *Id.* at 963 (“We hold that the Applicants’ process as claimed does not transform any article to a different state or thing.”).

has endorsed the machine-or-transformation test as the exclusive test.”<sup>82</sup> Rather, the Court categorized the test as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.”<sup>83</sup> The Court explained that while the machine-or-transformation test may work well for determining patentability of physical or tangible inventions, it would “create uncertainty” as to the patentability of more complex subject matter.<sup>84</sup> The Court warned that too narrow a test might render newer and more nuanced technologies unpatentable.<sup>85</sup> Interestingly, the CAFC recognized such an issue in its own analysis of the *Bilski* case, and predicted the Supreme Court expanding the patentability test in the future.<sup>86</sup> The Court ultimately affirmed the decision of the CAFC, holding the claims unpatentable as abstract ideas, yet the Court did so by confining its analysis to the principles established in *Benson*, *Flook*, and *Diehr*.<sup>87</sup> Under these cases, to determine if a patent is preemptive, “the key consideration is whether the patent threatens to (a) wholly preempt the fundamental principle or (b) be the only practical and useful application of the principle.”<sup>88</sup>

### *B. Patentability of Diagnostic Method Claims*

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<sup>82</sup> *Bilski*, 130 S. Ct. at 3226 (2010).

<sup>83</sup> *Id.* at 3227.

<sup>84</sup> *Id.* (“[T]he machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals.”).

<sup>85</sup> *Id.* (“In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain.”).

<sup>86</sup> *In re Bilski*, 545 F.3d at 956 (“[W]e agree that future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade. Thus, we recognize that the Supreme Court may ultimately decide to alter or perhaps even set aside this test to accommodate emerging technologies. And we certainly do not rule out the possibility that this court may in the future refine or augment the test or how it is applied. At present, however, and certainly for the present case, we see no need for such a departure and reaffirm that the machine-or-transformation test, properly applied, is the governing test for determining patent eligibility of a process under § 101.”).

<sup>87</sup> *Bilski*, 130 S. Ct. at 3229-30 (“Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court’s decisions in *Benson*, *Flook*, and *Diehr*, which show that petitioner’s claims are not patentable processes because they are attempts to patent abstract ideas.”).

<sup>88</sup> Russell, *supra* note 60 at 81.

There are three types of process patents typically related to the medical field: (1) medical procedures that do not require the use of any patented medical products, (2) methods for using a patented drug or device, and (3) techniques for isolating chemical compounds or building devices.<sup>89</sup> In 2009, the CAFC upheld the validity of two method patents owned by Prometheus Laboratories, Inc. (Prometheus).<sup>90</sup> The patents claim methods for optimizing the proper dosage of thiopurine drugs, which are used to treat both gastrointestinal and non-gastrointestinal autoimmune diseases.<sup>91</sup> The Prometheus patents involve a process for the measurement of two metabolites in order to “optimize therapeutic efficacy while minimizing toxic side effects.”<sup>92</sup> The patents contain two separate steps: “administering” a drug . . . to a patient, and “determining” the levels of drug metabolites . . . in the patient.<sup>93</sup> The measured metabolite levels are then compared to a range of metabolite concentration contained in the claims, “‘wherein’ the measured metabolite levels ‘indicate a need’ to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize efficacy of the treatment.”<sup>94</sup>

Prometheus marketed a test that used the technology described in the patents.<sup>95</sup> In 2004 Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) announced it would be selling

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<sup>89</sup> Margaret Kubick, Note, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INTELL. PROP. 280, 14, (2010).

<sup>90</sup> *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 581 F.3d 1336 (Fed. Cir. 2009).

<sup>91</sup> *Prometheus*, 581 F.3d at 1339; U.S. Patent No. 6,355,623 (filed Apr. 8, 1999) (describing a “[m]ethod of treating IBD/Crohn’s disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage”); U.S. Patent No. 6,680,302 (filed Dec. 27, 2001) (describing “[m]ethods of optimizing drug therapeutic efficacy for treatment of immune-mediated gastrointestinal disorders”).

<sup>92</sup> *Prometheus*, 581 F.3d at 1339.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* (quoting language from the patents at issue. Claim 1 of U.S. Patent No. 6,355,623 is representative of the claims asserted by Prometheus: “A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.”)

<sup>95</sup> *Id.* at 1340.

its own test, which measured the same metabolites as the Prometheus test, but used different metabolite levels to determine toxicity.<sup>96</sup> Prometheus sued Mayo for patent infringement.<sup>97</sup> The District Court for the Southern District of California granted Mayo’s motion for summary judgment of invalidity under § 101, finding that “the ‘administering’ and ‘determining’ steps are merely necessary data-gathering steps for any use of the correlations and that as constructed, the final step . . . is only a mental step.”<sup>98</sup>

On appeal the CAFC began its analysis by reviewing the machine-or-transformation test for process patent eligibility under § 101 it had recently utilized in the *Bilski* decision.<sup>99</sup> It held that the method of treatment claims were patentable subject matter as it satisfied the transformation prong of the test.<sup>100</sup> The court reasoned that the transformative step in the process was when the body metabolized the administered drug.<sup>101</sup> The fact that the change of the administered drug into therapeutic metabolites relied on natural process was not dispositive, for “quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law.”<sup>102</sup> The CAFC likewise found the determining steps transformative, as the levels of metabolite could not be ascertained without some form of manipulation or modification of the bodily sample to determine the concentration of the metabolites therein.<sup>103</sup> The court then concluded that the “administering” and “determining” steps were essential to the claimed process, and therefore were not merely data-gathering or

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

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

<sup>98</sup> *Prometheus*, 581 F.3d at 1341 (internal quotations omitted).

<sup>99</sup> *Id.* at 1342-43.

<sup>100</sup> *Id.* at 1344.

<sup>101</sup> *Id.* at 1346 (“The drugs do not pass through the body untouched without affecting it. In fact, the transformation that occurs, *viz.*, the effect on the body after metabolizing the artificially administered drugs, is the entire purpose of administering the drugs: the drugs are administered to provide 6-TG, which is thought to be the drugs’ active metabolite in the treatment of the disease, to a subject.”).

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

<sup>103</sup> *Prometheus*, 581 F.3d at 1347.

“insignificant extra-solution activity.”<sup>104</sup> The CAFC agreed with the district court that the “wherein” clauses of the claims were mental steps, but this did not render the entire process unpatentable.<sup>105</sup> The CAFC emphasized that the entire claimed process must be viewed as a whole.<sup>106</sup> Finally, the CAFC disagreed with the finding of the district court that the claims wholly preemptive of the correlations between metabolite levels and toxicity or efficacy.<sup>107</sup> The CAFC returned to the machine-or-transformation test,<sup>108</sup> and determined that “[t]he inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment.”<sup>109</sup>

Following the CAFC ruling the Supreme Court granted certiorari, vacated the judgment in light of its *Bilski* decision, and remanded the case back down to the CAFC for further consideration.<sup>110</sup> On remand the CAFC requested briefs from both parties addressing the effect of the *Bilski* decision the case at bar.<sup>111</sup>

The second *Prometheus* opinion follows a similar line of reasoning to the first opinion, despite the additional guidance from the *Bilski* decision. The CAFC recognized that in light of *Bilski*, the issue of patent eligibility turned on whether the Prometheus claims were drawn to a natural phenomenon, which would result in complete preemption if patented, or “whether the claims were drawn only to a particular application of that phenomenon, as in *Diehr*.”<sup>112</sup> According to the CAFC, the *Bilski* decision did not impose a “wholly different analysis or a

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<sup>104</sup> *Id.* at 1348.

<sup>105</sup> *Id.* (“A subsequent mental step does not, but itself, negate the transformative nature of prior steps.”).

<sup>106</sup> *Id.* at 1349.

<sup>107</sup> *Id.*

<sup>108</sup> *Prometheus*, 581 F.3d at 1349 (“[B]ecause the claims meet the machine-or-transformation test, they do not preempt a fundamental principle.”).

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

<sup>110</sup> *Prometheus*, 130 S. Ct. 3543 (2010).

<sup>111</sup> *Prometheus*, F.3d at 1353.

<sup>112</sup> *Id.* at 1354.

different result on remand.”<sup>113</sup> The *Bilski* decision served only to correct the CAFC’s original presumption that the machine-or-transformation test was the exclusive test for process patentability.<sup>114</sup> As a result, the CAFC once again held the diagnostic claims as patentable under § 101, using much of the same analysis as in the original opinion.<sup>115</sup>

The Supreme Court again granted certiorari in June 2011,<sup>116</sup> which seemingly indicates the CAFC misinterpreted the lesson of *Bilski*. On remand, Mayo argued that the *Bilski* decision “reaffirmed that preemption is the controlling standard for § 101” under Supreme Court precedent, and “made clear that while a machine-or-transformation test may inform the analysis, the test is not outcome determinative.”<sup>117</sup> Mayo maintains that Prometheus’s claims are invalid as preempting all practical use of a natural phenomenon, and that the claims satisfy the machine-or-transformation test “is merely insignificant post-solution activity.”<sup>118</sup>

#### V. *MYRIAD*: INTERSECTION OF DIAGNOSTIC METHOD PATENTS AND GENETIC TESTING

The *Myriad* case is especially compelling because it is an amalgamation of diagnostic method and gene patents. Myriad Genetics held seven U.S. patents regarding two isolated human genes (BRCA1 and BRCA2), mutations of which were associated with a predisposition to breast and ovarian cancers.<sup>119</sup> The Myriad patents originated with an international research initiative focused on breast cancer research. Several European and American research laboratories founded the Breast Cancer Linkage Consortium (Consortium) in 1989 to promote the open exchange of data and ideas with the expressed goal of discovering the genetic basis of

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<sup>113</sup> *Id.* at 1355.

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

<sup>115</sup> *Id.* (“Thus, the Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the ‘useful and important clue, an investigative tool,’ leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101. They do not encompass laws of nature or preempt natural correlations.”).

<sup>116</sup> *Prometheus*, 131 S. Ct. 3027.

<sup>117</sup> *Prometheus*, 628 F.3d at 1354.

<sup>118</sup> *Id.*

<sup>119</sup> *Ass’n for Molecular Pathology*, 653 F.3d at 1334.

breast cancer.<sup>120</sup>

In 1990 a team from the Consortium localized the BRCA1 gene.<sup>121</sup> A year later another member of the Consortium, Mark Skolnick from the University of Utah, founded Myriad Genetics in order to capitalize on the research once the complete gene was sequenced.<sup>122</sup> Myriad successfully cloned and sequenced the BRCA1 gene in 1994.<sup>123</sup> In the United Kingdom in 1994, the Institute of Cancer Research localized the BRCA2 gene.<sup>124</sup> It was further characterized by Myriad.<sup>125</sup>

Beginning in 1995, Myriad sought U.S. patent protection for the isolated BRCA1/2 genes as well as methods of diagnostic testing for the genetic mutations contained therein.<sup>126</sup> The European Patent Office (EPO) granted Myriad and co-inventors several patents based on these genes.<sup>127</sup> The method claims patented by Myriad have been divided into two categories: method for “comparing” and “analyzing” DNA sequences,<sup>128</sup> and method for screening potential cancer therapeutics through changes in cell growth rates.<sup>129</sup> The second type of claim is found in patent 5,747,282 (the ‘282 patent) and is directed to “a method for identifying potential cancer therapeutics by utilizing cells into which an altered BRCA1 gene known to cause cancer has

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<sup>120</sup> Paradise, *supra* note 15 at 143.

<sup>121</sup> Matthijs & Van Ommen, *supra* note 4 at 319; Paradise, *supra* note 81, at 143.

<sup>122</sup> Matthijs & Van Ommen, *supra* note 4 at 320.

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

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> U.S. Patent No. 5,747, 282 (filed June 7, 1995) (claiming “[a]n isolated DNA coding for a BRCA 1 polypeptide. . . .” and “a method for screening potential cancer therapeutics” using “an BRCA 1 gene. . . .”); U.S. Patent No. 5,837,492 (filed Apr. 29, 1996) (claiming “[a]n isolated DNA molecule coding for a BRCA2 polypeptide. . . .”); U.S. Patent No. 5,693,473 (filed June 7, 1995) (claiming “[a]n isolated DNA comprising an altered BRCA1 DNA. . . .”); U.S. Patent No. 5,709,999 (filed June 7, 1995) (claiming “[a] method for detecting a germline alteration in a BRCA1 gene. . . .”); U.S. Patent No. 5,710,001 (filed June 7, 1995) (claiming “[a] method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor. . . .”); U.S. Patent No. 5,753,441 (filed Jan. 5, 1996) (claiming “[a] method for screening germline of a human subject for an alteration of a BRCA1 gene. . . .”); U.S. Patent No. 6,033,857 (filed Mar. 20, 1998) (claiming “A method for identifying a mutant BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele. . . .”).

<sup>127</sup> Matthijs & Van Ommen, *supra* note 4 at 320.

<sup>128</sup> *Ass’n for Molecular Pathology*, 653 F.3d at 1355.

<sup>129</sup> *Id.* at 1357.



been inserted.”<sup>130</sup> The growth rates of the artificial cancer cells are compared to determine the efficacy of a potential cancer therapeutic.<sup>131</sup>

In 2009 the ACLU brought suit against Myriad Genetics on behalf of several medical organizations, researchers, genetic counselors, and patients to challenge the patentability of fifteen composition and method claims in U.S. patents relating to human genetics.<sup>132</sup> The ACLU charged that the Myriad patent claims were invalid as covering “products of nature, laws of nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought.”<sup>133</sup>

The Southern District of New York held that the patents claiming at isolated DNA sequences, as well as the patents claiming comparisons of DNA sequences, were unpatentable under § 101.<sup>134</sup> On appeal, the CAFC majority reversed the district court’s holding that isolated DNA is unpatentable under § 101.<sup>135</sup> However, each member of the three-panel judge wrote a separate opinion on this issue.<sup>136</sup> While a great deal of the attention surrounding this case has been focused on the claims regarding the patentability of DNA,<sup>137</sup> due to the recent controversy generated by such patents, the CAFC’s conclusions regarding the patentability of Myriad’s

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<sup>130</sup> *Id.* at 1337; *See also* U.S. Patent No. 5,747, 282 (filed June 7, 1995) (claiming specifically “A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.”).

<sup>131</sup> *Ass’n for Molecular Pathology*, 702 F.Supp.2d at 237.

<sup>132</sup> *Ass’n for Molecular Pathology*, 653 F.3d at 1333-34; Joshua D. Sarnoff, *Patent Eligible Medical and Biotechnology Inventions after Bilski, Prometheus, and Myriad*, 19 TEX. INT’L PROP. L.J. 393, 408 (2011).

<sup>133</sup> *Ass’n for Molecular Pathology*, 702 F.Supp.2d at 184.

<sup>134</sup> *Id.* at 185.

<sup>135</sup> *Ass’n for Molecular Pathology*, 653 F.3 at 1350.

<sup>136</sup> *See generally id.* at 1350 (concluding that claims relating to isolated DNA are patent-eligible subject matter under § 101, regardless of limitation to cDNA or not); *id.* at 1361 (Moore, J., concurring-in-part) (emphasizing certain chemical considerations of particular importance); *id.* at 1373 (Bryson, J., concurring-in-part and dissenting-in-part) (finding isolated DNA claims not directed to patentable subject matter).

<sup>137</sup> *E.g.*, Gene Quinn, *As Predicted, Federal Circuit Rule Isolated DNA Patentable*, IPWatchdog (July 29, 2011, 2:12 PM), <http://ipwatchdog.com/2011/07/29/federal-circuit-rules-isolated-dna-patentable/id=18487/>; *Federal Circuit: Isolated Human DNA Molecules are Patentable*, Patently-O (July 29, 2011, 12:32 PM), <http://www.patentlyo.com/patent/2011/07/federal-circuit-isolated-human-dna-molecules-are-patentable.html>.

diagnostic method claims deserve attention as well.<sup>138</sup>

The CAFC affirmed the district court's ruling that the "comparing" and "analyzing" claims were unpatentable under § 101.<sup>139</sup> The CAFC found that the claims were drawn to "the abstract mental process of comparing two nucleotide sequences" and declined to extend Myriad's claims to include the extraction and sequencing steps of DNA preparation prior to analysis.<sup>140</sup> The CAFC distinguished its earlier *Prometheus* decision, which held that the claims at issue contained transformative steps as written, and the "determining" step of the claims "was both transformative and central to the purpose of the claims."<sup>141</sup> In contrast, the CAFC found the Myriad claims did not include a determinative, gene sequencing step.<sup>142</sup> The comparison between gene sequences could be accomplished by inspection alone.<sup>143</sup>

However, the CAFC disagreed with the district court regarding the patentability of the second type of method claim at issue (the '282 patent). Again the CAFC referenced its *Prometheus* decision when analyzing the Myriad claim.<sup>144</sup> The court found that the claim included the transformative steps of: "(1) 'growing' host cells transformed with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic, (2) 'determining' the growth rate of the host cell with or without the potential therapeutic, and (3) 'comparing' the growth rate of the host cells."<sup>145</sup> These steps were found to be "central to the purpose of the

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<sup>138</sup> Hodes, *supra* note 21 at 230.

<sup>139</sup> *Id.* at 1357.

<sup>140</sup> *Id.* ("The claims do not specify any action prior to the step of 'comparing' or 'analyzing' two sequences; the claims recite just the one step of 'comparing' or 'analyzing.' Moreover, those terms' plain meaning does not include Myriad's proposed sample-processing steps; neither comparing nor analyzing means or implies 'extracting' or 'sequencing' DNA or otherwise 'processing' a human sample.").

<sup>141</sup> *Id.*

<sup>142</sup> *Ass'n for Molecular Pathology*, 653 F.3d at 1357.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

claimed process.”<sup>146</sup> The court further determined that the claims were narrow enough to avoid preempting a natural phenomenon.<sup>147</sup> This claim was held to concern patentable subject matter under §101.<sup>148</sup>

## VI. IMPACT OF MYRIAD AND THE FUTURE OF GENETIC DIAGNOSTIC METHOD CLAIMS

Since *Prometheus* was relied upon so heavily for both CAFC *Myriad* opinions, the forthcoming Supreme Court *Prometheus* ruling is likely to impact the *Myriad* line of cases and subsequent diagnostic patent cases.<sup>149</sup> It has been suggested that the Court’s continued involvement in the *Prometheus* line of cases indicates that the machine-or-transformation test is not the appropriate method for determining patentability of diagnostic method claims.<sup>150</sup> Some insight as to how the Supreme Court may analyze *Prometheus* can be found in the dissenting opinion of Justice Breyer in *LabCorp*.<sup>151</sup> Justice Breyer, joined by Justices Stevens and Souter, dissented from the dismissal after cert had originally been granted.<sup>152</sup> In his opinion, Justice Breyer stated he would have held the disputed claim (methods for detecting vitamin B and folic acid deficiencies in patients) invalid as patenting a natural phenomenon.<sup>153</sup> According to Justice Breyer, the claimed process “is no more than an instruction to read some numbers in light of medical knowledge.”<sup>154</sup> As Justice Breyer’s opinion is not a majority ruling, it has no binding

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<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 1358 (“The claim does not cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound. Rather, it is tied to specific host cells transformed with specific genes and grown in the presence or absence of a specific type of therapeutic. Moreover, the claim is tied to measuring a therapeutic effect on the cells solely by changes in the cells’ growth rate.”).

<sup>148</sup> *Ass’n for Molecular Pathology*, 653 F.3d at 1358

<sup>149</sup> Jacob D. Moore, Note, *The Forgotten Victim in the Human Gene Patenting Debate: Pharmaceutical Companies*, 63 FLA. L. REV. 1277, 1287 (suggesting that the viability of *Myriad*’s method claims remains unresolved until a Supreme Court opinion in *Prometheus*).

<sup>150</sup> *Id.* at 1287.

<sup>151</sup> *Metabolite Laboratories Inc.*, 548 U.S. at 125.

<sup>152</sup> *Id.*

<sup>153</sup> *Id.* at 138.

<sup>154</sup> *Id.* at 137.

effect up on lower courts.<sup>155</sup> Indeed, the CAFC has rejected or declined to discuss his reasoning.<sup>156</sup>

Oral arguments at the Supreme Court for *Prometheus* seemed to focus on the issue of preemption.<sup>157</sup> The Court must consider the line between natural phenomena and patentable subject matter: how much “application” must there be to a law of nature to a particular process before it is deemed patentable?<sup>158</sup> The decision is expected to be close,<sup>159</sup> and more likely to provide additional guidance in light of specific circumstances of future cases than a definitive legal principle.

Whatever the outcome of *Prometheus* is, it will impact the developing doctrine of medical diagnostic patents. This is an important and controversial area of law, potentially affecting scientific research and patient care as it relates to human genetics.<sup>160</sup> However, even if the *Prometheus* decision invalidates the diagnostic method claims at issue in *Myriad*, other laboratories will still be unable to complete diagnostic testing using the BRCA1/2 genes, as the patents covering the genes themselves are still valid, and will potentially remain so until the Supreme Court hears the *Myriad* case.<sup>161</sup>

#### A. Policy Impact

Although Justice Breyer’s *LabCorp* opinion<sup>162</sup> has no binding effect upon lower courts,

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<sup>155</sup> *Prometheus*, 581 F.3d at 1350 n.3; *Prometheus*, 628 F.3d at 1356 n.2.

<sup>156</sup> *Prometheus*, 581 F.3d at 1350 n.3; *Prometheus*, 628 F.3d at 1356 n.2.

<sup>157</sup> Jonas Anderson, *Summary of Mayo v. Prometheus Oral Argument*, Patently-O (Dec. 8, 2011, 11:25 AM), <http://www.patentlyo.com/patent/2011/12/summary-of-mayo-v-prometheus-oral-argument.html>.

<sup>158</sup> *Id.*

<sup>159</sup> Denise W. DeFranco, *Mayo v. Prometheus Guest Post: The Hot-Button Issues*, Patently-O (Dec. 11, 2011, 12:57 PM), <http://www.patentlyo.com/patent/2011/12/mayo-v-prometheus-guest-post-the-hot-button-issues.html>.

<sup>160</sup> Paradise, *supra* note 15 at 134.

<sup>161</sup> *Supreme Court: No Move Yet on Denying Human Gene Patents*, Patently-O (Feb. 21, 2012, 12:42 PM), <http://www.patentlyo.com/patent/2012/02/supreme-court-no-move-yet-on-denying-human-gene-patents.html> (noting the link between the *Prometheus* decision and the *Myriad* case).

<sup>162</sup> *Metabolite Laboratories, Inc.*, 548 U.S. 124 (Breyer, JJ., dissenting).

the public policy arguments it discussed have been referenced in the *Bilski*,<sup>163</sup> and *Myriad II*<sup>164</sup> opinions. Justice Breyer felt it was the Court's provision to "contribute to the important ongoing debate, among both specialists and generalists, as to whether the patent system, as currently administered and enforced, adequately reflects the 'careful balance' that 'the federal patent laws . . . embod[y].'"<sup>165</sup> Breyer recognized that patent restrictions may impact the ability of doctors to provide optimal medical care, divert resources from providing medical care in order to avoid patent infringement, and increase the cost of health care.<sup>166</sup>

Experts have argued that the machine-or-transformation test as put forth in *Bilski* is not well-suited for determining the patentability of the types of diagnostic and genetic testing methods that are increasingly used in modern medicine.<sup>167</sup> Perhaps the Supreme Court will modify the machine-or-transformation test, or disseminate a new test more suited for this type of application when it announces its *Prometheus* decision in the near future.

The courts have made repeated calls to Congress to address method claim patentability through legislation. One of the reasons Justice Breyer felt the Supreme Court should hear the *Laboratory Corp.* case was to "help Congress determine whether legislation is needed."<sup>168</sup> Under the current law, medical practitioners who perform a patented medical or surgical procedure on the body will not be held liable for patent infringement.<sup>169</sup> This exemption does not apply to the use of patented pharmaceuticals or machines, or "biotechnology," though the

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<sup>163</sup> *Bilski*, 130 S. Ct. 3218 (Stevens, JJ., concurring) (referencing the argument that patents may inhibit research by increasing costs and discourage the free exchange of information.).

<sup>164</sup> *Ass'n for Molecular Pathology*, 653 F.3d at 1380 (Bryson, J., dissenting).

<sup>165</sup> *Metabolite Laboratories, Inc.*, 548 U.S. at 138 (Breyer, JJ., dissenting) (citation omitted).

<sup>166</sup> *Metabolite Laboratories, Inc.*, 548 U.S. at 138 (Breyer, JJ., dissenting).

<sup>167</sup> Brian P. Murphy and Daniel P. Murphy, *Bilski's "Machine-or-Transformation" Test Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 780 (2010).

<sup>168</sup> *Metabolite Laboratories, Inc.*, 548 U.S. at 138 (Breyer, JJ., dissenting).

<sup>169</sup> 35 U.S.C. §287(c) (2011).

term “biotechnology” is not defined in the statute.<sup>170</sup> One option may be for Congress to provide a definition of “biotechnology” that includes all patents relating to genetic sequencing. Another may be to provide an exemption for diagnostic testing similar to the “medical or surgical procedure” currently existing.

There is evidence that Congress taking note of these issues. On September 16, 2011, President Obama signed the Leahy-Smith America Invents Act into law. The Act provides for substantial changes to the Patent office,<sup>171</sup> including a provision requiring the Director of the USPTO to conduct a study “on effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist.”<sup>172</sup> The directives for the study appear to address many of the concerns raised by the plaintiffs in *Myriad* regarding the impact of genetic diagnostic tests.<sup>173</sup> Depending on the outcome of this study, future legislation may be enacted directly concerning these tests. If Congress feels that patents on “genetic diagnostic tests” are detrimental to patient health, then it is up to Congress to pass legislation as an appropriate remedy.

### 1. Arguments against the patentability of diagnostic method patents

Some critics of gene patenting argue that gene patenting is akin to a “land grab” over a

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

<sup>171</sup> Press Release, The White House, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011) (<http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim>).

<sup>172</sup> Leahy-Smith American Invents Act, Pub. L. No. 112-29, § 27, 125 Stat. 284 (2011).

<sup>173</sup> Leahy-Smith American Invents Act, Pub. L. No. 112-29, § 27(b)(1)-(4), 125 Stat. 284 (2011) (“(b) ITEMS INCLUDED IN STUDY.--The study shall include an examination of at least the following: (1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses. (2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test. (3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures. (4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.”).

finite number of human genes.<sup>174</sup> Once the entire human genome has been isolated and patented, researchers and doctors cannot legally utilize the patented genes without permission (in the form of a license) from the patent holder. There is a fear that this will result in high costs on future innovators and the underuse of genetic information, which will stunt further research.<sup>175</sup>

A gene patent grant to a biotechnology firm or organization will exclude many others who initially worked on the research leading to the patented test.<sup>176</sup> This policy is often counter to the spirit of scientific research.<sup>177</sup> The Breast Cancer Linkage Consortium invited membership to any researcher willing to share results from his or her studies.<sup>178</sup> The Human Genome Project openly disseminated the completed gene sequences as soon as they were completed.<sup>179</sup> Much of the information used by Myriad was already in the public domain because of these kinds of policies.<sup>180</sup>

Several of the plaintiffs represented by the ACLU in the *Myriad* cases are patients who wish to obtain the BRCA1/2 genetic testing, but are unable to afford the test.<sup>181</sup> Due to the exclusionary nature of a patent grant, owners of a patent are able to have almost a monopolistic control over the patented subject matter.<sup>182</sup> This concept is especially evident in genetic testing “because either there is no way to ‘invent around’ and put similar products on the market, or

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<sup>174</sup> Beyan & Jensen, *supra* note 6.

<sup>175</sup> *Id.*

<sup>176</sup> Matthijs & Van Ommen, *supra* note 4 at 323 (“Allowing patent protection to only one organisation tends to ignore and disregard in terms of IP rights the contribution of all the other collaborators.”).

<sup>177</sup> *Id.* at 322-323.

<sup>178</sup> Paradise, *supra* note 15 at 143.

<sup>179</sup> Nat’l Human Genome Research Inst., Nat’l Institutes of Health, *The Human Genome Project Completion: Frequently Asked Questions*, <http://www.genome.gov/11006943> (last updated Oct. 30, 2010) (“Every part of the genome sequenced by the Human Genome Project was made public immediately - in fact, new data on the genome is posted every 24 hours.”).

<sup>180</sup> Paradise, *supra* note 15 at 143; see, e.g., Yoshio Miki, et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, *Science*, 66, Oct. 1994, <http://www.sciencemag.org/content/266/5182/66.full.pdf>.

<sup>181</sup> *Ass’n for Molecular Pathology*, 702 F.Supp.2d at 188-90.

<sup>182</sup> Rebecca S. Eisenberg, *Genomic Patents and Product Development Incentives*, in *HUMAN DNA: LAW AND POLICY INTERNATIONAL AND COMPARATIVE PERSPECTIVES* 373, 374 (Bartha Maria Knoppers ed., 1997).

because the diagnostic laboratories lack the power (i.e. a patent portfolio or a suitable substitute for the diagnostic test) to negotiate reasonable conditions.”<sup>183</sup> This has led to inflation in the cost of Myriad’s test.<sup>184</sup>

Myriad has likewise impeded patient access to the BRCA1 and BRCA2 genetic test, as it did not license the test or did not do so at terms acceptable to laboratories.<sup>185</sup> Consequently “all the tests would have to be performed in its own laboratories in Utah.”<sup>186</sup> In the United States, gene patent holders have successfully deterred other laboratories from performing diagnostic tests out of fear of patent infringement lawsuits.<sup>187</sup> A major concern is that doctors and patients can no longer obtain second opinions on tests that can carry considerable medical implications, such as breast or ovarian cancer.<sup>188</sup>

The Myriad patents have also inhibited the development of new tests for BRCA1 and BRCA2 gene mutations.<sup>189</sup> The quality of the diagnostic test may be impacted by the *Myriad* decision. Different mutations in the BRCA1 and BRCA2 genes were found by different laboratories using many different testing techniques.<sup>190</sup> “When only a single lab offers a given test it is impossible to apply the ‘gold standard’ of quality assurance--proficiency testing--which requires analysis of the same sample by more than one provider.”<sup>191</sup> Without the collaborative effort of many resources, the further progression of diagnostic genetic tests is restricted.

## 2. Arguments for Diagnostic Patents

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<sup>183</sup> Matthijs & Van Ommen, *supra* note 4 at 321.

<sup>184</sup> Crichton, *supra* note 16 (“[A] test for breast cancer that could be done for \$1,000 now costs \$3,000.”).

<sup>185</sup> Matthijs & Van Ommen, *supra* note 4 at 320.

<sup>186</sup> *Id.*

<sup>187</sup> *Id.* at 321.

<sup>188</sup> Rochelle P. Dreyfuss & James P. Evans, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1366 (2011).

<sup>189</sup> Matthijs & Van Ommen, *supra* note 4 at 321 (“[R]egrettably, more than ten years were lost for the development of novel technologies applied to BRCA.”)

<sup>190</sup> *Id.* at 322.

<sup>191</sup> Dreyfuss & Evans, *supra* note 188 at 1366.



Proponents of diagnostic method patenting emphasize that the purpose of the U.S. patent system is to encourage commercial development of new technologies.<sup>192</sup> The right of exclusion afforded a patent owner “is how patents motivate firms to invest in [research and development], an investment that might be unprofitable if free riders were permitted to enter the market for new technologies that prove unsuccessful without having shared in the initial cost and risk.”<sup>193</sup>

During the *Myriad* cases, the ACLU launched a high-profile campaign that attracted media attention to a polarizing issue.<sup>194</sup> However, some would argue that the ACLU concerns are exaggerated: “Generally speaking, published statements criticizing human gene patents tend to provide little documented evidence of specific instances where such fears have actually manifested themselves.”<sup>195</sup> While patents do convey a right to exclude, that right is not self-enforcing.<sup>196</sup> A patent is only restrictive when the patent owner successfully brings an action for patent infringement.<sup>197</sup>

Advocates of genetic method patents may find support in the current practices of the USPTO. The USPTO allows for certain patent applications to be made “special” which enables an application to be examined earlier.<sup>198</sup> Among the criteria for making a patent application eligible for “special” status are applications relating to the treatment and cure for HIV/AIDS and cancer.<sup>199</sup> One could argue that the diagnostic patents allowed to Myriad Genetics (method of

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<sup>192</sup> Eisenberg, *supra* note 182 at 373.

<sup>193</sup> *Id.* at 374.

<sup>194</sup> Lauren M. Dune, Note, “Come, Let us Return to Reason”: *Association of Molecular Pathology v. USPTO*, 20 DePaul J. Art, Tech. & Intell. Prop. L. 473, 475 (2010); see also Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, <http://www.nytimes.com/2007/02/13/opinion/13crichton.html> (“For years we’ve been promised the coming era of personalized medicine — medicine suited to our particular body makeup. Gene patents destroy that dream.”)

<sup>195</sup> Holman, Christopher M., *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 299 (2007).

<sup>196</sup> *Id.* at 305.

<sup>197</sup> *Id.*

<sup>198</sup> MANUAL OF PATENT EXAMINING PROCEDURE § 708.02(X) (8th ed. 2001) (“New applications ordinarily are taken up for examination in the order of their effective United States filing dates.”).

<sup>199</sup> *Id.* (“In view of the importance of developing treatments and cures for HIV/AIDS and cancer and the desirability

seeking potential cancer therapies) are akin to the patent applications afforded special status at the USPTO. Determining the genetic cause of serious diseases could lead to breakthroughs in treatments. Early detection of genetic predisposition for certain forms of cancer will aid doctors in effectively counseling their patients.<sup>200</sup> It follows then, that the USPTO finds value in granting patent protection to inventions relating to ameliorating debilitating and serious diseases.

*B. Analysis in Myriad affecting genetic method patents*

Both the ACLU and Myriad Genetics independently petitioned the CAFC for rehearing following the decision.<sup>201</sup> Both requests were denied, leaving certiorari by the Supreme Court as the only option remaining for either party.<sup>202</sup> The Supreme Court may vacate the CAFC ruling and remand for reconsideration in light of its decision in *Prometheus*, as it did for *Prometheus* after *Bilski*. Many believe it is highly likely that the Supreme Court will hear a case involving the DNA composition claims, and such a case would invariably impact the related method claims.<sup>203</sup> The ACLU has filed a petition for a writ of certiorari asking the Court to address whether or not human genes are patentable.<sup>204</sup> The Court has deferred deciding whether or not to grant the writ of certiorari, perhaps due to the potential influence the pending *Prometheus* opinion will have on *Myriad*.<sup>205</sup>

After the CAFC ruling, Myriad Genetics' claims for isolated DNA and method of screening potential cancer therapeutics are still valid, while the method claims of analyzing and

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of prompt disclosure of advances made in these fields, the U.S. Patent and Trademark Office will accord 'special' status to patent applications relating to HIV/AIDS and cancer.”).

<sup>200</sup> *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE, <http://www.cancer.gov/cancertopics/factsheet/risk/brca> (last visited Jan. 22, 2012).

<sup>201</sup> Mary Beth Tung, *Myriad: Isolated DNA claims from “ball bats in trees,” and “kidneys” to “magic microscopes.”*, IPWatchdog (Sept. 25, 2011, 8:00 AM), <http://ipwatchdog.com/2011/09/25/myriad-isolated-dna-claims/id=19397/>.

<sup>202</sup> *Id.*

<sup>203</sup> Hodes, *supra* note 21 at 234.

<sup>204</sup> Petition for Writ of Certiorari, *Ass’n for Molecular Pathology* (2011).

<sup>205</sup> *Supreme Court: No Move Yet on Denying Human Gene Patents*, Patently-O (Feb. 21, 2012, 12:42 PM), <http://www.patentlyo.com/patent/2012/02/supreme-court-no-move-yet-on-denying-human-gene-patents.html>.

comparing the isolated DNA sequences are invalid.<sup>206</sup> In theory, other hospitals and laboratories are now able to offer BRCA1 and BRCA2 gene mutation diagnostic testing; however, in order to perform such testing, they will be unable to use the isolated BRCA1 and BRCA2 genes as those are still covered by a valid patent. It is thus necessary for clinicians to deal with Myriad Genetics, who has been identified in a report by the Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) as raising barriers to patient access to breast cancer diagnoses, and failing to deposit new mutations into public databases.<sup>207</sup> The inability to invent around a patented technology creates problems for both product markets and innovation markets.<sup>208</sup>

## VII. CONCLUSION

During the past twenty years great strides have been made regarding the diagnosis and treatment of several genetic diseases. Much of this is owed to a great deal of time and resources by teams of researchers, several of whom now seek patent protection for their inventions. But where is the appropriate line between protecting and encouraging innovation and creating barriers for doctors who want to use these tests and treatments to care for patients? The judicial response has at times been as dynamic as the controversy surrounding the cases. *Myriad* has shown that, for now, the CAFC is willing to uphold patents related to isolated genetic sequences and diagnostic methods utilizing genetic sequences. Within the near future the Supreme Court will decide if the CAFC's approach to method patents is correct. Meanwhile, the America Invents Act indicates that the legislative branch is starting to pay attention to this very important issue.

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<sup>206</sup> *Federal Circuit: Isolated Human DNA Molecules are Patentable*, Patently-O (July 29, 2011, 12:32 PM) <http://www.patentlyo.com/patent/2011/07/federal-circuit-isolated-human-dna-molecules-are-patentable.html>.

<sup>207</sup> Dreyfuss & Evans, *supra* note 188 at 1369.

<sup>208</sup> *Id.* at 1370.