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THE SUPREME COURT HOLDS GENES ARE PATENT-INELIGIBLE PRODUCTS OF NATURE

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**Introduction**

In June 2013, the U.S. Supreme Court issued its third decision in as many years on judicially created doctrines of patent ineligibility.<sup>1</sup> In *Association for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>2</sup> the Court held that an “isolated” DNA molecule is patent-ineligible if its sequence is the same as a naturally occurring sequence, although a molecule whose sequence does not occur in nature is patent-eligible. This article discusses the *Myriad* decision in the context of recent Supreme Court jurisprudence on the doctrines of patent ineligibility, and its possible effects on intellectual property protection in biotechnology and other technology areas.

**Summary of *Myriad***

The claims at issue in *Myriad* were to sequences of DNA based on human genes known as BRCA1 and BRCA2 and portions thereof.<sup>3</sup> The patentee (Myriad) had identified the location of these genes in the human genome, where a heritable mutation can confer an increased susceptibility to developing breast cancer.<sup>4</sup> In patenting the sequences, Myriad was able to exclude others from offering genetic tests to patients and clients to determine whether they carried the susceptible mutation, in competition with Myriad's own proprietary tests.<sup>5</sup>

Several plaintiffs sued Myriad in the Southern District of New York seeking a declaration that the claims are invalid.<sup>6</sup> Among their contentions was that DNA sequences that can be found in nature, such as within human genes, should be excluded from patent eligibility because they are products of nature.<sup>7</sup> Myriad disagreed, contending that because it specifically claimed “isolated” DNA, in keeping with U.S. Patent and Trade Office (U.S.P.T.O.) guidelines,<sup>8</sup> the claimed subject matter was not a product of nature because such molecules do not naturally exist in an isolated form.<sup>9</sup> The district court held for the plaintiffs, finding the claims invalid as being impermissibly drawn to patent-ineligible subject matter.<sup>10</sup>

The Federal Circuit reversed, holding that isolated DNA molecules are chemically distinct from sequences of nucleotides found within genes and therefore were products not of nature but of human manufacture.<sup>11</sup> The plaintiffs petitioned for certiorari to the Supreme Court, which granted the petition, vacated the holding, and remanded the case to the Federal Circuit in light of its holding in another patent-eligibility case it had handed down in the interim, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>12</sup> On remand, the Federal Circuit again found the claims to isolated DNA to be valid, and the plaintiffs again were granted review by the Supreme Court.<sup>13</sup>

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In a unanimous decision, the Court held that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated.”<sup>14</sup> In reaching its decision, the Court addressed the requirements of 35 U.S.C. § 101<sup>15</sup> and the exceptions from patent eligibility it had carved from that section, stating that it had “long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.”<sup>16</sup> In turn, it held that isolated DNA molecules are “products of nature” and therefore fall “squarely within the law of nature exception,” at least insofar as the same sequence occurs naturally.<sup>17</sup>

However, the Court also found that some of the claimed subject matter at issue may be patent-eligible. Specifically, Myriad had also claimed BRCA1 and BRCA2 sequences in the form of a synthetic type of DNA molecule known as cDNA.<sup>18</sup> The sequence of nucleotides in a cDNA molecule often differs from that of naturally occurring genomic DNA in that interspersed throughout a sequence of genomic DNA are portions called introns that are removed in the creation of cDNA.<sup>19</sup> Therefore, notwithstanding its prohibition on patenting isolated genes, the Court held that cDNA is not categorically excluded from patent eligibility.<sup>20</sup> Rather, the patent eligibility of a given cDNA molecule will depend on whether its sequence matches that of a naturally occurring DNA or, alternatively, reflects the removal of an intronic sequence.<sup>21</sup>

An important aspect of this portion of the holding--that a cDNA molecule is ineligible for patenting if its sequence matches that of a naturally occurring molecule such as genomic DNA--is that the test for whether a DNA molecule is patent-eligible is not merely whether or not it is synthetic. All cDNA molecules are, by definition, synthetic, yet the Court ruled that some are not patent-eligible. Rather, whether assembled in a laboratory, nucleotide by nucleotide (which is the practical embodiment of a claim to an “isolated” gene) or plucked from within a cell and shorn of all other associated genetic materials, proteins, and other molecules with which it is naturally associated (which, in fact, is not how genes are actually “isolated” for genetic testing),<sup>22</sup> a DNA molecule with a naturally occurring sequence is not patent eligible.<sup>23</sup> By the same token, the Court noted that molecules of recombinant DNA, whose sequence is cobbled together from disparate sources of material and thus is artificial, remains eligible for patenting.<sup>24</sup>

**Impact of *Myriad* in Light of *Prometheus* and *Bilski***

In many respects, the direct, practical consequences of *Myriad* have yet to be determined. Although there are estimated to be several thousand patents in force that claim endogenous human gene sequences, many are expected to begin expiring in the not too distant future.<sup>25</sup> For example, the claims invalidated by the *Myriad* decision itself would have expired in 2015 in any event.<sup>26</sup> Furthermore, since the advent of gene patenting in the 1980s,<sup>27</sup> public disclosure of unpatented human gene sequences in publicly available databases already profoundly minimized the patentable scope of new claims to human gene sequences, having deprived them of novelty.<sup>28</sup> Nevertheless, the U.S.P.T.O. issued preliminary guidance to its examiners to comply with *Myriad* by rejecting “product claims drawn solely to naturally occurring nucleic acids or fragments thereof.”<sup>29</sup>

The patent-eligibility of methods of using gene sequences was not before the Court.<sup>30</sup> Underscoring this is the fact that, after *Myriad* was handed down, the patentee proceeded to assert other claims, drawn to methods of using BRCA1 and BRCA2 sequences in performing genetic testing.<sup>31</sup> Thus, conclusions that the Supreme Court's *Myriad* decision would unleash a multitude of new providers of genetic testing for breast cancer susceptibility, and thereby drive down the price of such tests, may have been premature, as such claims were not even before the Court.<sup>32</sup> From that perspective, it may

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appear that the direct effect of the decision on the field of diagnostic genetic testing--and on the related, nascent field of personalized medicine, which is thought to hold such promise--may be quite small because companies' patent portfolios do not rely exclusively on claims to compositions of isolated DNA.<sup>33</sup>

And yet, it remains possible that the claims newly asserted by *Myriad* may ultimately be invalidated as well. In part of its holding that was not presented to the Supreme Court in *Myriad*, the Federal Circuit held that some diagnostic method claims, “comparing” and “analyzing” an individual's genetic sequences to reference sequences of BRCA1 and BRCA2, were ineligible for patenting, falling within the exclusion of “abstract mental processes.”<sup>34</sup> In so holding, the court quoted the Supreme Court's 2010 decision in *Bilski v. Kappos*,<sup>35</sup> in which the Court held that “the prohibition against abstract ideas cannot be circumvented by attempting to limit the use of [a] formula to a particular technological environment.”<sup>36</sup>

In last year's *Prometheus* decision, on which the initial remand of *Myriad* to the Federal Circuit was predicated,<sup>37</sup> the Court held that methods drawn to determining a safe but effective dose of a particular medicine to administer \*33 to a patient was patent-ineligible because it fell within the exclusion from eligibility of laws of nature.<sup>38</sup> In describing how to determine whether a method is excluded from patent eligibility under this exception, the Court stated that an “inventive concept” that is something more than a “well-understood, routine, conventional activity previously engaged in by scientists who work in the field” must be included in a claim reciting a natural law in order for it to be patent-eligible.<sup>39</sup> In turn, the Federal Circuit held that the “challenged method claims [in the *Myriad* case] were indistinguishable from the claims” held to be patent ineligible in *Prometheus* and therefore excluded from patent eligibility themselves.<sup>40</sup> Thus, to the degree that claims to genetic testing methods may be considered drawn to “abstract mental processes” in view of *Bilski*, or “laws of nature” without an “inventive concept” in view of *Prometheus*, they may well be found invalid for failing to satisfy the patent eligibility requirements of § 101,<sup>41</sup> notwithstanding the Court's dicta in *Myriad* that eligibility of “applications of knowledge about the BRCA1 and BRCA2 genes” had not been challenged in that case.<sup>42</sup>

In another respect, however, the decision that at least certain cDNA molecules remain patent-eligible would seem to provide patent applicants and litigants with an argument that the requirement of something more than ““routine, conventional activity” for patent eligibility articulated by the Court in *Prometheus* is a limited one.<sup>43</sup> The process for synthesizing cDNA is certainly a “routine, conventional activity” by molecular biologists, provided that some of the endogenous sequence it is based upon is known.<sup>44</sup> And, in a broader sense, the differences between cDNA and the naturally occurring molecule that its sequence is directly derived from, referred to as mRNA, may be no greater than differences between endogenous genes and synthetic copies thereof from the perspective of chemical structure if not function.<sup>45</sup> Thus, cDNA molecules can be eligible for patenting, even though they are made by using patent-ineligible DNA molecules in a ““routine, conventional” way,<sup>46</sup> which would seem to cabin the holding in *Prometheus* that something more is necessary for patent eligibility.

### Beyond Genes

The Court may have considered that it was crafting a compromise by allowing some cDNA molecules to retain patent-eligible status while excluding isolated genomic DNA.<sup>47</sup> cDNA has long been recognized as a particularly valuable type of DNA because it codes for therapeutic proteins yet lacks the introns present in genomic DNA, making it shorter and easier to manipulate and use.<sup>48</sup> However, at least with regard to the potential for future therapeutic usefulness of

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portions of genomic DNA from which cDNA cannot be derived, the decision may have been shortsighted. It is believed that only a very small percentage of the human genome encodes exons, with introns, sequences between genes, and other sequences from which cDNA cannot be produced constituting the remainder.<sup>49</sup> Although this vast proportion of the genome does not encode proteins, it has other functions related to regulating protein expression in ways that are continuing to be investigated, with potential diagnostic and therapeutic applications.<sup>50</sup> Thus, an over-emphasis on the historically significant value status of cDNA may have come at the expense of recognizing new and future applications of other genetic molecules.

Furthermore, although on its face *Myriad* may appear limited to genetic material, its rationale may be just as easily applied to other molecules that are discovered in nature but “isolated” and purified from naturally occurring contaminants and associated molecules, or synthetic replicas of such molecules (e.g., a bactericide produced by a mold, a protein produced by an animal that has therapeutic properties or by a plant that affects vegetable longevity, a chemical produced by a plant that can function as a drug, or a compound found in crude oil that functions as a lubricant).<sup>51</sup> For example, in a letter addressed to the U.S. Attorney General and the Solicitor General when *Myriad* was on remand to the Federal Circuit, numerous “industrial, environmental, food and agricultural biotechnology companies” warned against a ruling that would overturn the more than 100-year-old policy of the U.S.P.T.O. of granting “patents on new and useful preparations of naturally-sourced chemicals; fungal, bacterial, or algal cultures; enzyme preparations; and other isolated, purified, or modified biological products,” which would “create significant uncertainty” as to patent strength and value in their industries.<sup>52</sup>

Indeed, there are many examples of U.S. court decisions holding that naturally occurring molecules, in addition to DNA, that are isolated and purified can be patented, including the porcine enzyme chymosin,<sup>53</sup> vitamin B-12,<sup>54</sup> prostaglandins,<sup>55</sup> a compound produced by strawberries that is responsible for their flavor (2-methyl-2-pentenoic acid),<sup>56</sup> and adrenaline.<sup>57</sup> However, there are also numerous examples where patent protection for molecules that were purified from natural sources was denied, including a synthetic replica of a naturally occurring dye (alizarine),<sup>58</sup> purified tungsten,<sup>59</sup> cellulose,<sup>60</sup> vanadium,<sup>61</sup> uranium,<sup>62</sup> and ultramarine.<sup>63</sup>

During oral argument in *Myriad*, Justice Breyer, at least, appeared to wrestle with this issue. He stated his understanding that the exclusion from patent eligibility for “products of nature” was “hornbook law”<sup>64</sup> -- a characterization that may be considered overly assured, at least with regard to purified or isolated products, considering the seemingly contradictory precedents cited above. Justice Alito asked why isolated DNA ought to be excluded from patent eligibility if a medicinal compound isolated from a plant is patent-eligible.<sup>65</sup> Although counsel responded that functional alteration is required for patent-eligibility of isolated natural products and that isolating DNA does not alter its function<sup>66</sup> --a dubious contention in and of itself--this line of reasoning did not make its way into the written decision. Thus, it remains unclear whether *Myriad* will be brought to bear on other isolated natural products.<sup>67</sup> In at least one case so far, a patent challenger has asked the Federal Circuit to invalidate claims to human embryonic stem cells on the basis that they are drawn from patent-ineligible products of nature under *Myriad*.<sup>68</sup>

In fact, the Court did not cite the varied, if somewhat aged, case law cited above on whether isolated molecules fall within the “products of nature” exclusion, although the district court did cite some of it in its ruling.<sup>69</sup> The omission may be because most of the decisions were not issued by the Supreme Court, which elected to rely on its own precedents, although there are Supreme Court cases from the 19th century denying patent protection to molecules that were purified from natural sources.<sup>70</sup>

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The legal foundation for the prevailing policy of considering isolated genes to be patent eligible is commonly believed to be traceable to a decision from 1911 by then-District Court Judge Learned Hand, *Parke-Davis & Co. v. H.K. Mulford Co.*<sup>71</sup> Although characterized as dicta, and from a trial court no less,<sup>72</sup> Judge Hand's conclusion that adrenalin purified from adrenal glands can be patented<sup>73</sup> is regarded as a seminal case on the general question of whether molecules purified from natural sources can be patented.<sup>74</sup>

The *Myriad* Court referred instead, however, to its own precedents in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, in which it had held that combinations of naturally occurring strains of bacteria for use as agricultural inoculants are not patent eligible,<sup>75</sup> and *Diamond v. Chakrabarty*, in which it had held that genetically modified bacteria are patent eligible,<sup>76</sup> although neither case dealt directly with the question of whether isolated, naturally occurring molecules fall within the “product of nature” exception to patent eligibility. The Court found that the patentee's claims were more akin to the patent-ineligible claims in *Funk Brothers* than to the patent-eligible claims in *Chakrabarty*.<sup>77</sup> In this way, it reiterated the products of nature exclusion and may also have pulled into the exclusion a broader category of products isolated from natural sources, intentionally or otherwise.

### The Specter of Preemption

What is the purpose of the doctrines of exclusion from patent eligibility? Why did the Court in *Myriad* consider it important to categorically exclude isolated genes from the realm of patents? The ostensible answer is an apparent concern that overreach of patenting may impede, rather than promote, the “Progress of Science and useful Arts,” the constitutional purpose underlying the patent regime.<sup>78</sup> Much as the Court stated in *Bilski*<sup>79</sup> and *Prometheus*<sup>80</sup> that patents should not go so far as to “preempt” the use of a natural law lest such preemption have the counterproductive effect of inhibiting innovation,<sup>81</sup> here the Court expressed its belief that patents should not “tie up” the “basic tools of scientific and technological work” and thereby “inhibit future innovation.”<sup>82</sup>

But is this concern justified here? And is the Court the appropriate body to make that determination in any case? For example, *Myriad*'s policy was that it “allowed scientists to conduct research studies on BRCA1 and BRCA2 freely, the result of which has been the publication of over” 8,000 research papers, “representing the work of over 18,000 scientists.”<sup>83</sup> This continued study of the patented genes by basic researchers throughout the life of the patents, is in keeping with evidence that basic science researchers are generally unencumbered by concerns that their work may infringe third-party patent rights.<sup>84</sup> Among the reasons accounting for this general lack of “preemptive effect” of patents on basic research is that basic researchers simply infringe on patents anyway, either because they are unaware of them or because they consider their conduct to fall within a “research exemption” from infringement liability.<sup>85</sup> For their part, industrial patent holders tolerate infringement of their patent rights by basic researchers in part because the “small prospective gains,” coupled with “bad publicity” from bringing suit against such defendants and universities, discourage them from doing so, whereas permitting such infringement “can increase the value of the patented technology.”<sup>86</sup> If the Court were so concerned with patents impeding progress, it is curious that it did not address the strong evidence that gene patents actually do not preempt scientific progress and, in fact, promote it. Indeed, the Court's 1980 *Chakrabarty* decision,<sup>87</sup> conferring patent-eligibility status on genetically modified bacteria, is widely credited with enabling a strong biotechnology industry to flourish in the United States.<sup>88</sup>

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There are, however, those whose activities have been curtailed because of third-party gene patents. Specifically, patent holders, such as the patentee in *Myriad*, have enforced their patents against clinical laboratories that offer fee-for-service genetic diagnostic testing covered by claims to genetic sequences, which has caused the laboratories to stop offering testing and to forgo their own research.<sup>89</sup> Thus, gene patents do in fact have a preemptive effect. But whether this effect goes beyond the preemption patents generally are designed to effect--e.g., by enabling patentees to exclude competitors<sup>90</sup>--and has a more profound effect on squelching scientific inquiry in general is less clear.

Thus, the Court may not be in the best position to resolve this question and its reinvigorated focus on § 101 may be ill-conceived.<sup>91</sup> Chief Judge Randall R. Rader of the Federal Circuit, speaking at the Annual Meeting of \*35 the New York State Bar Association's Intellectual Property Law Section in January 2013, stated that the Supreme Court was exerting undue judicial activism in its § 101 jurisprudence.<sup>92</sup> Discussing *Prometheus*, he noted that the exclusion from patent eligibility of natural phenomena was judicially created and unnecessary.<sup>93</sup> Elsewhere, Judge Rader has lamented the extent to which courts have strayed from the course laid out in *Chakrabarty*, wherein the Court stated that its task in interpreting § 101 was a "narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted,"<sup>94</sup> as a reason for the disorienting proliferation of § 101 case law.<sup>95</sup>

As it had in *Prometheus*,<sup>96</sup> the Court stated that a proper balance was needed to foster a patent regime that provides incentives to drive innovation and that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas, and too broad an interpretation of this exclusionary principle could eviscerate patent law."<sup>97</sup> Perhaps, however, Congress is in the better position to determine whether the doctrines of exclusions from patent eligibility are a needed and beneficial way to promote scientific progress and to craft policy accordingly.<sup>98</sup> For example, if it were determined that gene patents may have a net effect of promoting scientific progress, provided proper safeguards of basic research are in place, Congress could codify an appropriately targeted version of the common law "research exemption" to patent infringement.<sup>99</sup> Or perhaps health care or consumer protection legislation could be brought to bear to assure availability and affordability of medical diagnostics and treatment, while allowing patentees to profit reasonably from their investments in research and development,<sup>100</sup> matters the patent laws are not generally designed to address.

A related issue is the Court's difficulty with, and short-comings in addressing, the technical details of *Myriad*.<sup>101</sup> Of particular note was a one-paragraph concurring opinion by Justice Scalia, in which he declared that he was "unable to affirm those details on [his] own knowledge or even [his] own belief" yet felt sufficiently informed to concur in the judgment.<sup>102</sup> Some have opined that such a statement sends a poor message to lower courts and juries, who wrestle mightily with complex technical issues in patent litigation.<sup>103</sup> In this regard, it is interesting to note that Judge Hand, in the *Parke-Davis* case that is credited with establishing the legal foundation that eventually culminated in rendering gene patents eligible for patenting, also noted "the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions" as were before him.<sup>104</sup> In that respect, Justice Scalia's concurrence has brought us full circle.

#### Footnotes



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- a1 **TEIGE P. SHEEHAN**, Ph.D., is an attorney in the Albany office of Heslin Rothenberg Farley & Mesiti, P.C. This article first appeared, in a slightly different format, in the Fall 2013 issue of *Bright Ideas*, a publication of the Intellectual Property Law Section of the New York State Bar Association.
- 1 The Court had ruled on patent eligibility issues in June 2010 (in *Bilski v. Kappas*, 561 U.S. 593 (2010) and in March 2012 (in *Mayo Collaborative Servs. v. Prometheus laboratories, Inc.*, 132 S. Ct. 1289 (2012)).
- 2 133 S. Ct. 2107 (2013).
- 3 *Id.* at 2113.
- 4 *Id.* at 2118, n.6.
- 5 *Id.* at 2113.
- 6 *Id.* at 2114.
- 7 *Id.*
- 8 “A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature \* \* \* DNA compounds having naturally occurring sequences are eligible for patenting when isolated from their natural state and purified ....” *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093.
- 9 *Myriad*, 133 S. Ct. at 2118.
- 10 *Id.* at 2114.
- 11 *Id.*
- 12 132 S. Ct. 1289. See Teige P. Sheehan, *Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability*, 21 Bright Ideas No. 2, 3, 6 (Fall 2012).
- 13 133 S. Ct. at 2114.
- 14 *Id.* at 2111.
- 15 ““Whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement therefor, may obtain a patent therefor, subject to the conditions and requirements of” the Patent Act. *Myriad*, 133 S. Ct. at 2116 (quoting 35 U.S.C. § 101).
- 16 *Id.* at 2116 (internal quotation marks omitted).
- 17 *Id.* at 2117. Note the that the transferrable nature of the Court's analysis between, here, “products of nature” and “laws of nature” as excluded from patent eligibility is not uncommon in its § 101 jurisprudence, which occasionally goes so far as to characterize in one opinion an invention as falling within one exception, then subsequently classifying that holding as pertaining to another exception. Sheehan, *supra* note 12, at 3, 6 & n.14.
- 18 *Myriad*, 133 S. Ct. at 2119.
- 19 *Id.* at 2112.
- 20 *Id.* at 2119.
- 21 *Id.*

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- 22 [Brief of Professor Christopher M. Holman as Amicus Curiae Supporting Neither Party at 6, 689 F.3d 1303 \(Fed. Cir. 2012\)](#) (Appeal No. 2010-1406); Posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2012/07/scientist-law-professor-files-amicus-brief-in-myrriad-case.html](http://www.patentdocs.org/2012/07/scientist-law-professor-files-amicus-brief-in-myrriad-case.html) (July 11, 2012).
- 23 *Myriad*, 133 S. Ct. at 2118-19.
- 24 *Id.* at 2120.
- 25 Gregory D. Graff, Devon Phillips, Zhen Lei, Sooyoung Oh, Carol Nottenburgh, & Philip G. Pardey, *Not Quite a Myriad of Gene Patents*, 31 *Nature Biotechnology* 404 (2013); posting by Kevin E. Noonan to Patent Docs, <http://www.patentdocs.org/2013/05/the-myrriad-case-and-gene-patents-much-ado-about-nothing.html> (May 14, 2013).
- 26 *Stakeholder Reactions Varied on Impact of Supreme Court's Myriad DNA Decision*, [2013] 86 *Pat. Trademark & Copyright J.* (BNA) No. 2119, at 402 (June 21, 2013) (*Stakeholder Reactions*).
- 27 *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1333 (Fed. Cir. 2012).
- 28 35 U.S.C. §102.
- 29 Letter from Andrew H. Hirshfeld, Deputy Comm'r Patent Examination Policy, U.S.P.T.O., to Patent Examining Corps, dated June 13, 2013, available at <http://patentdocs.typepad.com/files/uspto-myrriad-memorandum.pdf>.
- 30 *Myriad*, 133 S. Ct. at 2119-20.
- 31 Posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2013/07/myriad-genetics-files-infringement-suit-against-gene-by-genefor-genetic-diagnostic-testing-of-brca-genes.html](http://www.patentdocs.org/2013/07/myriad-genetics-files-infringement-suit-against-gene-by-genefor-genetic-diagnostic-testing-of-brca-genes.html) (July 10, 2013); posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2013/07/myriad-genetics-files-suit-against-ambry-genetics-for-genetk-diagnostic-testing-of-rca-genes.html](http://www.patentdocs.org/2013/07/myriad-genetics-files-suit-against-ambry-genetics-for-genetk-diagnostic-testing-of-rca-genes.html) (July 9, 2013).
- 32 Posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2013/06/does-the-myrriad-decision-presage-a-golden-age-of-patent-freepersonalized-edicine.html](http://www.patentdocs.org/2013/06/does-the-myrriad-decision-presage-a-golden-age-of-patent-freepersonalized-edicine.html) (June 19, 2013).
- 33 *Stakeholder Reactions*, *supra* note 26, at 402-03.
- 34 689 F.3d 1303, 1334 (2012).
- 35 *Id.*
- 36 561 U.S. 593 (internal quotation marks omitted).
- 37 *Myriad*, 133 S. Ct. at 2114.
- 38 132 S. Ct. at 1305.
- 39 *Id.* at 1298-99.
- 40 689 F.3d at 1335.
- 41 *Myriad Criticized for Lack of Guidance, Putting Too Much Foots on Section 101*, [2013] 86 *Pat. Trademark & Copyright J.* (BNA) No. 2119, at 405 (June 21, 2013) (*Myriad Criticized for Lack of Guidance*).
- 42 133 S. Ct. at 2120.
- 43 Posting by Grantland Drutchas to Patent Docs, [http:// www.patentdocs.org/2013/06/the-myrriad-supreme-court-decision-where-does-it-leave-the-inventive-concept-test.html](http://www.patentdocs.org/2013/06/the-myrriad-supreme-court-decision-where-does-it-leave-the-inventive-concept-test.html) (June 16, 2013).



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- 44 *Id.*
- 45 [Brief of Professor Christopher M. Holman as Amicus Curiae Supporting Neither Party at 8, 11, 689 F.3d 1303 \(Fed. Cir. 2012\) \(Appeal No. 2010-1406\).](#)
- 46 Posting by Grantland Drutchas to Patent Docs, [http:// www.patentdocs.org/2013/06/the-myrriad-supreme-court-decision-where-does-it-leave-the-inventive-concept-test.html](http://www.patentdocs.org/2013/06/the-myrriad-supreme-court-decision-where-does-it-leave-the-inventive-concept-test.html) (June 16, 2013).
- 47 Posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2013/04/what-we-may-learn-from-the-myriad-oral-argument.html](http://www.patentdocs.org/2013/04/what-we-may-learn-from-the-myriad-oral-argument.html) (April 18, 2013).
- 48 *Stakeholder Reactions supra* note 26, at 402, 402-103.
- 49 Matthew J. Hangauer, Ian W. Vaughn & Michael T. McManus, *Pervasive Transcription of the Human Genome Produces Thousands of Previously Unidentified Long Intergenic Noncoding RNAs*, 9 PLOS Genetics 1 (2013).
- 50 Kevin Chen & Nikolaus Rajewsky, *The Evolution of Gene Regulation by Transcription Factors and microRNAs*, 8 Nature Rev. Genetics 93 (2007); Jakub O. Westholm & Eric C. Lai, *Mirtrons: microRNA Biogenesis Via Splicing*, 93 Biochimie 1897 (2011).
- 51 Posting by Kevin E. Noonan to Patent Docs, [http:// www.patentdocs.org/2013/04/what-we-may-learn-from-the-myrriad-oral-argument.html](http://www.patentdocs.org/2013/04/what-we-may-learn-from-the-myrriad-oral-argument.html) (April 18, 2013); posting by Sean Brennan to Patent Docs, [http:// www.patentdocs.org/2013/07/after-myrriad-a-herd-of-elephants-in-the-room.html](http://www.patentdocs.org/2013/07/after-myrriad-a-herd-of-elephants-in-the-room.html) (July 3, 2013).
- 52 Letter to Hon. Eric H. Holder, Jr., U.S. Attorney General and Hon. Donald Verrilli, Jr., U.S. Solicitor General (June 12, 2012), [http:// patentdocs.typepad.com/files/myriad-letter-1.pdf](http://patentdocs.typepad.com/files/myriad-letter-1.pdf).
- 53 *Blumenthal V. Burrell*, 53 F. 105, 107 (2d Cir. 1892).
- 54 *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 157, 164 (4th Cir. 1958).
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