

## *Association for Molecular Pathology v. Myriad Genetics, Inc.: Progress by Principles*

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# **ASSOCIATION FOR MOLECULAR PATHOLOGY v. MYRIAD GENETICS, INC.: PROGRESS BY PRINCIPLES**

EMILY J. BOLYARD\*

*“Liberty is the only thing you cannot have  
unless you are willing to give it to others.”*

– William Allen White

As the world of biotechnology has raced ahead during the past century, accomplishing enormous feats in the name of science and medicine, patent law has grappled with achieving the correct balance between incentivizing such innovation on the one hand, and impeding further advancement on the other.<sup>1</sup> It can be difficult to strike this balance when granting patents on claimed products and processes, and failing to do so has the ability to create a monopolistic, exclusive right over a basic tool of scientific or technological work, preempting others from further use and contribution to humanity’s progress.<sup>2</sup>

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\* J.D. Candidate, 2015, University of Maryland Francis King Carey School of Law; B.A., 2012, University of Maryland–College Park. I would like to thank the *Journal of Health Care Law and Policy* staff for their thorough work and helpful critique along the road to publication. For their eternal wisdom, encouragement, and support in all of life’s endeavors, I would like to thank my grandparents, parents, sisters, and close friends.

1. Francis S. Collins, M.D., Ph.D., Director of the National Institutes of Health and former Director of the Human Genome Project at NIH, once posited in an interview that: “Patenting tends to get people’s juices flowing when you put the word “gene” and the word “patent” in the same sentence. And understandably so. This is stuff we’re carrying around—all of us—inside all of our cells. Should somebody be able to lay claim to it?” *Transcript: Bob Abernethy’s Interview with Dr. Francis Collins, Director of the Human Genome Project at the National Institutes of Health, Religion & Ethics Newsweekly, PBS (June 16, 2000)*, <http://www.pbs.org/wnet/religionandethics/2000/06/16/transcript-bob-abernethys-interview-with-dr-francis-collins-director-of-the-human-genome-project-at-the-national-institutes-of-health/15204/>.

2. *See infra* Part II.B.

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court considered whether human genes are patentable under the Patent Act of 1952.<sup>3</sup> Originally enacted in 1790, the Act allows patents to be granted on any new and useful process, machine, manufacture, or composition of matter, barring a judicially created exception for laws of nature, natural phenomena, and abstract ideas.<sup>4</sup> These three naturally occurring things are nonpatentable because they create the foundation of scientific and technological work.<sup>5</sup> In *Myriad*, the Court unanimously held that isolated DNA is nonpatentable, since such DNA is naturally occurring phenomena under the exception, and merely isolating it is not sufficient to make it otherwise.<sup>6</sup> However, the Court held that complimentary DNA (“cDNA”) is patentable, as it is not similarly naturally occurring.<sup>7</sup>

The Court reached this conclusion by following precedent in a number of ways, most notably in its emphasis on, and analysis of, the *principles* behind both patent law’s protections and the law’s exception regarding patentable subject matter.<sup>8</sup> In doing so, the Court accomplished precisely those principles’ objective: striking the balance of patent law’s double-edged sword by promoting further scientific progress while also proscribing the improper restriction of science and technology’s basic tools.<sup>9</sup> The correct decision in *Myriad* was a colossal win for science, public health, and personalized medicine, and it came at the cost of a mere slap on the wrist for the biotech industry.<sup>10</sup>

## I. THE CASE

During the early 1990s, teams of genetic researchers began the search for a human gene<sup>11</sup> correlating with an increased risk of breast or ovarian cancer.<sup>12</sup> A team of researchers determined that one such possible gene

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3. See *infra* Part III.

4. See *infra* Part II.A–B.

5. See *infra* Part II.B.

6. See *infra* Part III.

7. See *infra* Part III.

8. See *infra* Part IV.A.

9. See *infra* Part IV.B.

10. See *infra* Part IV.B.

11. A gene is a piece of DNA used by cells to create one or more specific proteins. See Edward R. Winstead, *GNN’s Genome Glossary*, GENOME NEWS NETWORK, <http://www.genomenetwork.org/resources/glossary/> (last visited Oct. 13, 2014) (defining “gene”).

12. *Ass’n for Molecular Pathology v. U.S. PTO*, 669 F. Supp. 2d 365, 377 (S.D.N.Y. 2009), *summ. j. granted for plaintiff*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated, remanded sub nom* by *Ass’n for Molecular Pathology v.*

was located on human chromosome 17, and another team of researchers thereafter sequenced<sup>13</sup> that precise gene, naming it *BRCA1*.<sup>14</sup> The team that sequenced this gene subsequently formed Myriad Genetics, a for-profit corporation located in Salt Lake City, Utah.<sup>15</sup> Myriad soon identified another gene similar to *BRCA1*, and named this second gene *BRCA2*.<sup>16</sup> Myriad sought and successfully obtained a number of patents on both the *BRCA1* and *BRCA2* (“*BRCA1/2*”) genes, holding the patents through either ownership or exclusive license.<sup>17</sup>

Every human being carries the *BRCA1/2* genes, but each person’s individual gene sequences may differ.<sup>18</sup> Any given gene is composed of a unique sequence of four nucleotides: A, T, C, and G.<sup>19</sup> Although this combination is typically arranged in strings of hundreds or thousands of nucleotides that are considered “normal” for a particular gene, variations are common.<sup>20</sup> Because the human body uses genes as the “blueprints” for producing proteins and other biological products required for good health, particular variations can significantly impact an individual’s well-being.<sup>21</sup> Specific variations or “mutations” in the *BRCA1/2* genes’ sequences—sequences where certain nucleotides have either been deleted or substituted with abnormal nucleotides—are correlated with an increased risk of breast and ovarian cancer, and may also correlate with other types of cancer.<sup>22</sup> Women with these mutations have a forty to eighty percent chance of developing breast cancer over the course of their lives.<sup>23</sup>

Once a gene’s “normal” sequence has been identified, as Myriad did for *BRCA1/2*, genetic experts can examine any individual’s particular gene sequence and compare it to the normal sequence, which allows for a determination of whether or not the individual’s gene sequence is healthy.<sup>24</sup> In addition, scientists can create cDNA, which is a type of DNA molecule that contains only the protein-coding nucleotide segments of DNA, or

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Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) to 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

13. Sequencing is the process of determining the exact order of DNA nucleotides (A, T, C, and G) making up a particular piece of DNA. *See* Winstead, *supra* note 11 (defining “sequence” and “nucleotide”).

14. 669 F. Supp. 2d at 377.

15. *Id.* at 376, 377.

16. *Id.* at 378.

17. *Id.* at 377–78.

18. *Id.* at 378.

19. *Id.* at 377.

20. *Id.*

21. *Id.*

22. *Id.* at 377–78.

23. *Id.* at 378.

24. *Id.* at 377–78.

“exons.”<sup>25</sup> In the late 1990s, a number of genetic clinicians began offering and conducting genetic testing services for individuals regarding *BRCA1/2*.<sup>26</sup> Myriad quickly took the position that any *BRCA1/2*-related activity was an infringement on Myriad’s numerous patents on the genes, and sent either cease-and-desist letters or letters proposing very narrow licensing conditions to a number of laboratories and physicians engaging in the alleged infringing conduct.<sup>27</sup>

The procedural history carrying this case to its most recent appearance before the Supreme Court is lengthy and complex. The lawsuit was initiated when a number of advocacy groups,<sup>28</sup> professional organizations,<sup>29</sup> leaders of medical and research institutions,<sup>30</sup> and individual women<sup>31</sup> filed suit against the United States Patent and

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25. *Ass’n for Molecular Pathology v. U.S. PTO*, 702 F. Supp. 2d 181, 194, 198 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated, remanded sub nom by Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) to 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

26. *See* 669 F. Supp. 2d at 377–79 (identifying a number of clinicians who were engaged in these services in the late 1990s following the initial discovery of *BRCA1* in 1990).

27. *Id.* at 378–79. Among these laboratories were the University of Pennsylvania Genetic Diagnostic Laboratory and the Yale DNA Diagnostics Laboratory, which subsequently ceased offering *BRCA1/2* testing. *Id.*

28. These organizations included Breast Cancer Action, a national organization working with researchers to support innovative approaches to breast cancer, and Boston Women’s Health Book Collective, a women’s health organization seeking to educate the public about genetic analysis. These organizations explained that they would be able to inform the public about alternatives to Myriad’s genetic testing services, and that their members would directly benefit, were the patents invalidated. *Id.* at 374–75.

29. These professional organizations included the Ass’n for Molecular Pathology, the American College of Medical Genetics, the American Society for Clinical Pathology, and the College of American Pathologists. These plaintiffs argued that their members—including geneticists, pathologists, and laboratory professionals—were ready, willing, and able to conduct further research and genetic testing regarding *BRCA1/2*, were the patents invalidated. *Id.* at 370–71.

30. Among these individuals were: Drs. Haig Kazazian and Arupa Ganguly, co-Directors of the University of Pennsylvania Genetic Diagnostic Laboratory; Dr. Wendy Chung, Director of Clinical Genetics and Clinical Oncogenetics at Columbia University; Doctor Harry Ostrer, Director of the Human Genetics Program in the Department of Pediatrics at New York University; Dr. David Ledbetter, Director of the Division of Medical Genetics at Emory University School of Medicine; Dr. Stephen T. Warren, the William Patterson Timmie Professor of Human Genetics and Professor of Biochemistry and Professor of Pediatrics at Emory University; Ellen Matloff, Director of the Yale Cancer Genetic Counseling Program; and Ms. Elsa W. Reich, Professor of Pediatrics in the Human Genetics Program at NYU’s School of Medicine Department of Pediatrics. *Id.* at 372–74. These directors and professionals were responsible for genetic testing laboratories and related services at their respective institutions, and argued that they would conduct clinical testing of *BRCA1/2* on their own instead of sending samples to Myriad, were the patents invalidated. *Id.*

31. These women were diagnosed with breast or ovarian cancer, or had a family history of the diseases (or both). Lisbeth Ceriani, Runi Limary, Genae Girard, Patrice Fortune, Vicky Thomason, and Kathleen Raker argued either that they could not afford Myriad’s costly *BRCA*

Trademark Office (“PTO”), Myriad, and the University of Utah Research Foundation<sup>32</sup> (“UURF”), in the United States District Court for the Southern District of New York on May 12, 2009.<sup>33</sup> The plaintiffs (“AMP”) challenged the validity of fifteen claims contained in seven patents that the PTO had granted Myriad and UURF.<sup>34</sup> These claims covered *BRCA1/2* themselves (both in isolated and cDNA form), certain mutations of those genes, and methods related to genetic testing services.<sup>35</sup> AMP alleged that the patents were unlawful under § 101 of the Patent Act,<sup>36</sup> Article I, section 8, clause 8 of the Constitution,<sup>37</sup> and the First<sup>38</sup> and Fourteenth<sup>39</sup> Amendments, asserting that the patents covered products of nature, laws of nature or natural phenomena, and abstract ideas or basic human knowledge.<sup>40</sup> AMP filed a motion for summary judgment, which was stayed pending the resolution of the defendants’ (“Myriad”) motion to dismiss for lack of subject matter jurisdiction, lack of personal jurisdiction, and failure to state a claim, which the district court denied on November 1, 2009.<sup>41</sup>

The district court granted AMP’s motion for summary judgment and declared the claims-in-suit invalid.<sup>42</sup> The district court explained that, despite the fact that the patents were granted pursuant to the PTO’s formal policy of granting patents on DNA sequences so long as they were claimed in the form of “isolated and purified” DNA,<sup>43</sup> the *BRCA1/2* DNA was not sufficiently altered from its natural state (i.e., as it exists within the body)

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testing or that they could not obtain a second opinion in addition to Myriad’s, due to Myriad’s patent claims. *Id.* at 375–76.

32. The UURF is a not-for-profit corporation in Salt Lake City, Utah, and an owner or part-owner of all of the patents being challenged. *Id.* at 376–77.

33. *See id.* at 365, 370–77 (identifying each of the plaintiffs and defendants).

34. *Id.* at 380.

35. *Id.* at 369; *see also* Ass’n for Molecular Pathology v. U.S. PTO, 702 F. Supp. 2d 181, 185, 211–14 & nn.25–36 (S.D.N.Y. 2010) (identifying and describing each of the 15 claims in turn), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated, remanded sub nom* by Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) *to* 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

36. 35 U.S.C. § 101 (2012).

37. U.S. CONST. art. 1, § 8, cl. 8.

38. U.S. CONST. amend. I.

39. U.S. CONST. amend. XIV.

40. 669 F. Supp. 2d at 369–70. Laws of nature, natural phenomena, and abstract ideas are not patentable under the judicially created exception to 35 U.S.C. § 101. *See infra* Part II.B.

41. *See* 669 F. Supp. 2d at 365, 370 (dismissing defendants’ motions to dismiss).

42. Ass’n for Molecular Pathology v. U.S. PTO, 702 F. Supp. 2d 181, 184–85 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated, remanded sub nom* by Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) *to* 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

43. *See id.* at 185, 211 n.25 (describing this PTO practice).

for it to constitute patentable subject matter.<sup>44</sup> Furthermore, the court found that the methods claims<sup>45</sup> involving methods to compare DNA sequences were nonpatentable abstract mental processes.<sup>46</sup> The district court thus agreed with AMP and concluded that both categories of the claims at hand—those covering the compositions of DNA and those covering the methods used to compare DNA in genetic testing—claimed nonpatentable subject matter under 35 U.S.C. § 101.<sup>47</sup> The court applied the doctrine of constitutional avoidance to AMP’s additional constitutional claims against the PTO, reasoning that the court was precluded from addressing those issues since AMP had received the relief sought in the complaint.<sup>48</sup>

Myriad appealed to the United States Court of Appeals for the Federal Circuit, which affirmed in part and reversed in part the lower court’s decision.<sup>49</sup> Addressing AMP’s challenges to both Myriad’s composition claims and its method claims in turn, the Federal Circuit concluded that the isolated DNA, including *BRCA 1/2* cDNA, as well as *one* of the methods claims, were patent eligible.<sup>50</sup> First, the Federal Circuit explained that in addition to comporting with the long-held practices of the PTO, isolated DNA is patentable because it has a “markedly different chemical nature” from its native counterpart located in the human body.<sup>51</sup> Next, the Federal Circuit agreed with the lower court as to methods of comparing or analyzing DNA sequences, finding these claims to be nonpatentable

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44. *Id.* at 185.

45. Method claims fall under the larger umbrella term of process claims. *See* 35 U.S.C. § 100(b) (2012) (defining “process” when used in Title 35 of the United States Code as “mean[ing] process, art or method”). Process claims, including method claims, are to be distinguished from products claims. *See, e.g., In re Kollar*, 286 F.3d 1326, 1328, 1332 (Fed. Cir. 2002) (finding that the PTO’s Board of Patent Appeals and Interferences had “fail[ed] to recognize the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps.”). One treatise on patents defines “Patentable Subject Matter” as “four categories of subject matter . . . . Three are structural (products): machines, manufacturers, compositions of matter; one is operational (process).” 1 DONALD S. CHISUM, CHISUM ON PATENTS, pt. 1, Glossary.

46. 702 F. Supp. 2d at 185.

47. *Id.* Included in the district court’s holding that the composition claims to isolated DNA were invalid were Myriad’s claims to *BRCA1/2* cDNA. *Id.* at 230. The fact that the cDNA molecules contain only protein-coding exons was not sufficient to render the cDNA “markedly different” from its natural counterpart. *Id.* For further discussion on cDNA, see *supra* note 25 and accompanying text.

48. 702 F. Supp. 2d at 237–38.

49. *Ass’n for Molecular Pathology v. U.S. PTO*, 653 F.3d 1329, 1333 (Fed. Cir. 2011), *vacated, remanded sub nom by Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) to 689 F.3d 1303 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 133 S. Ct. 2107 (2013).

50. *Id.* at 1350, 1355, 1358.

51. *Id.* at 1354.

abstract mental processes.<sup>52</sup> The Federal Circuit, however, distinguished Myriad's claim to a method for screening potential cancer therapeutics from the other methods claims, finding the former method patent eligible.<sup>53</sup>

After the Federal Circuit denied AMP's petition for rehearing,<sup>54</sup> the United States Supreme Court granted AMP's writ of certiorari.<sup>55</sup> The Supreme Court vacated the Federal Circuit's judgment and remanded the case to the Federal Circuit for further consideration in light of the Supreme Court's decision<sup>56</sup> in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>57</sup> On remand, the Federal Circuit decided the case exactly as it had before—the appellate court reversed the district court's decision as to Myriad's composition claims, holding that isolated DNA (including cDNA) was patent eligible, and affirmed the district court's decision as to most of Myriad's methods claims, holding that techniques for comparing or analyzing DNA were not patent eligible.<sup>58</sup> Lastly, the Federal Circuit again held that Myriad's particular method claim regarding

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52. *Id.* at 1355, 135; *see also supra* notes 45–46 and accompanying text (indicating the district court's decision).

53. 653 F.3d at 1357–58.

54. *Ass'n for Molecular Pathology v. U.S. PTO*, No. 2010-1406, 2011 U.S. App. LEXIS 21143, at \*9 (Fed. Cir. Sept. 13, 2011) (mem.).

55. *Ass'n for Molecular Pathology v. U.S. PTO*, 182 L. Ed. 2d 613 (2012) (mem.).

56. 132 S. Ct. 1289 (2012). For further discussion on *Mayo*, *see infra* Part II.B.

57. 182 L. Ed. 2d 613 (2012).

58. *Ass'n for Molecular Pathology v. U.S. PTO*, 689 F.3d 1303, 1309 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 133 S. Ct. 2107 (2013). It is worth noting that the Federal Circuit's decision here was fragmented—although Judges Lourie, Moore, and Bryson all agreed as to the patentability of cDNA and the methods claims, the three judges reasoned differently regarding the patentability of isolated DNA. Judge Lourie, writing for the majority, found that isolated DNA is patent eligible because isolating DNA requires the severing of chemical bonds, a chemical alteration that creates a new molecule with a unique chemical composition sufficiently distinct from its naturally occurring equivalent. *Id.* at 1308, 1327–28. Judge Moore, concurring in part, wrote separately to explain her reasoning behind finding isolated DNA patentable. *Id.* at 1337 (Moore, J., concurring in part). Judge Moore did not find that the severed chemical bonds, alone, were sufficient to direct the claims to human genes to patentable subject matter. *Id.* at 1341. Instead, she found the different and beneficial utility in the “truncat[ed]” DNA, in addition to the severed chemical bonds, to be the crucial factor rendering shorter DNA sequences patentable. *Id.* at 1341–42. Regarding longer strands of DNA, where most or all of the gene is encompassed in the claim, Judge Moore explained that the beneficial utility stemming from shorter DNA fragments is not similarly present. *Id.* at 1343. Instead, she found these claims were patentable due to Congress's authorization of an expansive scope of patentable subject matter, and furthermore, due to the PTO's longstanding practice of granting such patents and the reliance of patent holders. *Id.* Notably, she explained that she might have concluded that such isolated DNA segments are patent ineligible had she been deciding the case “on a blank canvas,” especially in light of *Mayo*. *Id.* Lastly, Judge Bryson—concurring in part and dissenting in part—found the isolated DNA to be patent ineligible. *Id.* at 1348 (Bryson, J., concurring in part and dissenting in part). He did not find the cleaving of covalent bonds sufficient to make the isolated DNA claims patentable; instead, he found that the functional portion of the DNA—the nucleotide sequence—remained identical to its naturally occurring counterpart, and thus the structural similarities between the two dwarfed the structural differences. *Id.* at 1355.

the screening of potential cancer therapeutics using changes in cell growth rates was patent eligible.<sup>59</sup>

AMP appealed once again to the Supreme Court upon writ of certiorari, which the Court granted, certifying only the first question presented in the appellants' petition: are human genes patentable?<sup>60</sup>

## II. LEGAL BACKGROUND

Ever since the passage of the Patent Act of 1790, both Congress and the judiciary have largely endorsed an expansive approach with regards to what constitutes patentable subject matter for purposes of patent protection.<sup>61</sup> Part II.A of this Note describes the history of this liberal approach to patentable subject matter eligibility.<sup>62</sup> Part II.B sets forth the Supreme Court's long-held exception to this broad eligibility, and outlines the nuances in the Court's reasoning.<sup>63</sup> Part II.C explains the Supreme Court's limited decisions interpreting 35 U.S.C. § 101 in the world of "products" claims.<sup>64</sup> Lastly, Part II.D discusses the Court's stance on its proper role in interpreting § 101 amid legislative and executive action, and describes such action as it pertains to DNA patents.<sup>65</sup>

### A. *Patent Law's Generosity Regarding Subject Matter Eligibility*

Congress passed the first Patent Act in 1790, subsequently modifying the Act's language in 1793, pursuant to its powers under the Progress Clause of the United States Constitution.<sup>66</sup> Article 8, section 8, clause 8 of the Constitution grants Congress the authority to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>67</sup> Purely a matter of federal law, patent law has a number of

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59. *See id.* at 1309 (majority opinion) (reversing the district court's decision that this method claim was directed to a patent-ineligible scientific principle).

60. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694, 695 (2012) (mem.) (limiting grant of petition for writ of certiorari to the first issue presented); *see also* *Petition for a Writ of Certiorari at i, Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2012 WL 4502947, at \*i.

61. *See infra* Part II.A.

62. *See infra* Part II.A.

63. *See infra* Part II.B.

64. *See infra* Part II.C.

65. *See infra* Part II.D.

66. *Bilski v. Kappos*, 130 S. Ct. 3218, 3236, 3242–43 (2010) (describing the Act's legislative history).

67. U.S. CONST. art. 1, § 8, cl. 8.

both *formal* (or procedural) and *substantive* requirements.<sup>68</sup> Among these substantive requirements are: patentable subject matter, utility, novelty, and nonobviousness.<sup>69</sup> Patentable subject matter, or those things that can be granted a patent, is now defined by 35 U.S.C. § 101, a statutory provision that has remained virtually identical to that codified in 1793:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.<sup>70</sup>

The only change in this language to date is the substitution of “process” for “art”—a minor modification resulting from Congress’s passage of the Patent Act of 1952.<sup>71</sup>

Both Congress and the Supreme Court have interpreted this statutory provision governing patentable subject matter generously.<sup>72</sup> In harmony with Thomas Jefferson’s philosophy behind the 1793 Act,<sup>73</sup> that “ingenuity should receive a liberal encouragement,” Congress declared in its Committee Reports accompanying the 1952 Act that patentable subject matter should “include anything under the sun that is made by man.”<sup>74</sup> The Supreme Court has since reaffirmed this fundamental principle of patent

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68. See 35 U.S.C. §§ 103, 111 (2012) (requiring a claimed invention to meet the substantive requirement of non-obvious subject matter and the procedural requirement of a written application in order to be granted a patent).

69. 35 U.S.C. §§ 101–103; see also Melissa F. Wasserman, *The PTO’s Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 388–89 (2011) (“On a daily basis, the PTO must make difficult substantive patent law decisions on issues—such as the patentability of subject matter and standards for nonobviousness . . .”).

70. 35 U.S.C. § 101. Compare *id.*, with The Patent Act of February 21, 1793, ch. 11, § 1, 1 Stat. 318, 318–21 (“Be it enacted . . . [t]hat when any person or persons . . . shall allege that he or they have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement [thereof], not known or used before the application . . . and praying that a patent may be granted therefor, it shall and may be lawful for the said Secretary of State, to cause letters patent to be made out . . .”).

71. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308–09 (1980) (explaining that the 1952 Act replaced the word “art” with “process,” but “otherwise left [the existing] language intact”).

72. See, e.g., *id.* (according a “broad construction” of § 101 after finding that Congress meant for the patent laws to be given wide scope as demonstrated by Congress’s choice of statutory language and the provision’s legislative history).

73. Thomas Jefferson authored the 1793 Act, so his philosophy is inherently tied to the Act. *Id.* at 308.

74. *Id.* at 308–09 (citing S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952); 5 WRITINGS OF THOMAS JEFFERSON 75–76 (Washington ed., 1871)).

law in its decisions concerning § 101 eligibility.<sup>75</sup> Illustratively, the Court has explained that the four categories of potentially patentable subject matter—processes, machines, manufactures, and compositions of matter—are to be understood and interpreted broadly per their ordinary, everyday meanings.<sup>76</sup> The Court has reiterated that it will not read limitations into § 101 or otherwise narrow its reach where Congress has not first indicated such intentions.<sup>77</sup>

*B. The Exception to § 101, and the Shift Towards a Thorough Principles-Based Justification*

Although patentable subject matter eligibility is broad under § 101, there is a longstanding, judicially created, implicit exception to this general principle: laws of nature, natural phenomena, and abstract ideas are not patent eligible.<sup>78</sup> Mindfully, the Court has cautioned that the exception cannot be construed too widely given that all inventions use laws of nature, natural phenomena, or abstract ideas to some degree; thus, too extensive of an exception could “eviscerate” patent law’s protection.<sup>79</sup> Although the Court has altered its portrayal of the exception,<sup>80</sup> and its choice of descriptive jargon has evolved,<sup>81</sup> the articulated principles and policy motives behind the exception have remained steadfast, and the Court has

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75. See, e.g., *Bilski v. Kappos*, 130 S. Ct. 3218, 3221 (2010) (“Congress plainly contemplated that the patent laws would be given wide scope . . . .”) (citation omitted) (internal quotation marks omitted); *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (explaining that the Court must be mindful of the 1952 “anything under the sun” Committee Reports).

76. See *Diehr*, 450 U.S. at 182 (explaining that Congress’s choice of the word “process” in the 1952 Act will be interpreted as its ordinary, contemporary sense, unless otherwise defined); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (explaining that the statutory definition of “process” is broad).

77. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l*, 534 U.S. 124, 145–46 (2001) (citing *Chakrabarty* in declining to limit the reach of § 101 where Congress has declined to do so); *Diehr*, 450 U.S. at 182 (same); *Chakrabarty*, 447 U.S. at 308 (“We have . . . cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.”) (citation omitted) (internal quotation omitted).

78. *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1293 (2012).

79. *Id.*

80. Compare *id.* (identifying the exception as solitary—“an important implicit exception”), with *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (explaining that precedent provides three specific exceptions to § 101’s broad patent eligibility) (citations omitted).

81. Compare *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (forbidding a patent on a law of nature, which encompassed “manifestations of laws of nature” or the “phenomena of nature”), with *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (explaining that phenomena of nature, mental processes, and abstract intellectual concepts are not patentable), and *Chakrabarty*, 447 U.S. at 309 (1980) (articulating the exception as comprising of laws of nature, physical phenomena, and abstract ideas).

consistently applied this exception to both “process” and “products” claims under § 101.<sup>82</sup>

Dating all the way back to the decisions of *Le Roy v. Tatham*<sup>83</sup> and *O’Reilly v. Morse*,<sup>84</sup> the Supreme Court has expressed a desire to refrain from granting patents on the use of natural properties and powers; doing so would not only give the patentee a monopoly on new discoveries in physical science involving those properties and powers, but would also stifle further progress by barring other inventors from using them, thus ultimately impeding the public’s ability to benefit from the patent system.<sup>85</sup> In *Le Roy*, the Court reversed the lower court’s grant of a patentee’s claim on the use of machinery whenever the machinery was used to form lead pipes under extreme pressure and heat.<sup>86</sup> The Court explained that a patentable invention exists in the processes used to apply natural agencies—not in the discovery of the agencies itself.<sup>87</sup> The Court further reasoned that patenting the effect or result of a process would be “against the avowed policy of the patent laws,” as creating a monopoly on a given result would discourage further invention in arts and manufactures.<sup>88</sup>

In more modern cases, the Supreme Court identified the policy reasons behind the “laws of nature, natural phenomena, and abstract ideas” exception, but did not discuss the purpose of the exception in as much depth as the *Le Roy* and *Morse* Courts. For example, in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *Diamond v. Diehr*, *Diamond v. Chakrabarty*, and *Bilski v. Kappos*, the Court explained that these three aforementioned “manifestations of nature” were nonpatentable because they were part of the “storehouse of knowledge of men,” which is “free to all and reserved exclusively to none.”<sup>89</sup> In *Gottschalk v. Benson* and *Parker v. Flook*, the

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82. See, e.g., *Benson*, 409 U.S. at 67–68 (explaining that the principles stated in *Funk Bros.*, which dealt with a “product” claim, apply equally to a “process” claim).

83. 55 U.S. 156 (1853).

84. 56 U.S. 62 (1854).

85. See, e.g., *id.* at 113 (invalidating Morse’s 8th claim involving the electro-magnetic telegraph, since his attempt to claim the exclusive right to every improvement of the technique of using electric currents to create letters or marks at a distance would (1) allow him to avail himself of all new discoveries using this technique, (2) “shut the door” on future inventors’ possibly less-complicated and less-expensive inventions, and (3) bar the public’s ability to benefit).

86. *Le Roy*, 55 U.S. at 176–77 (finding the lower court’s jury instruction erroneous).

87. *Id.* at 175.

88. *Id.*

89. This reasoning was first articulated in *Funk Bros.* in 1948, and then cited in the subsequent opinions. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (citations omitted) (explaining that natural phenomena, such as the natural qualities of a bacteria, are part of the storehouse of knowledge of all men, for they are manifestations of the laws of nature, free to all and reserved exclusively to none); *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (citation omitted) (internal quotation marks omitted) (“The concepts covered by these exceptions are part of the storehouse of knowledge of all men[,] free to all and reserved

Court reasoned that laws of nature, natural phenomena, and abstract ideas are nonpatentable because they are “the basic tools of scientific and technological work.”<sup>90</sup> Although the Court’s opinions in these modern cases hinted at policy reasons for the exception, the opinions did not provide a substantial explanation as to *why* these “basic tools” of science and technology—or man’s “storehouse of knowledge”—are nonpatentable, as the *Le Roy* and *O’Reilly* Courts did.<sup>91</sup> The opinions in *Funk Bros.*, *Diehr*, *Chakrabarty*, *Bilski*, *Benson*, and *Flook* did not explain *why* patenting such things are essentially against the “avowed policy” of patent law.<sup>92</sup> This principles-based analysis, however, has not been so lacking in the Court’s most recent decisions.

In *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, the Supreme Court, in a unanimous opinion, articulated the reasoning behind its longstanding exception to § 101 much more profoundly than it had in its more recent decisions.<sup>93</sup> In addition to quoting the recent cases’ expressions of the exception existing for “basic tools of scientific and technological work,” which are “free to all and reserved exclusively to none,” the Court further explained why it is undesirable to monopolize these tools.<sup>94</sup> The Court used cases ranging from the age-old *Morse* to its recent 2010 *Bilski* decision, pulling language together from the array of opinions to bolster its assertion that “[t]he Court has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature.”<sup>95</sup> This assertion was afforded an entire subsection of the Court’s discussion, complete with law review and treatise support.<sup>96</sup> The Court gave concrete examples of the types of scientific and medical developments that could be inhibited should

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exclusively to none.”); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (same); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (same).

90. The Court first used this reasoning in the 1972 *Benson* decision. See *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). The reasoning was used again in *Flook* in 1978. See *Parker v. Flook*, 437 U.S. 584, 589 (1978) (citation omitted).

91. See *supra* notes 83–88 and accompanying text for a description of the *Le Roy* and *O’Reilly* holdings.

92. *Cf.* note 88 and accompanying text (indicating how *Le Roy* did explain why such patents are against the policy underlying patent law).

93. The Court cited *Benson* for the proposition that “the basic tools of scientific and technological work” are not patentable, but then further explained that “monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it . . . . At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.” *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S. Ct. 1289, 1293–94 (2012).

94. *Id.* at 1293 (quoting the language of the previous *Funk*, *Chakrabarty*, and *Benson* decisions before elaborating in its reasoning).

95. *Id.* at 1301.

96. *Id.* at 1301–02.

the claims at hand be deemed patentable.<sup>97</sup> The Court concluded by endorsing a balancing approach to governing inventive activity via patent law by describing patent protection as a “two-edged sword,” able to both stimulate creation, invention, and discovery through the promise of exclusive rights, and impede future invention through that exact exclusivity.<sup>98</sup>

Worth mentioning is a patentable subject matter case that reached the Supreme Court in 2006, which the Supreme Court ultimately did not review on the grounds that writ of certiorari had been improvidently granted.<sup>99</sup> In *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, Justice Breyer—who authored the above-discussed *Mayo* opinion six years later—argued in dissent that the Court indeed had authority to address the question presented of whether the patented process claim at stake was invalid for improperly seeking to “claim a monopoly over a scientific relationship.”<sup>100</sup> Describing the § 101 exception as a “principle find[ing] its roots in both English and American law,”<sup>101</sup> Breyer explained that the exception’s justification was that “sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ [which is] the constitutional objective of patent . . . protection.”<sup>102</sup> After a detailed portrayal of the apparent dangers in overprotection, Breyer encapsulated the exception as a reflection of the “basic judgment” that protection in such cases would too often severely impede the development of useful knowledge, despite the potential for some positive incentive effects.<sup>103</sup>

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97. *Id.* at 1302. Furthermore, the Court relied heavily upon the concern of inhibiting future research in dismissing several additional arguments as to why Prometheus’s claim on a method for determining the proper dosage of thiopurine drugs was patent eligible. *Id.* at 1303–05. For example, the Court rejected the argument that 35 U.S.C. § 112, among other sections, can sufficiently screen out those patents that do not extend beyond a mere law of nature, since unlike § 101, § 112 “does not focus on the possibility that a law of nature (or its equivalent) that meets [§ 112’s conditions] will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation.” *Id.* at 1303–04.

98. *Id.* at 1305.

99. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 125 (2006) (per curiam) (dismissing certiorari).

100. *Id.* at 125–26 (Breyer, J., dissenting). Justice Breyer found that the question presented was fully briefed and not too difficult to answer, and that a decision from “this generalist Court” could contribute to the debate as to whether the current patent system reflects the “careful balance” that the patent laws stand for. *Id.* at 126, 138.

101. *Id.* at 126 (citations omitted).

102. *Id.* at 126–27 (quoting U.S. CONST. art. 1, § 8, cl. 8).

103. *Id.* at 127–28. It is worth noting that Breyer artfully intertwined previous cases’ various terminology of “basic tools of scientific and technological work,” “storehouse of knowledge,” and “manifestations of laws of nature” that are “free to all men and reserved exclusively to none.” *Id.* (citations omitted); see also *supra* notes 91–92 and accompanying text. Breyer also explained that the three categories of nonpatentable subject matter are not easy to define, and that such abstract

C. “Processes” Versus “Products” Under § 101, and Precedent’s Consistency Regarding “Products” Analysis

The Court has indicated that it approaches patent claims under two separate lines of case law for matters of § 101 eligibility: the “processes” line of cases, and the “products” line of cases.<sup>104</sup> This approach mirrors § 101 itself, as “processes” case law understandably encompasses those claims falling under § 101’s “processes” category, and “products” case law encompasses claims falling under the remaining three categories: “machines,” “manufactures,” and “compositions of matter.”<sup>105</sup> The Supreme Court’s decision in *Diamond v. Chakrabarty* illustrates this divide in the case law. In *Chakrabarty*, the Court analyzed whether a patentee’s claimed microorganism fell under § 101’s “manufacture” or “composition of matter” categories in order to be deemed patentable subject matter.<sup>106</sup> In its opinion, the Court compared the facts of *Chakrabarty* to those of only one other case, *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,<sup>107</sup> since *Funk* was clearly a “products” case.<sup>108</sup>

In contrast with the plethora of process cases that it has reviewed, the Court has only considered two cases, *Funk* and *Chakrabarty*, wherein the issue was whether a product fell under one of § 101’s patent-eligible categories or instead under its three-item exception.<sup>109</sup> In *Funk*, the Court considered the patent eligibility of a claim to a cultured mixture of root-nodule bacteria, of interest being the patentee’s discovery of a mixture wherein multiple species of root-nodule bacteria did not inhibit each

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categories cannot easily be used to distinguish instances of likely beneficial, from likely harmful, protection. *Lab. Corp.*, 548 U.S. at 134.

104. See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294, 1298 (2012) (explaining that the cases most directly on point for analyzing the case at hand, concerning patent claims covering a medical diagnostic process, were *Diehr* and *Flook*, as they were two cases where the Court considered the patent eligibility of processes embodying natural laws); see also *infra* notes 109–12 and accompanying text.

105. See 35 U.S.C. § 101 (2012) (limiting patentable subject matter to processes, machines, manufacturers, or compositions of matter). For further discussion of this differentiation, see *supra* note 45.

106. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980).

107. *Id.* at 310.

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

109. All other cases that the Court has considered under the § 101 exception dealt with processes, rather than products. See, e.g., *Bilski v. Kappos*, 130 S. Ct. 3218, 3223 (2010) (considering a process for hedging funds); *Diamond v. Diehr*, 450 U.S. 175, 177 (1981) (determining whether a rubber-curing process was patentable subject matter under § 101); *Parker v. Flook*, 437 U.S. 584, 585, 588–90 (1978) (considering whether a method for updating alarm limits was a patentable process); *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972) (analyzing whether a computer-related method claim was a “process” under § 101).

other.<sup>110</sup> The Court held that the mixture was not patent eligible because the non-inhibitive qualities of the bacteria were qualities of the work of nature, similar to the qualities of metal or electricity.<sup>111</sup> The Court explained that the discovery of phenomena of nature is nonpatentable; a patentable invention lies instead in the application of the “manifestation of the laws of nature” to a new and useful end.<sup>112</sup> Aggregating non-inhibitive species of bacteria fell short of such an invention despite the obvious advantages of the mixture for commercial industry, since the advantage was in the “mere packaging” of the inoculants.<sup>113</sup> Allowing a patent in such a case would mean patenting a now-disclosed “ancient secret of nature.”<sup>114</sup>

The Court came out the other way regarding the patent eligibility of a product claim in *Chakrabarty*, but its analysis heavily mirrored *Funk*—albeit with subtle differences. In *Chakrabarty*, the Court considered whether a microbiologist’s invention of a genetically engineered bacteria capable of breaking down crude oil was patentable subject matter under § 101.<sup>115</sup> Holding that the engineered bacteria “plainly qualifie[d] as patentable subject matter,” the Court explained that the invention was a nonnaturally occurring product of human ingenuity, rather than an unknown natural phenomena.<sup>116</sup> Unlike in *Funk*, where the patentee had simply discovered a part of “nature’s handiwork,” the inventor in *Chakrabarty* had made a breakthrough of his *own* handiwork.<sup>117</sup> The *Chakrabarty* Court thus remained consistent with *Funk*’s distinction between discoveries of natural phenomena and actual inventions, but introduced a new term of art to describe nonpatentable products: “products of nature.”<sup>118</sup> The Court also

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110. *Funk*, 333 U.S. at 130. Prior to petitioner’s patent claim, root-nodule bacteria had long been used to infect the roots of leguminous plants, allowing the plants to take nitrogen from the air and convert it into organic nitrogenous compounds. However, only certain species of root-nodule bacteria was able to infect certain groups of leguminous plants. Furthermore, it had long been understood that different species of the bacteria inhibited each other when mixed, causing a decrease in their efficiency. For this reason, prior to the patented claim at hand, inoculants containing only one species of root-nodule bacteria were manufactured and sold. The patentee discovered that certain strains of the bacteria *did not* create a mutually inhibitive effect, and created a mixed culture capable of inoculating multiple cross-inoculation groups of plants. *Funk*, 333 U.S. at 128–30.

111. *Id.* at 130.

112. *Id.* (citing *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853)).

113. *Id.* at 130–32.

114. *Id.* at 132.

115. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980).

116. *Id.* at 309–10. Of note is that the capability to break down crude oil is possessed by no naturally occurring bacteria. *Id.* at 305, 311.

117. *Id.* at 310 (quoting *Funk*’s “handiwork of nature” expression).

118. *Id.* at 313 (explaining that the relevant distinction regarding patent eligibility is not between living and nonliving things, “but between products of nature . . . and human-made inventions”); *see also supra* 116–17 and accompanying text.

introduced a new description of what a nonnaturally occurring, product of human ingenuity resembles: a product “having a distinctive name, character, [and] use.”<sup>119</sup> Unlike the bacterial concoction in *Funk*, the bacteria invention in *Chakrabarty* had markedly different characteristics than any found in nature.<sup>120</sup>

*D. The Court will Interpret § 101 as is Without Formal Congressional Amendment*

The Supreme Court has reiterated that in the absence of formal congressional action regarding subject matter that the legislature wishes to exclude from § 101 eligibility, the Court will interpret § 101 broadly.<sup>121</sup> In *Chakrabarty*, the petitioner argued that genetically modified organisms could not qualify as patentable subject matter because Congress had not explicitly authorized any such protection.<sup>122</sup> The Court rejected this argument, explaining that although Congress, not the Court, must define patentability’s limits, it is “the province and duty of the judicial department to say what the law is” once Congress has spoken.<sup>123</sup> The Court ruled that Congress’s enactments of the 1930 Plant Patent Act (“PPA”) and 1970 Plant Variety Protection Act (“PVPA”) only demonstrated the legislature’s wish to protect cultivated plants via patent law, and were not to be interpreted as a congressional desire to exclude other living things from general utility patents granted pursuant to § 101.<sup>124</sup> Furthermore, the Court rejected the petitioner’s reliance on the Court’s previous brief warning to proceed with caution when expanding § 101 patentability to areas “unforeseen by Congress,” explaining that that statement did not announce a new principle that unforeseen areas are *per se* nonpatentable.<sup>125</sup>

In *J.E.M. Ag Supply v. Pioneer Hi-Bred Int’l*,<sup>126</sup> the Court built upon its analysis in *Chakrabarty* regarding Congress’s passage of the Plant

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119. *Chakrabarty*, 447 U.S. at 309–10 (citing *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

120. *Id.* at 310.

121. *Id.* at 318.

122. *Id.* at 314.

123. *Id.* at 315 (quoting *Marbury v. Madison*, 1 Cranch 137, 177 (1803)) (internal quotation marks omitted).

124. *Id.* at 310–13.

125. *Id.* at 314–15 (quoting *Parker v. Flook*, 437 U.S. 584, 596 (1978)). The Court explained that, consistent with case law, a statute is not to be confined to the legislators’ contemplations at the time of drafting, and that this is especially true in the field of patent law since denying protections to unanticipated inventions would undermine the law’s purpose. *Id.* at 315–16 (citations omitted).

126. 534 U.S. 124 (2001).

Patent Act and Plant Variety Protection Act.<sup>127</sup> In deciding whether Congress meant to remove plants from § 101's patentable subject matter eligibility by enactment of the PPA and PVPA, the Court explained that the PTO had assigned § 101 utility patents for plants for sixteen years—issuing over 1,800 such patents—with no indication from Congress that those undertakings defied either the PPA or the PVPA.<sup>128</sup> Ultimately holding that neither act limited the scope of § 101's coverage as to plant patents, the Court explained that in addition to not only failing to pass legislation indicating disagreement with the PTO's actions, Congress had already explicitly recognized the availability of utility patents for plants via a statutory amendment.<sup>129</sup>

Regarding the specific subject matter of human DNA and genes, Congress has never passed legislation concerning its patentability under 35 U.S.C. § 101.<sup>130</sup> Congress did, however, pass the American Invents Act (“AIA”) in 2011,<sup>131</sup> which touched on the topic of genetic testing.<sup>132</sup> The AIA required the PTO 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>133</sup> A report and recommendations were due to the U.S. House of Representatives and Senate nine months from the bill's enactment.<sup>134</sup>

In contrast with the legislative branch's relatively limited activity, the PTO has taken a great deal of action pertaining to DNA patents. Beginning in the 1980s and continuing since, the PTO has granted thousands of § 101 patents claiming isolated human DNA, as well as tens of thousands of patents related to modified, non-native genes.<sup>135</sup> This longstanding practice was formalized in the PTO's 2001 Utility Examination Guidelines, which confirmed that both excised genes and cDNA are patent eligible as long as

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127. *Id.* at 130–46.

128. *Id.* at 132, 144–45.

129. *Id.* at 145.

130. The Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007), was introduced but never became law, as it died in committee. This bill would have amended Title 35 of the United States Code to prohibit the patenting of human genetic material. See *Text of the Genomic Research and Accessibility Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/110/hr977/text> (last visited Oct. 13, 2014) (“This bill was introduced on February 9, 2007, in a previous session of Congress, but was not enacted.”).

131. Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284–341.

132. § 27, 125 Stat. at 338.

133. *Id.*

134. *Id.*

135. *Ass'n for Molecular Pathology v. U.S. PTO*, 689 F.3d 1303, 1333 (Fed. Cir. 2012), *aff'd in part, rev'd in part sub nom*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). These numbers have been estimated at 2,645 “isolated DNA” patents, and more than 40,000 patents related to non-native, modified genes. *Id.*

they are sufficiently isolated and purified as to be different from their naturally occurring states.<sup>136</sup>

### III. THE COURT'S REASONING

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>137</sup> the United States Supreme Court affirmed in part and reversed in part the judgment of the United States Court of Appeals for the Federal Circuit in unanimously holding that a DNA segment is not patent eligible merely because it has been isolated from its natural state, but that cDNA is patent eligible because it is not naturally occurring.<sup>138</sup> In so holding, the Court concluded that Myriad's composition claims to the isolated *BRCA1/2* genes—claims to the genes themselves and the information they encode—were not patent eligible, but that their cDNA claims were patentable; the Court did not analyze Myriad's methods claims.<sup>139</sup>

Writing for the unanimous Court, Justice Thomas began by explaining in rather thorough detail the science behind DNA, genes, and genetic sequencing.<sup>140</sup> In a style that could be grasped by the average reader, Justice Thomas described how a single gene is encoded as DNA, how DNA is made of chains of four different nucleotides, how some DNA codes for proteins, how scientists are able to extract DNA from cells, and how experts are able to create synthetic DNA, or cDNA.<sup>141</sup> He then explained how the study of genetics can lead to valuable medical breakthroughs by examining mutations of DNA sequences, and how Myriad accomplished just that by determining the location and sequence of the *BRCA1/2* genes.<sup>142</sup> Thomas's scientific analysis concluded with a description of the nine composition claims at issue in the case: claims to the isolated DNA of each *BRCA* gene, claims to the cDNA sequences of those genes, and claims to the isolated

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136. 2001 Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). These guidelines disagreed with commentators' arguments that genes are nonpatentable discoveries, as opposed to patentable inventions, and alternatively that genes are nonpatentable products of nature. *Id.* The Guidelines relied upon a district court case and a case from the United States Court of Customs and Patent appeals to support its conclusion that isolated, natural compounds and compositions can be patentable—even without any further change—as long as they are purified. *Id.*

137. 133 S. Ct. 2107 (2013).

138. *Id.* at 2111.

139. *Id.* at 2119–20.

140. *Id.* at 2111–12.

141. *Id.*

142. *Id.* at 2112–13.

DNA with any series of 15 nucleotides existing in either gene.<sup>143</sup> Products claims were the only type of claim before the Court.<sup>144</sup>

After describing the scientific background of the case, Justice Thomas shed light on the case's procedural posture.<sup>145</sup> Thomas first explained how the patents, if valid, would give Myriad the exclusive right to isolate *BRCA1/2* as well as the right to create synthetic cDNA of those genes.<sup>146</sup> Thomas also noted that Myriad had secured a monopoly on *BRCA1/2* testing by sending cease-and-desist letters to, and filing patent infringement suits against, multiple laboratories.<sup>147</sup> Next, Thomas explained the Federal Circuit's holding and analysis of Myriad's composition claims when hearing the case on remand.<sup>148</sup> He articulated how the lower court's three judges had differed in their conclusions and reasoning concerning isolated DNA, ultimately holding that the DNA was patent eligible under §101.<sup>149</sup> Thomas concluded his description of the lower court's holding by emphasizing that although all three of the Federal Circuit judges had expressed different opinions regarding isolated DNA's patentability, they had agreed that the claims relating to cDNA were patent eligible.<sup>150</sup>

In deciding the case, the unanimous Court began by identifying the long-held exception to patentable subject matter under 35 U.S.C. § 101: laws of nature, natural phenomena, and abstract ideas.<sup>151</sup> The Court highlighted the purpose behind the long-held exception, explaining how the exception's existence prevents the "considerable danger that the grant of [such] patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'"<sup>152</sup> The exception was described as having limits, however, due to the "delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'impeding the flow of information that might permit, indeed spur, invention.'"<sup>153</sup>

After explaining the purpose of § 101's exception, the Court distinguished the facts of *Myriad* from those of *Diamond v. Chakrabarty*.<sup>154</sup>

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143. *Id.* at 2113.

144. The Court declined to address any methods claims. *Id.* at 2119 (explicitly stating that no method claims were before the Court).

145. *Id.* at 2113–16.

146. *Id.* at 2113.

147. *Id.* at 2114.

148. *Id.* at 2114–15.

149. *Id.* (citations omitted). For further discussion of the three judges' separate opinions, see *supra* note 58.

150. *Myriad*, 133 S. Ct. at 2115 (citations omitted).

151. *Id.* at 2116 (citations omitted).

152. *Id.* (quoting *Mayo*, 132 S. Ct. at 1301).

153. *Id.* (quoting *Mayo*, 132 S. Ct. at 1293, 1305) (alteration omitted).

154. *Id.* at 2116–17.

The Court then reasoned through Myriad's four proposed arguments, finding that neither the novel discovery of the genes, nor the extensive research efforts required to locate the genes, nor the severing of natural chemical bonds, nor the PTO's past practices of awarding gene patents, alone, were able to save Myriad's composition claims.<sup>155</sup> After disposing of Myriad's various arguments, the Court distinguished cDNA from isolated DNA, declining to find cDNA as naturally occurring because a lab technician undeniably creates something new when he or she removes DNA's non-coding segments.<sup>156</sup>

The Supreme Court concluded by emphasizing what was *not* implicated by the decision: first, Myriad's method claims were not at issue because they were found to be so "well understood, widely used, and fairly uniform" that any scientist in the field of genetic sequencing would likely have used a similar process; second, the case did not involve patents on novel applications of knowledge about the *BRCA1/2* genes, which a number of Myriad's unchallenged claims were limited to; and third, the Court did not consider the patentability of DNA where its naturally occurring nucleotide sequence had been altered, because the patentability of an altered genetic code posed a different issue.<sup>157</sup>

Justice Scalia, concurring in part and concurring in the judgment, concluded that he was sufficiently persuaded from studying the lower courts' opinions and various expert briefs that isolated DNA is identical to its natural state of existence, and that cDNA is not similarly present in nature.<sup>158</sup> His very short, separate opinion was offered to emphasize that he did not join in those portions of the Court's opinion that delved into the details of "molecular biology," since he could not affirm such details based upon his own knowledge or belief.<sup>159</sup>

#### IV. ANALYSIS

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>160</sup> the Supreme Court unanimously held that a DNA segment cannot be patented merely because it has been isolated from its natural state, but that cDNA is patentable because it is not naturally occurring.<sup>161</sup> The Court was correct when it followed precedent in multiple ways, most importantly in

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155. *Id.* at 2117–18.

156. *Id.* at 2119.

157. *Id.* at 2119–20 (internal quotation marks omitted).

158. *Id.* at 2120 (Scalia, J., concurring in part and concurring in the judgment).

159. *Id.*

160. 133 S. Ct. 2107 (2013).

161. *Id.* at 2111 (majority opinion).

reinforcing the *Mayo* Court's recent, more thorough enunciation of the principles behind patent law.<sup>162</sup> Through the Court's continued return to a more in-depth, principle-driven justification of patentable subject matter under § 101 and its exceptions, *Myriad* was legally sound.<sup>163</sup> Moreover, *Myriad* manifested as good public policy in properly balancing the interests of all parties involved.<sup>164</sup>

*A. Following Precedent, the Court Clarified the Proper Analysis Regarding "Products" Under § 101, and Emphasized the Fundamental Principles Behind Patent Law*

The Court followed precedent in a number of ways when considering the merits of the case at hand, and in doing so, clarified for the PTO and the lower courts what the correct analysis is regarding products—namely compositions of matter—under § 101. First, the Court correctly followed its “products” line of cases under the longstanding products-processes divergence.<sup>165</sup> Second, the Court properly declined to give the PTO's past—and legally unsound—practices any deference.<sup>166</sup> Third, the Court aptly utilized the recently articulated *Mayo* version of § 101's exception when explaining the exception in the opening paragraphs of its opinion.<sup>167</sup> Lastly, the Court remained consistent with its recent focus on patent law's principles by declaring the delicate balance behind § 101 and its exception as a well-established standard to be applied.<sup>168</sup>

*1. The Court followed precedent when considering the patentability of isolated DNA under § 101*

The Court followed precedent when analyzing the merits of the case, first by identifying *Chakrabarty* as “central to [the] inquiry” at hand.”<sup>169</sup> As previously discussed, the Court has only considered two cases when interpreting § 101 and its exception in the context of products claims: *Chakrabarty* and *Funk*.<sup>170</sup> In *Myriad*, the Court used only these two cases

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162. See *infra* Part IV.A.

163. See *infra* Part IV.A.

164. See *infra* Part IV.B.

165. See *infra* Part IV.A.1.

166. See *infra* Part IV.A.2.

167. See *infra* Part IV.A.3.

168. See *infra* Part IV.A.3.

169. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013).

170. See *supra* notes 109–20 and accompanying text.

to distinguish and analogize the facts of the case at hand with precedent.<sup>171</sup> In addition, the Court remained in line with the major strands of analysis present in *Chakrabarty* and *Funk*, specifically *Chakrabarty*'s description of what a successful inventive product will look like, *Chakrabarty*'s "product of nature" language, and *Funk*'s discovery-invention distinction.<sup>172</sup>

The *Myriad* Court distinguished the case at hand from *Chakrabarty*, explaining that unlike the microbiologist in *Chakrabarty*, *Myriad* did not create anything "with markedly different characteristics from any found in nature" with its claims on isolated DNA.<sup>173</sup> Additionally, the Court utilized *Funk*'s discovery-invention distinction and found *Myriad*'s isolated DNA analogous to *Funk*'s bacterial mixture.<sup>174</sup> The DNA therefore "fell squarely within the law of nature exception," since a claim to a brilliant discovery of a natural thing—here, *Myriad*'s claim to the location of the *BRCA1/2* genes—cannot alone equate to a patentable invention.<sup>175</sup> cDNA, on the other hand, was not found to be a naturally occurring "product of nature," since an exons-only molecule created by a lab technician "is distinct from the DNA from which it was derived."<sup>176</sup> This part of the Court's holding was entirely consistent with the *Chakrabarty* Court's reasoning.<sup>177</sup>

In addition to being analytically correct, the Court's heavy reliance on *Chakrabarty* and *Funk* helped to remedy confusion among the PTO and the lower courts regarding the proper test to use when determining the patentability of compositions of matter. For example, in its 2001 Utility Examination Guidelines, the PTO explicitly declined to recognize *Funk*'s discovery-invention distinction, arguing that discoveries are patentable under the Constitution so long as other statutory requirements of Title 35 of the United States Code are met.<sup>178</sup> Moreover, the PTO did not discuss the precedent established in *Funk* and *Chakrabarty*, both of which clearly instruct that mere discoveries of "phenomena of nature" are nonpatentable.<sup>179</sup>

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171. 133 S. Ct. at 2116–17. The Federal Circuit likewise noted that *Chakrabarty* and *Funk* are the two cases setting out the primary framework for considering the patentability of compositions of matter such as isolated DNA. *Ass'n for Molecular Pathology v. U.S. PTO*, 689 F.3d 1303, 1326, 1340 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 133 S. Ct. 2107 (2013).

172. *See supra* notes 109–20 and accompanying text.

173. 133 S. Ct. at 2117 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)).

174. *Id.*

175. *Id.*

176. *Id.* at 2119.

177. *See supra* notes 115–20 and accompanying text.

178. 2001 Utility Examination Guidelines, *supra* note 136 at 1093–94.

179. *See id.* at 1092–99 (not once mentioning the term "phenomena of nature"); *see also supra* notes 104–20 and accompanying text.

In addition to the confusion over the patentability of “discoveries” under § 101, a strand of analysis has existed among the lower courts that is not present in Supreme Court precedent: the purification doctrine.<sup>180</sup> This concept of “purified” compounds weaved its way into the PTO Guidelines as well, illustrated by the PTO’s statement that the discovery of a gene may be the basis for a patent, as long as “purifying steps” have separated the gene from its surrounding molecules.<sup>181</sup> Consistent with Supreme Court precedent, the *Myriad* decision did not use the terms “pure” or “purification.”<sup>182</sup> Thus, the absence of such terms was legally sound and clarifying for the lower courts and the PTO.

2. *The Court properly declined to give deference to the PTO’s longstanding practice of granting patents on DNA-related claims*

The Court was correct when it refuted *Myriad*’s argument that the PTO’s past practices are entitled to deference under *J.E.M. Ag. Supply*.<sup>183</sup> In *J.E.M.*, the Court acknowledged that the PTO had issued thousands of patents on plants under § 101, with no indication from Congress that such practices violated either the PPA or the PVPA.<sup>184</sup> The *J.E.M.* Court, however, mentioned the PTO’s practices, not to give the PTO deference, but to illustrate Congress’s inaction as to any prohibition on the granting of plant patents under § 101.<sup>185</sup> Furthermore, the *J.E.M.* Court noted that Congress had recognized the patentability of plants via a statutory amendment.<sup>186</sup> The essential argument of *J.E.M.*—consistent with *Chakrabarty*—is that the Court will interpret § 101 as it is written, barring some formal, statutory amendment.<sup>187</sup> The *Myriad* decision was utterly in line with this reasoning when the Court distinguished the case at hand from *J.E.M.*, explaining that here, “Congress has not endorsed the views of the PTO in subsequent legislation.”<sup>188</sup>

Unlike the formal congressional action at hand in *J.E.M.*, Congress has never passed any statutory amendment recognizing the patentability of

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180. See, e.g., *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (explaining that patents for only a degree of purity to an extracted product are not new compositions of matter).

181. 2001 Utility Examination Guidelines, *supra* note 136 at 1093.

182. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107–20 (2013) (not once using these terms).

183. *Id.* at 2118.

184. See *supra* note 128 and accompanying text.

185. See *supra* notes 127–29.

186. See *supra* note 129 and accompanying text.

187. See *supra* Part II.D.

188. 133 S. Ct. at 2118.

human genes.<sup>189</sup> Rather, a bill was introduced—which later died in committee—to prohibit the patenting of human genetic material under Title 35 of the United States Code.<sup>190</sup> If anything, this kind of initiated congressional action plays in AMP’s favor. Regardless, the Supreme Court has made clear that absent *formal* congressional action via a statutory amendment, the Court will interpret § 101 as it stands.<sup>191</sup> The Court need not give the PTO deference, and this is especially so considering the PTO’s failure to correctly follow Supreme Court precedent regarding § 101 in the realm of DNA patents.<sup>192</sup> Notably, the Court’s refusal to give the PTO deference in the case at hand substantially weakened the lower Federal Circuit’s reasoning.<sup>193</sup>

3. *The Court remained consistent with precedent when articulating the § 101 exception and when emphasizing the fundamental principles behind it*

The Court followed precedent when articulating the § 101 exception and explaining the fundamental principles behind it. First, the Court identified the three-item exception as a solitary, implicit exception: “the rule against patents on naturally occurring things.”<sup>194</sup> This articulation followed that which was expressed in *Mayo*, where the Court described the three-part laws of nature, natural phenomena, and abstract ideas exception as one single exception instead of the plural “exceptions” expression of earlier cases.<sup>195</sup> In addition to following *Mayo*’s diction, this slight alteration in phrasing may have had a beneficial refining effect, for the three-part exception has not gone without its fair share of criticism.

For example, In *Lab. Corp. of Amer. Holdings*,<sup>196</sup> Justice Breyer explained that the three categories listed in the implicit exception to § 101 are not easily defined, and moreover cannot be easily used to distinguish instances of likely beneficial patent protection from instances that are likely harmful.<sup>197</sup> Similarly, in *Funk*, Justice Frankfurter explained that terms

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189. See *supra* Part II.D.

190. See *supra* note 130 and accompanying text.

191. See *supra* Part II.D.

192. See *supra* Part IV.A.1.

193. See *supra* note 58 (discussing Judge Moore’s dependence on the PTO’s practices in finding isolated DNA patentable, and how her judgment might have been altered had she been deciding the case on a blank canvas—i.e., with no deference given to the PTO).

194. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (citation omitted).

195. See *supra* note 80 and accompanying text.

196. 548 U.S. 124 (2006).

197. *Id.* at 134 (citations omitted).

such as “the work of nature” and the “laws of nature” are vague and malleable terms, and that focusing on the discovery-invention distinction is a better approach to determining patentability.<sup>198</sup> By remaining consistent with the *Mayo* Court’s approach to identifying the § 101 exception as a solitary exception, describing it as “[t]he rule against patents on naturally occurring things,” the *Myriad* Court condensed and simplified the exception to its essential premise.<sup>199</sup> This approach complements the Court’s return to an emphasis on the fundamental principles driving the exception as the true standard itself.<sup>200</sup>

In light of *Mayo*, the *Myriad* Court appropriately identified the delicate balance to be struck between incentivizing innovation and impeding the flow of information required for such innovation as the “well-established standard” to be applied in determining the patentability of *Myriad*’s claims.<sup>201</sup> As previously discussed, the *Mayo* Court recently took the approach of explaining the reasoning behind the § 101 exception more profoundly than the Court had in previous cases over the last half-century.<sup>202</sup> In *Mayo*, the Court went a step further beyond the statements that laws of nature, natural phenomena, and abstract ideas are nonpatentable because they are “tools of scientific and technological work” or part of the “storehouse of knowledge of men” and explained *why* these things are nonpatentable—specifically, they “tie up” the use of such tools and thus inhibit future innovation requiring them.<sup>203</sup> The *Mayo* Court then concluded by endorsing a balancing approach when determining subject matter patentability.<sup>204</sup> *Mayo* mirrored Justice Breyer’s earlier dissenting opinion in *Lab. Corp.*,<sup>205</sup> but due to *Lab. Corp.*’s weak precedential authority, the *Myriad* Court was correct in relying solely on *Mayo*.<sup>206</sup>

A common thread among cases dealing with § 101’s exception is the Court’s bar on claims that directly or indirectly preempt natural laws or phenomena after a determination that the inventor had attempted to preclude others from utilizing the laws or phenomena.<sup>207</sup> The Federal

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198. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132, 134–35 (1948) (Frankfurter, J., concurring).

199. 133 S. Ct. at 2116.

200. *See infra* notes 209–10 and accompanying text.

201. 133 S. Ct. at 2116.

202. *See supra* notes 93–98 and accompanying text.

203. *See supra* note 95 and accompanying text.

204. *See supra* note 98 and accompanying text.

205. *See supra* notes 100–03 and accompanying text.

206. *See supra* note 99 and accompanying text (explaining that *Lab. Corp.* was granted writ of certiorari, but was later dismissed as improvidently granted).

207. *In re Bergy*, 596 F.2d 952, 988–96 (C.C.P.A. 1979) (Baldwin, J., concurring) (discussing a number of cases where the Supreme Court centered its analysis on the phenomenon making the

Circuit even found this standard to be *Mayo*'s rallying point in more ways than one: the majority opinion described *Mayo* as "provid[ing] valuable insights and illuminat[ing] broad, foundational principles" and found the *Mayo* opinion to be "focused on [the Court's] concern that permitting patents on particular subject matter would prevent use by others" of the laws of nature at hand.<sup>208</sup> The *Mayo* and now *Myriad* Courts' focus on the fundamental principles justifying § 101's exception—specifically, that naturally occurring things are nonpatentable *because* granting patents on such tools of science and technology would "tie up" the use of them and thus inhibit further invention—is not novel for the Court, but rather a return to the well-reasoned, more thorough analyses of early cases such as *Le Roy* and *Morse*.<sup>209</sup> By paring down *Mayo*'s robust and thorough reasoning into an equally-principled, but more workable, explicit "standard,"<sup>210</sup> the *Myriad* Court has set an excellent foundation for future cases to come.

*B. In Bolstering the Court's Return to an Emphasis on Patent Law's Fundamental Principles, the Court Achieved Balanced Public Policy*

By continuing the Supreme Court's return to an approach that highlights the essential principles of patent law when deciding § 101 patentable subject matter cases, the *Myriad* Court achieved exactly what patent law strives to attain. By proscribing patents on claims to isolated DNA but allowing patents on claims to cDNA and certain other related claims, the Court struck the balance between incentivizing further invention on the one hand, and impeding the flow of information required for further invention on the other.<sup>211</sup> This healthy compromise manifested as a mere

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invention valuable and then determined whether or not the inventor attempted to preclude others from using those phenomena).

208. *Ass'n for Molecular Pathology v. U.S. PTO*, 689 F.3d 1303, 1326, 1331 (Fed. Cir. 2012), *aff'd in part, rev'd in part*, 133 S. Ct. 2107 (2013).

209. *See supra* Part II.B.

210. *See supra* notes 194–200 and accompanying text. Unlike in *Mayo*, the *Myriad* Court did not delve into nearly as comprehensive of an analysis of the policy reasons for the exception; for example, the Court refrained from giving concrete examples of possible scientific and medical advancements that could be inhibited. *Cf. supra* notes 95–97 and accompanying text (discussing *Mayo*'s thorough analysis).

211. *See supra* Part III; *see also* Ker Than, *7 Takeaways from Supreme Court's Gene Patent Decision*, NAT'L GEOGRAPHIC (June 14, 2013), [http://news.nationalgeographic.com/news/2013/06/130614-supreme-court-gene-patent-ruling-human-genome-science/?rptregcta=reg\\_free\\_np&rptregcampaign=20131016\\_rw\\_membership\\_r1p\\_us\\_dr\\_w#finished](http://news.nationalgeographic.com/news/2013/06/130614-supreme-court-gene-patent-ruling-human-genome-science/?rptregcta=reg_free_np&rptregcampaign=20131016_rw_membership_r1p_us_dr_w#finished).

slap on the wrist for the biotech industry, and an enormous win for science, public health, and medicine.<sup>212</sup>

Although initial impressions regarding the effect of the *Myriad* decision on the biotech industry were conflicting,<sup>213</sup> it has become clear that the repercussions of holding isolated DNA patent ineligible were not at all as dire as formerly predicted.<sup>214</sup> Although *Myriad*'s stock price and the NASDAQ index for biotech companies immediately rose and then fell following the Supreme Court's ruling, both have since returned to the levels that they were at before the ruling.<sup>215</sup> Even *Myriad* itself hailed the decision as a "victory" in a press release immediately following the decision.<sup>216</sup> Much of this is likely largely attributed to the fact that the real moneymakers in the realm of genetic research and testing are patents for claims related to synthetic DNA and method-related claims.<sup>217</sup> In *Myriad*, the Court explicitly held that cDNA is patentable subject matter, and then deliberately took the initiative to spell out exactly what was not implicated by its decision.<sup>218</sup> By "merely hold[ing] that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material," the Court left intact

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212. See, e.g., Heidi Ledford, *Myriad Ruling Causes Confusion*, 498 NATURE 281, 281 (2013) (describing a geneticist's and chief medical officer's jubilant reactions following announcement of the *Myriad* decision); Grace Wyler, *Why the Biotech Industry is Rejoicing Over the End of Gene Patents*, MOTHERBOARD (June 17, 2013, 9:00 AM), <http://motherboard.vice.com/blog/why-the-biotech-industry-is-rejoicing-over-the-end-of-gene-patents> (noting that Greg Graff, a Colorado State University professor, described the ruling's effect on the biotech industry as a "shot in the arm").

213. See Ledford, *supra* note 212 (explaining that a "grey area" between the rulings on isolated and modified DNA puzzled observers, and that some of the confusion stemmed from how the justices defined "synthetic DNA").

214. See, e.g., Wyler, *supra* note 212.

215. See *id.* (explaining the ruling's initial repercussions for stock prices and the NASDAQ index); *MYGN Historical Prices—Myriad Genetics, Inc.*, YAHOO! FINANCE, <http://finance.yahoo.com/q/hp?s=MYGN&a=05&b=6&c=2013&d=00&e=15&f=2015&g=d> (last visited Jan. 16, 2015) (comparing *Myriad*'s June 2013 stock price fluctuations to the current price as of Jan. 15, 2015).

216. See Steve Porter, *Myriad Genetics Court Ruling a Partial Victory for All Sides*, INNOVATIONNEWS (June 19, 2013), <http://innovationnews.com/blogs/editorially-speaking/myriad-genetics-court-ruling-a-partial-victory-for-both-sides/> (noting that *Myriad*'s attorney, Rick Marsh, declared the victory a ruling for the diagnostics test maker by stating that the balance of the company's patent estate remained valid and enforceable and thus the company was happy with the Court's decision).

217. See Than, *supra* note 211 (noting that Robert Cook-Deegan, professor at Duke University's Institute for Genome Sciences and Policy, described the cDNA patents as "the billion-dollar molecule patents"); see also Wyler, *supra* note 212 (explaining that what is done with a gene is what truly matters, because most commercial products tend to hinge the synthetic concepts rather than the isolated gene).

218. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–20 (2013).

Myriad's patents on methods for screening cancer therapeutics, as well as a number of Myriad's unchallenged claims.<sup>219</sup>

In contrast to the mere hiccup for Myriad and the rest of biotech, the *Myriad* decision was a cause for celebration for science, public health, and personalized medicine.<sup>220</sup> In holding that isolated DNA was nonpatentable subject matter, the Supreme Court threw out Myriad's monopoly over *BRCA1/2* testing services.<sup>221</sup> Just hours after the decision was announced, companies began offering competing testing services for the *BRCA1/2* genes, some at just one-third of Myriad's established price.<sup>222</sup> This tremendously lowered price will allow a large number of patients who could not previously afford the testing to obtain preliminary tests, and could even allow patients to obtain subsequent testing for purposes of secondary opinions on diagnoses.<sup>223</sup> Furthermore, now that the basic tool of science and technology—isolated DNA—cannot be the subject of a patent claim, “the doors of innovation” have been opened, allowing scientists and inventors to make further progress and discovery regarding DNA data.<sup>224</sup> Researchers will no longer have reason to complain about the “chilling effect” that the lack of this data has had on further advancement in the field of genetic sequencing.<sup>225</sup>

## V. CONCLUSION

In *Myriad*, the Supreme Court exalted the central principles of patent law, and did so by remaining entirely consistent with its established precedent.<sup>226</sup> By remaining aligned with its recent return to approaching § 101 cases with a complete analysis of the longstanding exception to patentable subject matter, the Court achieved the original purpose of patent protection—the Constitution's decree to “promote the Progress of Science and useful Arts.”<sup>227</sup> The Supreme Court successfully struck the balance to

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219. *Id.* at 2120. The Court foreshadowed the strength of these unchallenged claims, quoting Judge Bryson's language that “Myriad was in an excellent position to claim applications of . . . knowledge [about the *BRCA1/2* genes].” *Id.*

220. *See supra* note 212 and accompanying text.

221. *See supra* note 147 and accompanying text.

222. *See* Than, *supra* note 211; *see also* Noam Prywes, *The Supreme Court's Sketchy Science*, SLATE (June 14, 2013, 12:15 PM), [http://www.slate.com/articles/health\\_and\\_science/science/2013/06/supreme\\_court\\_patent\\_case\\_science\\_the\\_justices\\_misunderstand\\_molecular\\_biology.html](http://www.slate.com/articles/health_and_science/science/2013/06/supreme_court_patent_case_science_the_justices_misunderstand_molecular_biology.html) (indicating Myriad's past testing fees).

223. *See supra* note 31 (describing individual female plaintiffs' own experiences with affording genetic testing services).

224. Wyler, *supra* note 212.

225. Prywes, *supra* note 222.

226. *See supra* Part IV.A.

227. *See supra* note 67 and accompanying text.

patent law's double-edged sword, and established sound public policy in doing so.