

# FROM PINE STRAW TO CDNA: THE HISTORY OF THE “PRODUCT OF NATURE” DOCTRINE

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## I. INTRODUCTION

The evolution of the biotechnology market includes important landmark advancements in science including the development of vaccination,<sup>1</sup> antibiotics,<sup>2</sup> DNA sequencing,<sup>3</sup> recombinant DNA,<sup>4</sup> the polymerase chain reaction,<sup>5</sup> and the Human Genome Project.<sup>6</sup> These leaps forward have caused the biotechnology industry to become one of the fastest growing commercial markets worldwide, earning more than \$83.6 billion in total revenues in 2011 alone.<sup>7</sup> Just as with all other technological industries, the biotech industry relies on the protection of patents, copyrights, and trademarks to protect their investments in their research, products, and customer goodwill.<sup>8</sup> This much needed protection creates conflict in the court system with what is commonly referred to as the “product of nature” doctrine.<sup>9</sup> The product of nature doctrine prevents the issuance of patents that claim subject matter that consists entirely of natural phenomena.<sup>10</sup> This restriction is vague at best and all-encompassing at worst. The inherent nature of biological

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1. See generally Alexandra M. Stern & Howard Markel, *The History of Vaccines and Immunization: Familiar Patterns, New Challenges*, 24 HEALTH AFFAIRS 611, 611-12 (June 2005), available at <http://content.healthaffairs.org/content/24/3/611.full>.

2. See Jon Clardy et al., *The Natural History of Antibiotics*, 19 CURRENT BIOLOGY 437, 437 (June 2009), available at <http://www.sciencedirect.com/science/article/pii/S096098220900918X#>.

3. See generally Jay Shendure & Hanlee Ji, *Next-generation DNA Sequencing*, 26 NATURE BIOTECHNOLOGY 1135, 1135 (Oct. 2008), available at <http://www.nature.com/nbtjournal/v26/n10/full/nbt1486.html#f1>.

4. See JAMES D. WATSON ET AL., RECOMBINANT DNA: GENES AND GENOMES: A SHORT COURSE 75-76 (3d ed. 2007).

5. See generally JOHN M. S. BARTLETT & DAVID STIRLING, METHODS IN MOLECULAR BIOLOGY, VOL. 226: PCR PROTOCOLS 3 (2d ed. 2003).

6. See Terry Ng, *The Beneficial Effects of DNA Crunching: The Human Genome Project*, 1 THE MEDUCATOR 8 (2002), available at <http://digitalcommons.mcmaster.ca/cgi/viewcontent.cgi?article=1231&context=meducator>.

7. JACK W. PLUNKETT, PLUNKETT'S BIOTECH & GENETICS INDUSTRY ALMANAC 2013, 8 (1st ed. 2012).

8. See generally Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 15-23 (1990) (discussing the biotechnology industry's characteristics including high development costs and the general importance of patents to the industry).

9. See, e.g., Jonah D. Jackson, *Something Like the Sun: Why Even “Isolated and Purified” Genes Are Still Products of Nature*, 89 TEX. L. REV. 1453, 1454 (2011) (referring to the product of nature doctrine); See also Eileen M. Kane, *Patenting Genes and Genetic Methods: What's at Stake?*, 6 J. BUS. & TECH. L. 1, 2 (discussing the need for a modern interpretation of the product of nature doctrine due to the life sciences' inherent entanglement with the issue).

10. See generally DONALD S. CHISUM, 1-1 CHISUM ON PATENTS § 1.02[7] (2012).

research requires the involvement of organic—and even living—material in the hopes of advancing the art.<sup>11</sup> The two most recent Supreme Court cases involving this longstanding conflict between the complexities of modern biotechnology research and jurisprudential doctrine are *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*<sup>12</sup> and *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>13</sup>

This note seeks to determine the outer bounds of this doctrine. Primarily, this note examines the court's historical application of the product of nature bar. Additionally, this note seeks to determine to what degree, if any, the Supreme Court contributed to this line of cases in its decisions in *Prometheus* and *Myriad*. Because the changes brought by the America Invents Act ("AIA") do not materially affect the issues discussed in this comment, all mentions of statutes contained within Title 35 will be to the pre-AIA versions.<sup>14</sup>

## II. PRODUCT OF NATURE DOCTRINE: PURIFICATION AND PATENTABILITY

The statutory requirements for patent eligibility are laid out in Title 35 of the United States Code<sup>15</sup> and are supplemented by the Manual of Patent Examining Procedure ("MPEP").<sup>16</sup> These requirements include utility,<sup>17</sup> novelty,<sup>18</sup> non-obviousness,<sup>19</sup> and enablement.<sup>20</sup> Additionally the courts have supplemented these

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11. See Kane, *supra* note 9, at 32.

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

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

14. See generally Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (making important changes to American patent law, namely, switching from a "first to invent" to a "first to file" system).

15. See 35 U.S.C. §§ 101-03 (2006 & Supp. 2011).

16. MPEP §§ 2104-06 (8th ed. Rev. 9, Aug. 2012) (explaining generally patentable subject matter and laying out the four categories statutory subject matter: process, machine, manufacture, and composition of matter).

17. 35 U.S.C. § 101 (2006) (stating that a discovery or invention must be "new and useful" in order to be patentable).

18. 35 U.S.C. § 102(a) (2006 & Supp. 2011) (stating that in order to be patentable, an invention must not be "known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent").

19. 35 U.S.C. § 103(a) (2006 & Supp. 2011) (stating that an invention is not patentable if it "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains").

20. 35 U.S.C. § 112 (2006 & Supp. 2011) (stating that the inventor must write the description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains" to replicate the invention).

statutory requirements,<sup>21</sup> as well as supplied bars to the patentability of specific subject matters.

While the federal courts have long enforced a bar on patents that claim “products of nature,”<sup>22</sup> the origin of this doctrine is unclear.<sup>23</sup> The MPEP states “a claimed invention must not be directed to one of the judicially recognized exceptions, which have been specifically excluded from patent eligibility” including “laws of nature, natural phenomena, or abstract ideas.”<sup>24</sup> While these guidelines provide some instruction as to the scope of patentability, they provide little guidance as to what these terms of art—“laws of nature”, “natural phenomena”, or “abstract ideas”—actually mean in practice.<sup>25</sup> To determine the scope of the product of nature doctrine, this note will analyze the governing case law from its earliest days. While there exist early outlier patents that were issued despite their questionably natural claims,<sup>26</sup> two of the earliest cases that clearly acknowledge the existence of the product of nature doctrine are *American Wood-Paper Co. v. Fibre Disintegrating Co.* and *ex parte Latimer*.<sup>27</sup>

#### A. *American Wood-Paper Co. v. Fibre Disintegrating Co.* (1874)

While the origins of the doctrine at issue here are not precisely known, the Supreme Court laid the groundwork for decades to come in their ruling in *American Wood-Paper Co.*<sup>28</sup> In

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21. See generally *KSR International v. Teleflex*, 550 U.S. 398, 415 (2007) (contributing to the law on obviousness by reinforcing an “expansive and flexible approach”).

22. See generally *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123. (holding that fibers extracted from pine needles are not patentable because they are made by nature); see also *Am. Wood-Paper Co. v. Fibre Disintegrating Co.*, 90 U.S. 566 (1874); see also *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884).

23. Iver P. Cooper, *The “Product of Nature” Doctrine*, 1 BIOTECHNOLOGY AND THE LAW § 3.1 (2012).

24. MPEP § 706.03(a) (8th ed. Rev. 9, Aug. 2012) (explaining that the “judicially recognized exceptions include scientific truths, abstract ideas, mental processes, processes of human thinking, and systems that depend for their operation on human intelligence alone,” but are “collectively referred to as laws of nature, natural phenomena, or abstract ideas”).

25. See generally 35 U.S.C. § 101 (2006).

26. See generally U.S. Patent No. 141,072 (filed May 9, 1873 by Louis Pasteur for “Improvement in the Manufacture of Beer and Yeast” which includes a claim for “Yeast, free from organic germs of disease, as an article of manufacture”).

27. John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. PAT. & TRADEMARK OFF. SOC’Y 301, 320, n. 141 (2003).

28. See Linda J. Demaine & Aaron X. Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV.

this case, the Court was faced with an infringement suit involving a challenge to a patent claiming the invention of purified cellulose for the manufacture of paper.<sup>29</sup> Although the accused infringer's actions—which used a different source for the cellulose—fell within the language of the claims, they argued that the patent was invalid because it lacked invention.<sup>30</sup> Justice Strong reasoned that while a novel process to obtain a purified substance may be a patentable invention, the substance “itself cannot be called a new manufacture.”<sup>31</sup> While a pure version of the pulp had not been previously obtainable, pulp that was “approximately pure” was available.<sup>32</sup> The Court reasoned that this new, more-pure pulp was not significantly different than the prior art therefore it did not meet the minimum requirements for novelty and did not warrant protection.<sup>33</sup>

Therefore, the early standpoint of the Supreme Court—and thereby the patent system—was that in order to protect a previously known product, naturally occurring or otherwise, the product must be altered beyond mere purification unless doing so causes significant alteration to the preexisting product.<sup>34</sup>

#### B. *Ex parte Latimer* (1889)

In another of the earliest cases articulating the product of nature doctrine, *ex parte Latimer*, the Commissioner for Patents lays out a great starting point from which to build the modern state of the doctrine.<sup>35</sup> The applicant attempted to patent the method of extracting fibers from the pine needles of the *Pinus australis* tree, in addition to the fibers themselves.<sup>36</sup> In the primary examination, the examiner granted the claim directed to the method of extraction, but refused the claim on the fiber itself because it was not unique enough when compared to other vegetable-base fibers.<sup>37</sup>

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303, 332 (2002) (stating that this case was the “Supreme Court’s first examination of the patentability of ‘purified’ natural products”).

29. *Am. Wood-Paper Co.*, 90 U.S. at 594.

30. *Demaine & Fellmeth*, *supra* note 28, at 332.

31. *Am. Wood-Paper Co.*, 90 U.S. at 593-4.

32. *Id.* at 594.

33. *Demaine & Fellmeth*, *supra* note 28, at 332.

34. *Id.*

35. *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123, 125 (holding that “it is doubtful whether the invention would consist of anything more than the process of which the fiber could be taken from the natural leaf or needle in which it is produced by natural processes”).

36. *Id.*

37. *Id.*

Upon review by the Commissioner, the inventor's claim of the fiber itself was rejected for two reasons: the fiber was known<sup>38</sup> and the fiber was made by nature.<sup>39</sup> The Commissioner went on to paint a picture of what would come to be if such a claim was held to be valid by explaining that this type of patent could lead to all plant-life on the planet falling under someone's patent protection.<sup>40</sup> This policy argument—as we will see in future cases and writings—is one that has followed this doctrine to this very day. The analysis by the Commissioner in *ex parte Latimer* lays out their essential elements for the product of nature doctrine:<sup>41</sup>

1. An object that is in its naturally occurring state is not patentable subject matter.
2. The novelty of the method of production or the discovery of a product of nature are not sufficient to obtain patentability
3. The utility or value to the general public does not affect the patentability of the claim.<sup>42</sup>

Commissioner Hall appears to shed some light on the outer bounds of the product of nature doctrine. He explained that had there been a final step in the applicant's process which caused the fiber to be "withdrawn or separated from the leaf or needle in its natural state . . . [thus] giving it some new quality or function which it does not possess in its natural condition," the invention would likely be treated as something wholly new, not a product of nature, and patentable.<sup>43</sup> According to this analysis, something found in nature, but modified in such a way that it gains some

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38. *Id.* (explaining that the invention must not be known in order to be patentable); see also 35 U.S.C. § 102(a) (2006 & Supp. 2011) (novelty requirement).

39. *Ex parte Latimer*, 1889 Dec. Comm'r Pat. at 125 ("Nature made them so and not the process by which they are taken from the leaf or the needle. It cannot be said that the applicant in this case has made any discovery, or is entitled to patent the idea, or fact . . . because the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention . . .").

40. *Id.* at 126 ("[S]uccessively, patents might be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible.").

41. *Id.* at 126-27; see Conley & Makowski, *supra* note 27, at 322.

42. *Ex parte Latimer*, 1889 Dec. Comm'r Pat. at 127 ("[W]hile the production may be thus regarded as a very valuable one, the invention resides . . . exclusively in the process and not at all in the product.").

43. *Id.*

functionality, would satisfy the product of life hurdle of patentability.<sup>44</sup>

C. *Kuehmsted v. Farbenfabriken of Elberfeld Co. (1910)*

The unforgiving doctrine laid out by the courts in *American Wood-Paper Co.* and the office in *ex parte Latimer* did not survive unscathed for long.<sup>45</sup> Twenty years after *ex parte Latimer*, the Seventh Circuit was asked to tackle an issue involving the patent for acetyl salicylic acid or, as it is commonly known, aspirin.<sup>46</sup> The claims of the patent protected acetyl salicylic acid as an article of manufacture in a purified form.<sup>47</sup> The Seventh Circuit was asked to resolve whether the existence of an impure version of the compound amounted to prior art that should invalidate the patent.<sup>48</sup>

The Seventh Circuit took the approach that patentability is tied to the therapeutic effectiveness of the compound.<sup>49</sup> The original, prior-existing compound and what was covered by the patent were chemically identical, except that unlike the original, the patented article of manufacture exists in a purified state.<sup>50</sup> In examining the differences and similarities between the two, the court explained that the chemical formula being identical is not determinative where the chemical behavior and therapeutic value differ considerably due to the purified nature of the patent protected compound.<sup>51</sup>

The court upheld the patent explaining that the inventor has developed “a medicine indisputably beneficial to mankind” which is precisely the result that “patent policy was intended to promote.”<sup>52</sup> This policy led the court to explain that patentability is possible in cases where purification is the only difference,

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44. *See Id.*

45. *See Demaine & Fellmeth, supra* note 28, at 334.

46. *See* U.S. Patent No. 644,077 (filed Aug. 1, 1898).

47. *Farbenfabriken of Elberfeld Co. v. Kuehmsted*, 171 F. 887, 887-88 (N.D. Ill. 1909).

48. *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 703 (7th Cir. 1910).

49. *Id.* at 704-705; *see* Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 326 (1995) (explaining the court held that patentability may be found in a previously known compound “as long as the purified compound was useful in a manner that the original mixture was not”).

50. *Kuehmsted*, 179 F. at 705; *see also* Ashley McHugh, *Invalidating Gene Patents: Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 62 HASTINGS L.J. 185, 211 (2010).

51. *Kuehmsted*, 179 F. at 704; *see also* Richard S. Gipstein, *The Isolation and Purification Exception to the General Unpatentability of Products of Nature*, 4 COLUM. SCI. & TECH. L. REV. 1, 20 (2003).

52. *Kuehmsted*, 179 F. at 705.

when the purified form is “therapeutically available” while the original form is “therapeutically unavailable.”<sup>53</sup>

Since aspirin is not a naturally occurring compound, the court did not directly address the product of nature doctrine, but their analysis—in addition to adding to reasoning that would be drawn on by later court opinions—provides some guidance as to factors courts may look to in determining whether claimed subject matter is patentable.<sup>54</sup> Under this analysis, removing impurities in order to create functionality and utility in a substance that was previously known increases the patentability of the purified substance. Adding this to the rationale laid out in *ex parte Latimer*, we can reason that purification or modification of a previously-known substance in such a way that adds functionality constitutes sufficient grounds for a finding of patentable subject matter.<sup>55</sup>

#### D. *Parke-Davis & Co. v. H.K. Mulford Co. (1911)*

The reasoning used by the Seventh Circuit was adopted by renowned Judge Learned Hand in *Parke-Davis* when the validity of a patent concerning purified adrenaline was brought before the court during an infringement action.<sup>56</sup> The patent claimed the purified adrenaline itself, not the process by which it was purified.<sup>57</sup> The patent had been originally rejected by the patent examiner who misinterpreted an earlier case<sup>58</sup> and believed that no product patent was eligible even if obtained by a novel process.<sup>59</sup> This circumstance gave the court an opportunity to apply the purification situation—as in *Kuehmsted*—to a product that is biological in nature.<sup>60</sup>

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53. *Id.* at 705 (stating that the difference between the original compound and the protected compound “be one of purification only— strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable— patentability would follow”).

54. See *Davis*, *supra* note 49, at 326.

55. See *ex parte Latimer*, 1889 Dec. Comm’r Pat. 123, 127; *Davis*, *supra* note 49, at 326.

56. *Parke-Davis & Co. v. H. K. Mulford & Co.*(*Parke-Davis I*), 189 F. 95, 97 (C.C.S.D.N.Y. 1911).

57. U.S. Patent No. 730,176 (filed Jan. 14, 1903) (claim 1).

58. The examiner misinterpreted the Supreme Court’s holding in *American Wood-Paper Co. v. Fibre Disintegrating Co.* See *Gipstein*, *supra* note 51, at 13 (referring to *Am. Wood-Paper Co.*, 90 U.S. at 566 (1874)); See also *Demaine & Fellmeth*, *supra* note 28, at 337-38.

59. *Gipstein*, *supra* note 51, at 13.

60. *Parke-Davis I*, 189 F. at 103; see *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 703-05 (7th Cir. 1910).



Judge Hand reasoned similarly with the Seventh Circuit in *Kuehmsted*, and explained that through purification, the adrenaline “became for every purpose a new thing commercially and therapeutically.”<sup>61</sup> Judge Hand concluded that this new commercial and therapeutic utility was enough to establish patentable subject matter for purified adrenaline.<sup>62</sup> Upon review, the Second Circuit agreed with the reasoning of Judge Hand that although the “physiological characteristics of the glands” were merely purified and stable forms, this product was desired and “highly meritorious” and therefore warranted the protection granted by a patent.<sup>63</sup>

The reasoning by the courts in *Parke-Davis I* and *Parke-Davis II* has been interpreted to mean that—in these courts’ opinion—“the prohibition on patenting natural phenomena did not preclude patenting natural substances . . . in a purified form.”<sup>64</sup> This reasoning illustrated that the Court did not have a per se bar on all products that originated in nature, but further emphasizes the need for some labor to be employed to change—or purify—the material in some way that alters the utility of the material.<sup>65</sup>

At this point in the development of the scope of patentable subject matter, the courts seemed to invoke Locke’s labor theory of property.<sup>66</sup> In these cases, a patentee who has—through his own labor—modified a naturally occurring product in a way that makes it useful, therapeutic, or sufficiently meritorious is entitled to the protection afforded by the patent system.<sup>67</sup> While this notion of labor exertion creating patentable rights in property is relatively straight-forward, the courts continued to struggle with how far and to what degree this doctrine should allow or bar protection.<sup>68</sup> Further, critics have argued that this

61. *Parke-Davis I*, 189 F. at 103.

62. *Id.* at 103 (citing *Kuehmsted* as precedent that reinforced the reasoning that increased therapeutic utility with commercial utility can be a valid reason for finding a patent falls within patentable subject matter when the unpurified form of the substance would not).

63. *Parke-Davis & Co. v. H. K. Mulford Co.* (*Parke-Davis II*), 196 F. 496, 497 (2d Cir. 1912).

64. Jeffrey M. Kuhn, *Patentable Subject Matter Matters: New Uses for an Old Doctrine*, 22 BERKELEY TECH. L.J. 89, 94 (2007).

65. See Gipstein, *supra* note 51, at 31, 49-52.

66. See generally Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287, 297 (1988) (explaining that under Locke’s theory, goods become private property when labor is exerted upon them).

67. See Gipstein, *supra* note 51, at 18, 23, 64-65.

68. See Hughes, *supra* note 66, at 305-06; see, e.g., *Brenner v. Manson*, 383 U.S. 519, 533-36 (1965); *Mazer v. Stein*, 347 U.S. 201 (1954); *Int’l News Serv. v. Associated Press*, 248 U.S. 215 (1918).

“increased therapeutic value” test laid out in these cases mistakes utility for newness, claiming that just because a substance has been found to be useful does not mean that it meets the novelty requirements necessary for patent protection.<sup>69</sup>

E. *General Electric Co. v. De Forest Radio Co. (1928)*

The Third Circuit in *General Electric Co. v. De Forest Radio Co.* represented a return to the reasoning laid out by the Supreme Court in *American Wood-Paper Co.*<sup>70</sup> In *General Electric*, the court was asked to address the validity of a patent claiming purified metal tungsten.<sup>71</sup> The court succinctly stated the issue to be “[w]hether the tungsten of which the patent speaks is the tungsten of nature with its inherent quality of ductility or is a new metal produced by [the inventor] which is wholly different from anything that nature provides.”<sup>72</sup> If the metal was something purely natural, and the inventor was merely the first to discover it, it is not patentable subject matter.<sup>73</sup> Conversely, if the substance is not natural and instead possesses “characteristics different from those given by nature,” then the inventor is entitled to have patent protection.<sup>74</sup>

The Third Circuit held that the patentee had merely discovered the natural characteristics of tungsten, and had neither invented the material or its characteristics to a level sufficient to establish proper subject matter for patentability.<sup>75</sup> This strict adherence to the doctrines set forth in *ex parte Latimer* and *American Wood-Paper* constricted what was allowable under the product of nature doctrine. Under the reasoning set forth by this court, in order to prove patentability, the properties of the substance must have been created by the inventor rather than merely discovered—which by extension means that being therapeutic or commercially valuable does not factor into novelty.<sup>76</sup> This return to earlier doctrine helped delineate between the different patentability requirements—

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69. Demaine & Fellmeth, *supra* note 28, at 338-39.

70. *Id.* at 339-40.

71. *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 641 (1928).

72. *Id.* at 642.

73. *Id.*

74. *Id.*

75. *Id.* at 643.

76. *See generally* Conley & Makowski, *supra* note 27, at 323-24.

novelty, nonobviousness, utility, etc.—that had previously become blurred under *Kuehsted* and *Parke-Davis*.<sup>77</sup>

This decision further indicates the degree to which the court required innovation because pure tungsten, as claimed in the patent, does not exist in nature.<sup>78</sup> Because natural tungsten was brittle, and not as ductile as the purified form, the naturally occurring tungsten was different from the purified tungsten claimed in the patent, but because the characteristics were merely brought out by the purification and not created by the process, the court deemed it a natural characteristic of the element and therefore not patentable.<sup>79</sup>

#### F. *In re Marden* (1931)

The court's decision in *General Electric* was followed three years later by the Court of Customs and Patent Appeals in *In re Marden*, a pair of cases dealing with patents on uranium and vanadium as products.<sup>80</sup> Having chosen to apply the rationale in *General Electric*, these cases were easier to deal with than their predecessor case.<sup>81</sup> Unlike the material at issue in *General Electric*—tungsten—the elements at issue in these cases were ductile in their natural states.<sup>82</sup>

The Court of Customs and Patent Appeals (“CCPA”) quickly affirmed the rejection of claims in the uranium patent because not only were the material and its characteristics known at the time of filing, but the inventor did nothing to bring about the existence of the material or its characteristics.<sup>83</sup> Similarly, the claims of the vanadium patent were found to be invalid because a pure form of vanadium had “been known to the metal art for

77. See *Gen. Elec.*, 28 F.2d at 642 (showing that the other patentability requirements are separable from the 35 U.S.C. 101 eligibility requirements); see 35 U.S.C. 102, 103 (2006 & Supp. 2011).

78. See *Conley & Makowski*, *supra* note 27, at 323-24 (“The most controversial aspect of the *General Electric* decision arises from the fact that the pure tungsten claimed by Coolidge had not been found in nature. The district court observed that “[i]n nature tungsten is found only in combination with other elements . . .”).

79. See *id.* (“[The court’s] view was that since tungsten is an element, all of its properties are natural by definition. So the subject matter test that emerged from the case seemed to be a theoretical rather than empirical one: not whether the product is actually known to occur in nature in its claimed form, but whether it can occur in nature.”).

80. *In re Marden (Marden I)*, 47 F.2d 957, 957 (C.C.P.A. 1931) (case concerning uranium); *In re Marden (Marden II)*, 47 F.2d 958, 958 (C.C.P.A. 1931) (case concerning vanadium); see also *Conley & Makowski*, *supra* note 27, at 324-25.

81. *Conley & Makowski*, *supra* note 27, 325-26.

82. W. Lesser, *Nature or Nurture: Is There a Case Basis for a Judicially Created ‘Product of Nature’ Exclusion? Are Genes Somehow Different?*, 11 J. MARSHALL REV. INTELL. PROP. L. 318, 341 (2011).

83. *Marden I*, 47 F.2d at 957.

many years” and the “quality of purity of vanadium or its ductility is a quality of a natural product and as such is not patentable.”<sup>84</sup> In neither case did the court address any issue relating to the practical value of the materials—a reasoning that would be similar to that of the courts in *Kuehmsted* and *Parke-Davis*—but rather only addressed the novelty of the material itself and the source of the characteristics claimed.<sup>85</sup>

Later that year, drawing upon the reasoning in the *In re Marden* cases, the Patent Office Board of Appeals in *Ex parte Windaus* held a patent on purified vitamin D to be invalid despite the product being 1,000 times superior to the alternative.<sup>86</sup> This case, in collection with both *In re Marden* cases, has been interpreted to be an express rejection of the therapeutic value test set out by *Kuehmsted* and *Parke-Davis*.<sup>87</sup> Along with subsequent cases that reiterated these same rationales,<sup>88</sup> the court whose primary purpose was unification of the federal common law of patents guided the courts back to *American Wood-Paper*.<sup>89</sup>

#### G. *Dennis v. Pitner* (1939)

Although the Third Circuit and the CCPA articulated a stricter take on the purification doctrine than previous courts, the Seventh Circuit chose to reaffirm the therapeutic value test in *Dennis v. Pitner*.<sup>90</sup> The patent at issue claimed an insecticide that was extracted “from the root of the cube plant found in Peru or other South American countries.”<sup>91</sup> The defendants in the infringement litigation argued that the insecticide was merely a modified form of a naturally occurring product, and therefore did not warrant patent protection under the product of nature

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84. *Marden II*, 47 F.2d at 959.

85. See generally *Marden I*, 47 F.2d at 957 (discussing the properties of uranium); see generally *Marden II*, 47 F.2d at 959 (discussing the properties of vanadium).

86. *Ex parte Windaus*, No. 1931-2645, 15 U.S.P.Q. 45 (B.P.A.I. Dec. 30, 1931).

87. See *Demaine & Fellmeth*, *supra* note 28, at 340-41.

88. See generally *In re Ridgway*, 76 F.2d 602, 603 (C.C.P.A. 1935) (affirming the rejection of a patent claiming a purified abrasive chemical); *In re Merz*, 97 F.2d 599, 601 (C.C.P.A. 1938) (affirming the rejection of a patent claiming a purified ultramarine dye produced by a new process).

89. See *Demaine & Fellmeth*, *supra* note 28, at 342.

90. *Dennis v. Pitner*, 106 F.2d 142, 146 (7th Cir. 1939) (“Congress meant to be comprehensive and inclusive in patent coverage and liberal in patent protection, provided ‘any person’ either invent or discover a new and useful art, machine, manufacture, or composition of matter. It meant to cover all inventions and discoveries which were new and useful.”).

91. *Id.* at 143.

doctrine.<sup>92</sup> This logic would seem to have prevailed had the Seventh Circuit used the reasoning of the Third Circuit and the CCPA. Instead, the court chose to use a therapeutic value test that was even broader than that of *Kuehmsted*.<sup>93</sup> Contrary to prior holdings, the court held “[t]he discovery of a natural phenomenon, or of a quality or attribute of a well-known article, which discovery is of value to mankind, may be entitled to patent protection.”<sup>94</sup> Thus, rather than hinging on whether the inventor actually developed something that had not previously existed, patentability may be established by showing that “the inventor or discoverer made a new and useful contribution to society.”<sup>95</sup>

This case exemplifies the need that existed for a centralized appellate court that would be the sole source of patent common law, a need which was fulfilled with the establishment of the United States Court of Appeals for the Federal Circuit in 1982.<sup>96</sup> The broad *Dennis* allowance for the patentability of discoveries that were deemed to be beneficial to society was almost uniformly discounted by other jurisdictions due to the inherent disconnect with novelty generally required for protection.<sup>97</sup> After *Dennis*, the Patent Office Board of Appeals and CCPA continued to apply the holding of *American Wood-Paper*, neglecting to repeat the Seventh Circuit’s broad rule.<sup>98</sup>

#### H. *Merck & Co. v. Olin Mathieson Chemical Corp. (1958)*

With the passing of the Patent Act of 1952, including statutes affirmatively requiring novelty in order to achieve patentability, the split between the two schools of thought became significantly more important as the purification rules

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92. *Id.*

93. See Demaine & Fellmeth, *supra* note 28, at 343-44.

94. *Dennis*, 106 F.2d at 144.

95. *Id.* at 146.

96. See George C. Beighley, Jr., *The Court of Appeals for the Federal Circuit: Has it Fulfilled Congressional Expectations?*, 21 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 671, 673-74 (2011).

97. See generally Demaine & Fellmeth, *supra* note 28, at 344 (“Besides the court’s inability to rely on any precedent (other than its own) for its specific holding, a major factor contributing to *Dennis*’ unpersuasiveness was the determination that the ‘discovery of a natural phenomenon’ could be patentable if the discoverer made a useful contribution to society. This statement, seen through the eyes of a patent expert at the time, must have approached blasphemy.”).

98. See *In re Michalek*, 161 F.2d 253, 255 (C.C.P.A. 1947); *In re Crosley*, 159 F.2d 735, 737 (C.C.P.A. 1947); *In re King*, 107 F.2d 618, 619-20 (C.C.P.A. 1939); *In re Macallum*, 102 F.2d 614, 615-16 (C.C.P.A. 1939); *Ex parte Cavallito*, 1951 WL 4240 (B.P.A.I. May 16, 1950); *Ex parte Snell*, 1950 WL 4259 (B.P.A.I. Jan. 3, 1950); *Ex parte Sparhawk*, 1944 WL 6518 (B.P.A.I. Nov. 9, 1944) (all requiring actual invention rather than mere discovery or application of natural characteristics).

could very well have hinged on the first court's interpretation of the Act.<sup>99</sup> While a district court had already endorsed the therapeutic value test similar to *Kuehmsted* and *Dennis*,<sup>100</sup> the first circuit court to weigh in was the Fourth Circuit in *Merck & Co. v. Olin Mathieson Chemical Corp.*<sup>101</sup>

In a departure from CCPA precedent, the Fourth Circuit held that vitamin B<sub>12</sub> that had been isolated from animal livers was patentable subject matter.<sup>102</sup> The court directly addressed the new Patent Act of 1952, explaining that nothing in the statutory language precludes protection of a "product of nature" when it is a "new and useful composition of matter."<sup>103</sup> Shooting holes in the product of nature doctrine, the court went on to explain that because all raw materials, in some form or fashion, are products of nature "in the sense that nature provides the basic source materials," all new and useful compositions of matter are inherently composed of "existing elements and materials."<sup>104</sup>

Further, the Fourth Circuit stated that the product of nature doctrine can be separated into two separate doctrines: "that a patent may not be granted upon an old product though it be derived from a new source by a new and patentable process" and "that every step in the purification of a product is not a patentable advance, except, perhaps, as to the process, if the new product differs from the old 'merely in degree, and not in kind.'"<sup>105</sup> This analysis is not very helpful because the court borders on the obvious by explaining that an old product is not patentable. Further, explaining that a product that is not "different in kind" does not meet the novelty standard is equally plain to see. What the court seems to base its decision on is the added therapeutic and commercial usefulness of the vitamin in its purified form.<sup>106</sup>

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99. See *Demaine & Fellmeth*, *supra* note 28, at 349.

100. See *Sterling Drug Inc. v. Watson*, 135 F. Supp. 173, 175-76 (D.D.C. 1955) (upholding a patent on a naturally occurring compound because the uses for the compound were unexpected and nonobvious, and because the compound did not have "therapeutic value" unless it was isolated and purified); see also *Demaine & Fellmeth*, *supra* note 28, at 349.

101. See *Demaine & Fellmeth*, *supra* note 28, at 349.

102. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 164 (4th Cir. 1958) ("[W]e think the invention is meritorious, the product claims of the patent valid and entitled to a liberal construction.").

103. *Id.* at 161.

104. *Id.* at 161-62.

105. *Id.* at 162.

106. *Id.* at 164 ("From the natural fermentates, which, for this purpose, were wholly useless and were not known to contain the desired activity in even the slightest degree, products of great therapeutic and commercial worth have been developed.").

This decision, while directly citing *Parke-Davis*, expands the existing therapeutic value test to take into account commercially valuable products.<sup>107</sup> In doing so, the Fourth Circuit ignored existing Supreme Court precedent.<sup>108</sup> Never before had a court considered commercial value to be a strong criteria for a finding of patentable subject matter or novelty.<sup>109</sup>

The court in this case erred in taking into account commercial success. Novelty—or newness—is a factor completely independent from how well received a product is among consumers. Additionally, while the patent system is intended to foster innovation and promote business, it is still premised on innovation itself and not investment protection in the direct sense that the court seems to implicate here.<sup>110</sup> Premising patent protection on market demand for the product or the patentee's marketing experience would cause the patent system to benefit not the innovative drive that it was intended to foster, but rather pure commercialization.<sup>111</sup>

Further, the court here changed the focus from novelty of the product to novelty of the discovery.<sup>112</sup> Previously, if the product was a naturally occurring substance, it was not patentable under the understanding that anything found in nature cannot be new.<sup>113</sup> The focus in *Merck* switched to whether anyone had “produced even a comparable product” and whether the active substance had been “unidentified and unknown.”<sup>114</sup>

### I. *Ex parte Reed* (1961)

The influence of *Merck* on the Patent and Trademark Office was felt within a few years, resulting in two rulings from the

107. *Id.*

108. *See* Dow Chem. Co. v. Halliburton Oil Well Cementing Co., 324 U.S. 320, 330 (1945) (explaining that commercial value is “relevant only in a close case where all other proof leaves the question of invention in doubt”); *see also* Graham v. John Deere Co., 383 U.S. 1, 16-17 (1966); Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 153 (1950); Smith v. Hall, 301 U.S. 216, 233 (1937); McClain v. Ortmayer, 141 U.S. 419, 428-29 (1891).

109. Demaine & Fellmeth, *supra* note 28, at 351-52.

110. *Id.* at 352.

111. *See id.* at 352-53 (discussing various implications of using commercial success as a factor to determine patentability and pointing out that in the biotech industry, it is not uncommon for a product whose market had previously thought to have been small can overnight have a vastly increased market if a disorder is discovered to be more prevalent than previously thought).

112. Conley & Makowski, *supra* note 27, at 329.

113. *Id.* at 328-29.

114. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 162-63 (4th Cir. 1958).

Patent Office Board of Appeals about the same operative facts.<sup>115</sup> In *Reed I*, the board was asked to review the rejection of a patent application which claimed purified alpha-lipoic acid, a substance present in the liver.<sup>116</sup> The applicant argued that the acid was not present in a “microbiologically available form” in nature and in its natural form has “no value to either microorganism or man,” citing both *Merck* and *Sterling Drug, Inc. v. Watson* as persuasive precedent.<sup>117</sup> In dismissing the applicant’s appeal, the board distinguished the present facts from those of both cited cases by stating that the utility possessed by the purified alpha-lipoic acid is also possessed by the parent substance.<sup>118</sup> Additionally, in both *Merck* and *Sterling* the court was dealing with validity in a case involving a previously issued patent, as opposed to the present action which involved an appeal from a rejection of a patent application.<sup>119</sup> Finally, the court lists a long string of cases where the court has similarly held that a “substance merely extracted from its parent material even in purer form is devoid of invention.”<sup>120</sup>

Not being dissuaded by the board’s decision in *Reed I*, the applicants filed a petition for reconsideration, which was heard later that same year.<sup>121</sup> In an extremely short opinion, the board reversed itself holding that “[m]erely because there is evidence that a product exists in nature with other substances is not invariably sufficient reason for denying claims to such a product.”<sup>122</sup> The board tempered this statement by clarifying that “mere purity of an old product normally does not entitle one to a patent on the pure product.”<sup>123</sup> In this case, the board felt the

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115. See *Ex parte Reed (Reed I)*, 135 U.S.P.Q. 34 (Pat. Off. Bd. App. 1961); *Ex parte Reed (Reed II)*, 135 U.S.P.Q. 105 (Pat. Off. Bd. App. 1961).

116. *Reed I*, 135 U.S.P.Q. at 34.

117. *Id.*

118. *Id.* (“Here there is ample evidence that the claimed compound is present in liver and that liver has been used effectively for growth promotion or stimulation, whereas it appears from the cited cases that the parent material was not useful for the same purpose as the segregated material and it thus does not appear that the material could have been recognized as valuable for the stated purpose.”).

119. *Id.* (“In the present case there obviously is no question of sustaining the validity of an issued patent as we are concerned solely with the question of whether a patent should issue where the claimed product is shown to occur naturally in liver and other products . . .”).

120. *Id.*; see, e.g., *In re Davis*, 164 F.2d 626, 632 (C.C.P.A. 1947); *In re Michalek*, 161 F.2d 253, 255 (C.C.P.A. 1947); *In re King*, 107 F.2d 618, 619-20 (C.C.P.A. 1939); *In re Macallum*, 102 F.2d 614, 616 (C.C.P.A. 1939); *In re Merz*, 97 F.2d 599, 601 (C.C.P.A. 1938); *In re Ridgway*, 76 F.2d 602, 604 (C.C.P.A. 1935); *In re Marden*, 47 F.2d 958, 959 (C.C.P.A. 1931).

121. *Reed II*, 135 U.S.P.Q. 105, 105 (Pat. Off. Bd. App. 1961).

122. *Id.*

123. *Id.*



acid warranted protection because not only did the applicants obtain a pure form of the acid, but the pure form also had a new utility that had previously been unavailable.<sup>124</sup>

This decision by the board was in effect an endorsement of the Fourth Circuit's analysis in *Merck*, at least as far to say that purified substances that are naturally occurring are not per se unpatentable.<sup>125</sup> While the Patent Office Board of Appeals reversed course here in 1961, it would be almost a decade before the CCPA would follow.<sup>126</sup>

#### J. Application of Bergstrom (1970)

The isolation doctrine took another step towards acceptance nationally when the CCPA heard an appeal from the rejection of claims on two members of a family of compounds known collectively as prostaglandins.<sup>127</sup> These compounds were both known to be "useful in stimulating smooth muscle and in lowering blood pressure."<sup>128</sup> The examiner had rejected the application and the Board of Patent Appeals upheld that rejection on the grounds that the purified prostaglandins possessed the same properties and utility as their unpurified forms.<sup>129</sup>

The CCPA blatantly avoids the board's reasons for rejection in holding that there is no reason that a purified substance cannot be novel on its own.<sup>130</sup> Countering the solicitor's argument that anything that is discovered from nature is not patentable, the CCPA held that the prostaglandins did not exist in their purified forms in nature and because the claims at issue were not broad enough to encompass the unpurified prostaglandins, the claims were sufficiently novel.<sup>131</sup> The CCPA ended its analysis by explaining that whether the properties of the purified materials were shared by the source material is not relevant to the

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124. *Id.*

125. *Id.*; *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 162 (1958).

126. *See Demaine & Fellmeth, supra* note 28, at 356.

127. *In re Bergstrom*, 427 F.2d 1394, 1395 (C.C.P.A. 1970).

128. *Id.*

129. *Id.* at 1398 ("The consistent principle, and the one which we follow, is that a claim to a purified material cannot be allowed unless the purified material exhibits properties and utilities not possessed by the unpurified material.")

130. *Id.* at 1401.

131. *Id.* at 1401-02 (continuing on this line the CCPA stated, "by definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference, as seems to be the situation here, perforce the 'pure' materials are 'new' with respect to them").

question of patentable subject matter, but may be considered when determining obviousness 35 U.S.C. § 103.<sup>132</sup>

While the CCPA's stance on the purification doctrine was not uniform after *Bergstrom*, it certainly represented a trend within the courts towards acceptance of isolated, purified materials within the bounds of patentable subject matter. This uncertainty of the CCPA's stance was carried over into the United States Court of Appeals for the Federal Circuit after its inception in 1982, which later addressed the issue again in the early 1990's.<sup>133</sup>

#### K. *Amgen, Inc. v. Chugai Pharmaceutical Co. (1991)*

In the first case heard by the Federal Circuit, after its creation in 1982, the court adopted the decisions of its predecessor courts—including the CCPA—as binding precedent.<sup>134</sup> With this came the CCPA's uncertain stance on the purification doctrine. The Federal Circuit finally addressed the issue in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, a case involving two patents concerning a natural human protein called erythropoietin (EPO).<sup>135</sup> The plaintiff had secured a patent on isolated and purified recombinant DNA sequences, vectors and host cells that produce EPO, while the defendant held a patent on the protein itself.<sup>136</sup> The Federal Circuit upheld the district court's finding of validity and stated “[t]he subject matter of [the defendant's claim] was the novel *purified and isolated* sequence which codes for EPO.”<sup>137</sup> This simple statement was read as an affirmation of the isolation doctrine as described in *Bergstrom*.<sup>138</sup>

With the Federal Circuit endorsing the patentability of isolated and purified natural substances, the flood gates opened, allowing a huge number of patent applications to be filed with the Patent and Trademark Office on isolated, purified, naturally occurring DNA sequences.<sup>139</sup> While the courts had endorsed the

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132. *Id.* at 1402.

133. *See generally* Demaine & Fellmeth, *supra* note 28, at 357-58.

134. *See* South Corp. v. United States, 690 F. 2d 1368, 1370 (Fed. Cir. 1982).

135. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1203 (Fed. Cir. 1991) (explaining EPO “is a protein consisting of 165 amino acids which stimulates the production of red blood cells”).

136. *Id.*

137. *Id.* at 1206.

138. *See* Demaine & Fellmeth, *supra* note 28, at 358; *see also* Conley & Makowski, *supra* note 27, at 382-83.

139. *See* Demaine & Fellmeth, *supra* note 28, at 359 (“Applications for DNA sequences climbed from almost none in 1986 to nearly 1000 in 1996, and to more than 9000 in 1997. Close to 3,000 such patents had been issued by 1999. By mid-2000, the

patentability of these substances, Congressional intent shown in the legislative history of a patent statute passed in 1988 clearly states the traditional stance: removal of impurities does not create a new substance.<sup>140</sup> Regardless, the courts and the Patent and Trademark Office had taken little notice, and continued to enforce the doctrine adopted by the Federal Circuit.<sup>141</sup>

### III. PRODUCT OF NATURE DOCTRINE: THE PATENTABILITY OF LIFE

With the advent of biotechnology, the thought of scientifically altered life became a reality and with it posed the question to the patent system and the courts: can life be patented? Separate from the isolation doctrine previously discussed,<sup>142</sup> the more fundamental problem of patenting actual organisms left the realm of science fiction and ushered in a new question for the Supreme Court to answer. In order to see where the law is at this moment, it is prudent to see where the law came from. From there, an assessment of the current state of the doctrine becomes easier to identify. The analysis begins with understanding the basic underlying premise behind the doctrine: Something cannot be deemed to be new if it already exists in nature.<sup>143</sup>

#### A. *American Fruit Growers, Inc. v. Brogdex (1931)*

In an early case addressing the issue of patenting organic material, the Supreme Court was asked to address the validity of the claims of a patent protecting fruit that had been treated with borax to prevent mold.<sup>144</sup> The patentee argued that the fruit with borax was a new article of manufacture and therefore not found in nature, but the Court disagreed.<sup>145</sup> The Supreme Court reversed the lower court's holding and found the product to be unpatentable, stating "[t]here is no change in the name,

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PTO had issued over 6000 patents drawn to full-length genes from living organisms, and over 20,000 gene-related applications were pending before the PTO.")

140. See H.R. Rep. No. 807, at 21-22 (1986); S. Rep. No. 83, at 49-50 (explaining that the removal of impurities does not materially change a substance into another substance).

141. See Demaine & Fellmeth, *supra* note 28, at 358-959.

142. *Supra* Part II.

143. See David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 90 (1995); see also Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 552-54 (1989).

144. *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 6 (1931) (The patent at issue claimed "[f]resh citrus fruit of which the rind or skins carries borax in amount that is very small, but sufficient to render the fruit resistant to blue mold decay").

145. *Id.* at 6-13.

appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore.”<sup>146</sup>

Critics have argued that the Court’s reasoning in this case contained “little logic” because it would seem that taking something that clearly is a product of nature—a natural piece of fruit—and applying a treatment to it that adds extra utility, longer shelf life for example—should fall within the definition of article of manufacture and not product of nature.<sup>147</sup> What can be gleaned from this case is that the Supreme Court had a firm belief that products of nature were per se unpatentable.<sup>148</sup>

This type of reasoning continued to be used by the courts for many years following *American Fruit Growers*.<sup>149</sup> For example, the Patent Office Board of Appeals directly cited the logic of *American Fruit Growers* in *Ex parte Grayson*, a case concerning a patent claim that covered deveined shrimp.<sup>150</sup> In affirming the rejection, the board explained that *American Fruit Growers* still applies even though the applicant is only claiming part of the shrimp.<sup>151</sup> This decision has been generally treated as more reasonable than *American Fruit Growers* in that all that was left of the claimed product was naturally occurring matter, whereas the fruit treated with borax inherently includes unnatural elements.<sup>152</sup>

#### B. *Funk Brothers Seed Co. v. Kalo Inoculant Co. (1948)*

As biotechnology entered its early years, questions arose as to how the product of nature doctrine applied to applications and products of biomedical research.<sup>153</sup> In the seminal case *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, the Supreme Court was facing a challenge to the validity of a patent claiming a product

146. *Id.* at 12.

147. *See* Sease, *supra* note 143, at 555.

148. *Id.*

149. *Id.*

150. *See Ex parte Grayson*, 51 U.S.P.Q. 413, 413 (Pat. Off. Bd. App. 1941) (patent claiming “[a] fresh shrimp product comprising a shrimp having the head removed and a narrow channel cut through the shell thereof along the crest or back portion of the shrimp, extending from the cut head portion to a point adjacent the tail and to a depth sufficient to remove the vein and the waste matter contained therein, the remainder of the shell remaining intact and protecting the body of the shrimp from contact with the oxygen of the air”).

151. *Id.* (explaining “the part [applicant] is claiming is still in its natural state which has been changed in no manner”).

152. *See* Sease, *supra* note 143, at 556.

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

comprising a combination of Rhizobium bacteria.<sup>154</sup> The Court, in very clear language, held the patent to be invalid because it violated the product of nature doctrine.<sup>155</sup> Stating the doctrine as simplistically as possible—"patents cannot issue for the discovery of the phenomena of nature"—the Court explained that the qualities of the bacteria to be able to be mixed without detrimental effect is merely a quality of the bacteria and therefore not patentable.<sup>156</sup>

Distinguishing from the logic of many of the courts who struggled with the purification doctrine, the Supreme Court here made it clear that the patent requirement at issue was not novelty or utility, but rather in order for a patent to be valid there must be an inventive step.<sup>157</sup> Difficulty in the work or skill required to achieve the appropriate combination of bacteria was not relevant to the Court's analysis, because neither provide evidence as to the requisite creative mental step necessary for patent protection.<sup>158</sup>

While the Court did categorically hold that the patentee had not met the requirement of invention due to the bacterial being a product of nature, the Court shed little light on what would satisfy this requirement in a practical sense other than to say invention from a discovery "must come from the application of the law of nature to a new and useful end."<sup>159</sup> In stating this, the Court muddies the water as to what actual requirement was at issue here by creating circular logic: patentability requires invention in addition to the product being new and useful, but the test for invention is a new and useful application of a discovery.<sup>160</sup> Luckily—or unluckily, depending on your perspective—the Court had multiple opportunities to revisit the product of nature issue in the following years.

### C. *Diamond v. Chakrabarty* (1980)

In 1980, the Supreme Court weighed in on what would be a landmark case for the biotechnology industry and the product of

154. *Id.* at 128-29.

155. *Id.* at 131 ("Discovery of the fact that certain strains of species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable.")

156. *Id.* at 130-31.

157. *Id.* at 131 ("[A] product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.")

158. *See* Demaine & Fellmeth, *supra* note 28, at 378-79.

159. *Funk Bros. Seed Co.*, 333 U.S. at 130.

160. *See id.* at 130-31.

nature doctrine.<sup>161</sup> Dr. Ananda Chakrabarty, an employee of General Electric, worked on his personal research involving *Pseudomonas* bacteria and their involvement in hydrocarbon degradation.<sup>162</sup> These bacteria had the capability of breaking down various hydrocarbons into proteins, but were restricted as to what hydrocarbons each type of bacteria could digest.<sup>163</sup> Dr. Chakrabarty sought to develop one *Pseudomonas* bacteria that could break down a wide spectrum of hydrocarbons.<sup>164</sup> The hydrocarbon digesting capabilities of each bacteria strain was a result of enzymes produced by genes found not within the chromosomes of the bacteria, but rather on plasmids.<sup>165</sup> By mating the bacteria<sup>166</sup> and then irradiating them with UV rays,<sup>167</sup> Dr. Chakrabarty was successful in producing two bacteria that each contained a different set of four genes which aided in the digestion of hydrocarbons.<sup>168</sup>

Upon achieving the development of these genetically modified *Pseudomonas* bacteria, Dr. Chakrabarty considered the only patentable subject matter to be the method of constructing the bacteria and not the bacteria themselves due to the product of nature barrier.<sup>169</sup> The General Electric attorney that handled filing the patent application was not familiar with biological patents, and did not see any reason why Dr. Chakrabarty's work was not patent eligible.<sup>170</sup>

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161. Daniel J. Kevles, *Ananda Chakrabarty wins a patent: Biotechnology, law, and society, 1972-1980*, 25 HIST. STUD. PHYS. BIOL. SCI. 111, 133 (1994) (“*Diamond v. Chakrabarty* was thus a landmark decision, with far-reaching implications for American patent law and for biotechnology.”).

162. *Id.* at 113-14.

163. *Id.* at 113.

164. *Id.* at 115 (acting with two practical applications of the bacteria in mind: turning hydrocarbons into a cheap food source—the development of the bacteria occurred in the early 1970's before the price of oil made this goal economically unfeasible—and to aid in the cleanup of oil spills).

165. *Id.* at 115; see generally A. M. Chakrabarty, *Plasmids in Pseudomonas*, 10 ANN. REV. GENETICS 7, 8 (1976) (“Plasmids are genetic elements found outside the chromosome within the cells. They can replicate autonomously independent of the chromosome, and although considered nonessential for the cell, they often perform secondary functions that are vital to the cell under certain conditions.”).

166. Kevles, *supra* note 161, at 116.

167. U.S. Patent No. 4,259,444 col. 9 l. 10 (filed June 7, 1972).

168. Kevles, *supra* note 161, at 116 (“Each would consume large fractions not only of crude oil but also of Bunker C—the thick, sticky residuum left after the removal from the crude of its commercially valuable part—turning their hydrocarbons into bacterial cell meat that was seventy to eighty percent protein.”).

169. *Id.* at 117.

170. *Id.* (“MaLossi [the GE attorney] remembers, ‘When I first proposed to introduce the claims to the organism *per se*, I had occasion to speak to various patent attorneys who had worked in that type of technology . . . . What intrigued me was that all of them said that such claims were unpatentable, but they all gave me different reasons why. . . . What

The patent examiner charged with reviewing the *Pseudomonas* patent application rejected the claim of the bacteria itself because while the new bacteria was different in degree, they were not different in kind and thus were barred as a product of nature.<sup>171</sup> The Patent Office's internal board not only upheld the examiner's rejection, but they went a step further with their rejection by stating that the bacteria were not patentable because they were alive.<sup>172</sup> The board went on to explain the concern that allowing such claims to be patentable would be the first step towards patenting multi-cellular animals such as livestock.<sup>173</sup>

On appeal before the Court of Customs and Patent Appeals, Judge Giles S. Rich reasoned that it would be illogical to allow processes that relied on living organisms to function to fall within the scope of patentable subject matter, but deny a claim of "living manufacture or new composition of matter."<sup>174</sup> Judge Rich went on to dismiss the Patent Board's concern about the alleged slippery slope of allowing living organisms to be patentable, and state that this concern is irrelevant because the patentability of multi-cellular animals was not at issue in this case.<sup>175</sup>

The Supreme Court granted certiorari and affirmed the decision of the CCPA.<sup>176</sup> The Court distinguished the facts of this case from those of *Funk Bros.*, explaining "the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility."<sup>177</sup> The Court continued, explaining that Dr. Chakrabarty's "discovery is not nature's handiwork, but his own; accordingly it is patentable subject

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happened is that [the inadmissibility of claims to live matter] had become a canon of patent law and nobody questioned it.").

171. *Id.* at 118.

172. *Id.* (explaining that the board reasoned that while the statutory law did not prohibit the patenting of living organisms, it also did not explicitly allow *for it*).

173. *Id.*; See *Ex Parte Latimer*, 1889 Dec. Comm'r Pat. 123, 126 (expressing concern that expanding patent coverage to fibers found in pine trees would lead to patents covering all plants).

174. *In re Bergy*, 563 F.2d 1031, 1037 (C.C.P.A. 1977) ("It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101.").

175. *Id.* at 1038 ("As for the board's fears that our holding will of necessity, or 'logically,' make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched. In any case, that question is not before us . . .").

176. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

177. *Id.* at 310.

matter under §101.”<sup>178</sup> The Court concluded that the legislative history of § 101 supported a broad construction and explained that the Committee Reports from the Patent Act of 1952 intended patentable subject matter to “include anything under the sun.”<sup>179</sup> Addressing the public policy concerns regarding the potential negative ramifications of allowing life to be patented, the Supreme Court deferred to Congress, stating, “[t]he legislative process . . . is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection.”<sup>180</sup>

In essence, the Supreme Court ushered in a new era in biotechnology with their holding in *Chakrabarty*. A living organism can be patentable subject matter.<sup>181</sup> The Court shaped the future of the biotech industry with this ruling, the ramifications of which are still being felt today.<sup>182</sup>

#### D. *Ex parte Allen* (1987)

The next advance in the product of nature doctrine involved a patent claiming polyploid oysters.<sup>183</sup> The patent examiner rejected the applicant’s claims on obviousness grounds and because “the claimed invention is directed to nonstatutory subject matter.”<sup>184</sup> The Board of Patent Appeals and Interferences quickly dismissed the examiner’s subject matter rejection as being in clear violation of the Supreme Court’s holding in *Chakrabarty*.<sup>185</sup> The issue was not whether the claimed product was living, but rather whether the subject

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178. *Id.*

179. *Id.* at 309 (referencing S. REP NO. 1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399).

180. *Id.* at 314-17.

181. *Id.* at 318.

182. See Douglas Robinson & Nina Medlock, *Diamond v. Chakrabarty: A Retrospective on 25 Years of Biotech Patents*, INTELL. PROP. & TECH. L. J., Oct. 2005, at 12 (“It has been 25 years since this landmark decision, in which the Supreme Court held that a live, man-made microorganism is patentable subject matter. . . . *Chakrabarty* has affected the lives of virtually everyone in the United States, having contributed to a revolution in biotechnology that has resulted in the issuance of thousands of patents, the formation of hundreds of new companies, and the development of thousands of bioengineered plants and food products.”).

183. Polyploid oysters are oysters that contain three sets of chromosomes instead of the regular two. Sease, *supra* note 143, at 563.

184. *Ex parte Allen*, No. 86-1790, 2 U.S.P.Q.2d 1425 (B.P.A.I. Apr. 3, 1987).

185. *Id.* at 1426 (“[T]he Supreme Court made it clear in its decision in *Diamond v. Chakrabarty* . . . that Section 101 includes man-made life forms.”).



matter was actually man-made.<sup>186</sup> The board concluded that there was no evidence to support a finding that the oysters were anything but man-made, and accordingly reversed the § 101 rejection.<sup>187</sup>

While the board's analysis in this case is unremarkable as it is a literal application of simple Supreme Court precedent—that man-made life forms are patentable—this case has been described as controversial because it began a “new chapter in the history of the United States patent system, opening the door for the patenting of animals.”<sup>188</sup> Just four days after *Ex parte Allen* was decided, the Patent and Trademark Office published a notice announcing that “non-natural occurring non-human multi-cellular organisms, including animals,” were patentable subject matter.<sup>189</sup>

The reality of this notice was soon realized because in 1988, a patent was issued to Harvard University on any non-human mammal genetically engineered to incorporate in its genome an oncogene tied to a specific promoter, scientists at the university having reduced the claim to practice in the form of an oncomouse.<sup>190</sup> The “Harvard mouse” was altered to be highly susceptible to cancer, and develop cancer faster to provide researchers “a more effective model for studying how genes contribute to the development of cancer.”<sup>191</sup>

Recently, Congress addressed this issue by passing a statute contained within the AIA that specifies “[n]otwithstanding any other provision of law, no patent may issue on a claim directed or encompassing a human organism.”<sup>192</sup> The Patent Office quickly specified that this provision does not change the longstanding policy that human beings are not patentable.<sup>193</sup> While this

186. *Id.* at 1426-27 (“If the claimed subject matter occurs naturally, it is not patentable subject matter under Section 101.”).

187. *Id.* at 1427. The board ultimately affirmed the examiner's rejection of the patent based on unrelated obviousness grounds. *See id.* at 1427-29.

188. Robert S. Wasowski, *The Evolution of Patentable Compositions of Matter: The United States Patent Office Accepts Genetically Altered Animals as Patentable Subject Matter Under 35 U.S.C. Section 101*, 2 ADMIN. L.J. 309, 321 (1988).

189. USPTO, *Animals-Patentability*, 1077 Off. Gaz. Pat. & Trademark Office 24 (April 21, 1987).

190. Kevles, *supra* note 161, at 133; U.S. Patent No. 4,736,866 (filed June 22, 1984); *see* Sease, *supra* note 143, at 565.

191. Sease, *supra* note 143, at 565.

192. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, § 33(a) (2011) (codified as amended at 35 U.S.C. § 33(a)).

193. Memorandum from Robert W. Bahr, Acting Associate Commissioner for Patent Examination Policy, U.S. Patent and Trademark Office, to Patent Examining Corps (Sept. 20, 2011), available at [http://www.uspto.gov/aia\\_implementation/human-organism-memo.pdf](http://www.uspto.gov/aia_implementation/human-organism-memo.pdf).

understanding is clear, whether or not this statute affects the patentability of human tissue or things related thereto is untested by the courts.

#### IV. *PROMETHEUS, MYRIAD, AND THE CURRENT STATE OF THE PRODUCT OF NATURE DOCTRINE*

In the past few years, the Supreme Court has weighed in multiple times on the intersection of biotechnology and patent law. While these most recent cases may give practitioners additional guidance on the actual scope of § 101, alternatively they may simply serve to muddy the already cloudy water that is the product of nature doctrine.

##### A. *Mayo Collaborative Services v. Prometheus Laboratories (2012)*

On March 20, 2012, the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories*, in an opinion that would have far reaching effects on the biotech industry, as well as the patent system as a whole.<sup>194</sup> The case involved a dispute arising out of a patent that claimed a method of determining the effectiveness on a drug based on the level of thiopurine metabolites in the patient's blood.<sup>195</sup> The district court held the patent to be invalid, explaining that the correlation between the metabolite levels and the effectiveness of a drug is a natural phenomenon and therefore not eligible subject matter.<sup>196</sup> On appeal, the Federal Circuit reversed by applying the "machine and transformation" test.<sup>197</sup> The court held that the "administering a drug" and "determining the [metabolite] level" steps were sufficient transformation to warrant patent protection.<sup>198</sup> The Supreme Court granted certiorari and remanded the case in light of *Bilski*, which had determined that the "machine or transformation" test was not dispositive of

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194. N. Scott Pierce, *A Great Invisible Crashing: The Rise and Fall of Patent Eligibility Through Mayo v. Prometheus*, 23 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 186, 290 (2012) (explaining that *Mayo* could potentially result in an unpredictability that "will undermine the patent system as we know it and may, ultimately, lead to diminished reliance on patents as a means for advancement of our societal economic development").

195. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012); see also U.S. Patent No. 6,355,623 col. 20 l. 10 (filed Apr. 8, 1999).

196. *Prometheus Labs. Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336, 1341 (Fed. Cir. 2009).

197. *Id.* at 1349.

198. *Id.* at 1345–47.

patent eligibility.<sup>199</sup> On remand the Federal Circuit reaffirmed its prior holding, after which the case was appealed to the Supreme Court a second time.<sup>200</sup>

The Supreme Court was asked to answer whether the steps explained in the method claim did “significantly more than simply describe” the natural relationship between metabolite concentrations in blood and the chance of effectiveness of a certain dosage of a thiopurine drug.<sup>201</sup> This question acknowledges an underlying rule that the Court explained: If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself.<sup>202</sup> More succinctly, the Court explained that a patentee cannot merely identify a law of nature and then “add the instruction ‘apply the law.’”<sup>203</sup> In its analysis, the Court examined the patented claim by splitting it into three steps: the “administering” step, the “determining” step, and the “wherein” step.<sup>204</sup> The Court found that none of the steps, when taken individually, added anything unknown prior to the filing of the patent, aside from the underlying correlative law of nature.<sup>205</sup> Further, upon looking at all the steps when put together, the Court wrote that the process added “nothing to the laws of nature that [was] not already present when the steps [were] considered separately.”<sup>206</sup> Subsequently, the Court ruled that the patents violated the product of nature doctrine, therefore the claims at issue are invalid.<sup>207</sup>

The Supreme Court addressed the patentee’s argument that medical researchers would be dis-incentivized from their research if patent protection was not provided in their line of

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199. *Mayo Collaborative Servs.*, 130 S. Ct. at 3543; see *Bilski v. Kappos*, 130 S. Ct. 3218, 3221 (2010) (holding that the “machine or transformation” test is not the only test for patentable subject matter).

200. *Mayo Collaborative Servs.*, 628 F.3d at 1355.

201. *Mayo Collaborative Servs.*, 132 S. Ct. at 1297.

202. *Id.*

203. *Id.*

204. *Id.* at 1297–98.

205. *Id.* (explaining that the “administering” step merely identified the relevant audience—doctors who already use thiopurine drugs, the “determining” step merely tells the doctor to determine the metabolite level in the blood through whatever convention process the doctor wants, and the “wherein” step merely explains the correlation between the metabolite levels and the drug’s effectiveness); see also *Pierce*, *supra* note 194, at 284.

206. *Mayo Collaborative Servs.*, 132 S. Ct. at 1298.

207. *Id.* at 1305.

work.<sup>208</sup> Explaining that the opposing side made precisely the opposite argument, the Court pointed out that patent protection is a “two-edged sword” because although it can aid in providing incentives for research, it can simultaneously impede the flow of information and therefore slow scientific advancement.<sup>209</sup> Because of this, the Court explained that a departure from the established product of nature doctrine is not warranted because both sides have valid policy concerns.<sup>210</sup> Writers have taken this argument to be the Supreme Court using “public policy to expand the natural law exception to § 101, reasoning that inventions impermissibly inhibiting research of natural laws should not be patented.”<sup>211</sup> This reasoning by the Court is a complete turnaround from the days of patents being issued for their therapeutic merit. Instead of upholding a patent for being beneficial to society, here the Court invalidated a patent partially because the underlying law of nature may be too valuable to society to allow it to be patented.<sup>212</sup>

In all, the Court’s decision in *Mayo Collaborative Servs.* expanded the product of nature doctrine into the realm of process patents, by arguing that practitioners—the patentee in this case for example—were merely masking laws of nature with menial steps thereby turning the claim into a process, when all is really claimed in the law itself.<sup>213</sup> Critics of the *Mayo Collaborative Servs.* ruling argue that the Court’s analysis is inconsistent.<sup>214</sup> The Court explained that finding a “new way of using an existing drug” was different than finding the correlation claimed in the *Mayo Collaborative Servs.* patents.<sup>215</sup> The inherent flaw in this logic is that this new use for an existing drug is inherently the result of some underlying biochemical relationship with the new use.<sup>216</sup> This statement by the Court is far from new law, and in fact was a basic understanding within the patent community

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208. *Id.* at 1304.

209. *Id.* at 1304-05.

210. *Id.* at 1305 (“[W]e must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field product unforeseen results in another.”).

211. Laura A. Keay, *Morality’s Move Within U.S. Patent Law: From Moral Utility to Subject Matter*, 40 AIPLA Q.J. 409, 436 (2012).

212. *Mayo Collaborative Servs.*, 132 S. Ct. at 1293-94.

213. *Id.* at 1294.

214. *See, e.g.*, Denise DeFranco, *Mayo: A Force to be Reckoned With*, 4 NO. 6 LANDSLIDE 24, 27 (2012).

215. *Mayo Collaborative Servs.*, 132 S. Ct. at 1302.

216. *See* DeFranco, *supra* note 214, at 27 (giving the example that had the correlation described in the *Mayo Collaborative Servs.* patent been found to have an alternative use, it would be patentable regardless of the fact that its new found application must inherently be founded on a natural phenomenon).

because numerous patents have been issued based on the discovery of a new use for an old drug.<sup>217</sup> The Court's original logic, when taken to its logical conclusion, would make such patents invalid and thereby undermine a large portion of the pharmaceutical industry because finding a treatment for a medical issue that involves known, but previously unapplied in this context, elements would not be sufficient to warrant patent protection.<sup>218</sup>

In essence, *Mayo Collaborative Servs.* may illustrate a trend away from patentability of significant portions of the biotech industry including genetic material, diagnostic methods, and therapeutics in general. The product of nature doctrine was certainly broadened by *Mayo Collaborative Servs.* to include process claims that, in the Court's opinion, do not sufficiently improve upon what is otherwise a natural phenomenon.<sup>219</sup> The inherent intermingling of life in biotechnology has led to, and continues to lead to conflict with this amoebic doctrine. These conflicting interests did not wait long before the Court again weighed in on the issue.

B. *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013)

In June, 2013, the Supreme Court issued their most recent decision involving the product of nature doctrine.<sup>220</sup> The plaintiff, Myriad Genetics, had "located and sequenced two breast cancer susceptibility genes, now termed BRCA1 and BRCA2" in the mid-1990s.<sup>221</sup> From this, Myriad developed methods to test for the BRCA mutations in order to determine whether the patient was at a higher risk for breast and ovarian cancer.<sup>222</sup> Subsequently, Myriad filed for and was issued a variety of patents on the testing methods as well the composition of the isolated DNA molecules and the cDNA<sup>223</sup> molecules associated with the BRCA1 and BRCA2 genes.<sup>224</sup> Myriad aggressively enforced their patent rights and excluded others from using the BRCA genes to provide

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217. *See id.*

218. *See id.*

219. *Mayo Collaborative Servs.*, 132 S. Ct. at 1299.

220. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013).

221. *Patent Act of 1952 — Patentable Subject Matter — Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 127 HARV. L. REV. 388, 388 (2013).

222. *Id.*

223. *See Myriad*, 133 S. Ct. at 2112 (briefly explaining what constitutes cDNA).

224. *Id.* at 2113 ("Once it found the location and sequence of the BRCA1 and BRCA2 genes, *Myriad* sought and obtained a number of patents.")

medical diagnoses and treatment to patients at risk of breast and ovarian cancer.<sup>225</sup>

A group of women who requested genetic testing for the BRCA1 and BRCA2 genes, along with advocacy groups, and several doctors including Dr. Harry Ostrer, a researcher who previously used competing labs to perform the tests, filed a declaratory judgment action challenging the validity of the Myriad patents.<sup>226</sup> The plaintiffs asserted that the Myriad patents claiming isolated genomic DNA and cDNA were invalid because they merely claimed products of nature.<sup>227</sup>

The district court held both the composition of matter claims and the method claims to be invalid under §101.<sup>228</sup> Judge Sweet succinctly explained that “products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product.”<sup>229</sup> After examining the over one hundred years of case law on the topic, Judge Sweet concluded that the DNA claimed by Myriad was not “markedly different” from native DNA, and therefore held the claims to be invalid.<sup>230</sup>

On appeal the Federal Circuit affirmed in part and reversed in part.<sup>231</sup> The Federal Circuit agreed that some of the method claims were invalid, but held that isolated genomic DNA, as well as cDNA, is patentable subject matter.<sup>232</sup> Judge Lourie, writing for the court, explains that the claimed compositions “exist in a distinctive chemical form—as distinctive chemical molecules—

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225. See David S. Olson, *Patent Protection for Genetic Innovation: Monsanto and Myriad*, 2013 CATO SUP. CT. REV. 283, 293 (2013).

226. See *id.* at 293; see also *Myriad*, 133 S. Ct. at 2114 (“Some years later, petitioner Ostrer, along with medical patients, advocacy groups, and other doctors, filed this lawsuit seeking a declaration that Myriad’s patents are invalid under 35 U.S.C. § 101.”).

227. *Myriad*, 133 S. Ct. at 2114; see also U.S. Patent No. 5,747,282 col. 153–54 (filed Jun. 7, 1995); U.S. Patent No. 5,693,473 col. 159 l. 58–63 (filed Jun. 7, 1995); U.S. Patent No. 5,837,492 col. 167 l. 16–36 (filed Apr. 29, 1996).

228. *Ass’n for Molecular Pathology v. U.S.P.T.O.*, 702 F. Supp. 2d 181, 220–37 (S.D.N.Y. 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated and remanded*, 132 S. Ct. 1794 (2012), *aff’d in part, rev’d in part*, 689 F.3d 1303 (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).

229. *Id.* at 222.

230. *Id.* at 232.

231. *Ass’n for Molecular Pathology v. U.S.P.T.O.*, 653 F.3d 1329, 1358 (Fed. Cir. 2011), *vacated and remanded*, 132 S. Ct. 1794 (2012), *aff’d in part, rev’d in part*, 689 F.3d 1303 (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).

232. *Id.* at 1354 (“In contrast, a portion of a native DNA molecule—an isolated DNA—has markedly different chemical nature from the native DNA. It is, therefore, patentable subject matter.”).

from DNAs in the human body, *i.e.*, native DNA.”<sup>233</sup> According to Judge Lourie, the markedly different aspect of isolated DNA exists because of the precise location the DNA has been cleaved,<sup>234</sup> leaving just a small portion of the naturally occurring DNA strand.<sup>235</sup> Further, Judge Lourie distinguishes this process of isolating DNA from purification, which merely “makes pure what was the same material, but was previously impure,” thereby distinguishing this case from *Parke-Davis* and *In re Marden*.<sup>236</sup> Based on these findings the Federal Circuit held the composition of matter claims on both genomic DNA and cDNA to be patent eligible.<sup>237</sup> On appeal, the Supreme Court vacated the Federal Circuit’s holding and remanded it back for further consideration in light of *Mayo Collaborative Servs.*<sup>238</sup>

On remand, the Federal Circuit narrowly construed the Court’s decision in *Mayo Collaborative Servs.*, explaining that *Funk Bros.* and *Chakrabarty* are “clearly more analogous” to the composition claims’ eligibility in *Myriad*.<sup>239</sup> While Judge Lourie’s majority opinion focuses on the more traditional product of nature approach,<sup>240</sup> Judge Moore was convinced on more policy oriented grounds.<sup>241</sup> The Federal Circuit thus again held all composition matter claims valid,<sup>242</sup> and the case was once again appealed to the Supreme Court.

In the most recent case concerning patent eligibility under 35 U.S.C. § 101, the Supreme Court unanimously held that isolated genomic DNA was not patent eligible,<sup>243</sup> but cDNA was sufficiently distinct from any naturally occurring substance and

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233. *Id.* at 1351.

234. *Id.* (explaining cleaving involves having the “covalent bonds in its backbone chemically severed”).

235. *Id.*

236. *Id.* at 1352.

237. *Id.* at 1350.

238. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794, 1794 (2012).

239. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1340 (Fed. Cir. 2012).

240. *Id.* at 1331 (“Because isolated DNAs, not just cDNAs, have a markedly different chemical structure compared to native DNAs, we reject the government’s earlier proposed ‘magic microscope’ test, as it misunderstands the difference between science and invention and fails to take into account the existence of molecules as separate chemical entities.”).

241. *Id.* at 1348 (Moore, J., concurring) (“I will not strip an entire industry of the property rights it has invested in, earned, and owned for decades unchallenged under the facts of this case.”).

242. *Id.* at 1337.

243. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013).

therefore was not a product of nature.<sup>244</sup> The Court explained that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”<sup>245</sup> Therefore, the patentability of Myriad’s genomic DNA claims were not aided by language in the specifications that indicate Myriad located a specific gene, that such gene was unknown prior to Myriad’s discovery, or that such discovery took “extensive research efforts.”<sup>246</sup> Further, the Court explicitly rejected the argument that mere isolation can be grounds for a finding of patent eligibility.<sup>247</sup> Therefore, because all Myriad had done was discover the gene and isolate it from its natural state, the claims covering genomic DNA were held invalid.<sup>248</sup>

While the Court walked through why several of Myriad’s arguments failed to establish eligibility for genomic DNA, the analysis used to conclude cDNA was patent eligible was exceedingly brief.<sup>249</sup> Justice Thomas succinctly stated that “cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments.”<sup>250</sup> The Court dismisses the petitioners’ arguments against cDNA patentability and concludes “the lab technician unquestionably creates something new when cDNA is made” because it is “distinct from the DNA from which it was derived.”<sup>251</sup> After this minimal analysis, the Court concludes “cDNA is not a ‘product of nature’ and is patent eligible under § 101.”<sup>252</sup>

Other than the direct impact on patents claiming genomic DNA, it is difficult to say what the long term impact will be from the Court’s decision in *Myriad*. Critics of the decision have argued that the analysis used by the Court against genomic DNA is inconsistent with the analysis used to come to the opposite conclusion about cDNA.<sup>253</sup> Regardless of critical response, the Court once again supplied data points to use as guides for future

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244. *Id.* at 2119.

245. *Id.* at 2117.

246. *Id.* at 2117–18.

247. *Id.* at 2118 (“Nor are Myriad’s claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule.”).

248. *Id.* at 2116–2118.

249. *Id.* at 2119.

250. *Id.*

251. *Id.*

252. *Id.*

253. *See, e.g.,* Gregory Dolin, *Patents at the Supreme Court: It Could’ve Been Worse*, 2013 CATO SUP. CT. REV. 267, 280 (2013) (“The legal analysis leading to the conclusion of patent ineligibility for isolated DNA is thus irreconcilable with the legal analysis leading to the conclusion of patent eligibility for cDNA.”).



courts attempting to navigate § 101.<sup>254</sup> What is clear from the Court's decision in *Myriad* and *Prometheus* is that the product of nature doctrine remains a powerful and amorphous doctrine that continues to raise novel questions of first impression.<sup>255</sup> There is little doubt that *Myriad* in no way constitutes an end to the Court's input on the topic. Stay tuned.

*William D. Sprott*

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254. *See id.*

255. *Id.* at 281-82.