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**Subject:** May 2016 subject matter eligibility update comment

To whom it may concern,

Defining the boundaries of subject matter eligibility has a substantial effect on shaping the level of incentivization the patent system offers for potential research, and as such particular care must be taken when defining and communicating what counts as patentable subject matter. To this end, I argued in my recent publication in the Harvard Journal of Law and Technology (attached in pdf, also accessible at <http://jolt.law.harvard.edu/assets/articlePDFs/v30/30HarvJLTexh569.pdf>) that the USPTO has taken too restrictive of a view of the Supreme Court's *Myriad* holding, and that the patenting of isolated and purified non-information encoding natural products should be explicitly allowed by the USPTO's subject matter eligibility guidance. I urge the office to take this suggestion under consideration as they draft the next update to the subject matter eligibility guidelines.

Sincerely,

Evan Tallmadge

PATENTING NATURAL PRODUCTS AFTER *MYRIAD*

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I. INTRODUCTION

Taxol, an anti-cancer drug, is one of the most successful natural product drugs on the market, with annual sales peaking at almost \$1.6 billion in 2000.<sup>1</sup> Starting from a *Taxus brevifolia* (the Pacific Yew

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1. Mitch Jacoby, *Taxol*, CHEMICAL & ENGINEERING NEWS (June 20, 2005), <https://pubs.acs.org/cen/coverstory/83/8325/8325taxol.html> [<https://perma.cc/MF2X-27ZU>]; see also Jonathan Fahey, *Taxol’s Next Stand*, FORBES (May 28, 2001), <http://www.forbes.com/forbes/2001/0528/214.html> (last visited May 4, 2017).

tree) sample and using bioactivity-directed screening,<sup>2</sup> researchers at the Research Triangle Institute's Natural Product Laboratory isolated and characterized a compound from the bark of the Pacific Yew Tree that they named "Taxol."<sup>3</sup> Taxol exhibited potent antileukemic and antitumor activities in animals,<sup>4</sup> but its complex structure made direct synthesis infeasible at the time.<sup>5</sup>

Taxol's development into a drug was slowed by the labor- and material-intensive extraction from the harvested *Taxus brevifolia* bark.<sup>6</sup> However, there were important indications of anti-cancer efficacy in both mice<sup>7</sup> and xenografts.<sup>8</sup> In 1982, researchers elucidated the mechanism of action of Taxol, which works by slowing cell division by stabilizing the microtubules used to separate chromosomes in mitosis.<sup>9</sup> These results were promising enough that the National Cancer Institute ("NCI") began animal toxicology studies, which led to an Investigational New Drug Application ("NDA") in 1982.<sup>10</sup> Phase I trials began in 1984, followed by Phase II trials in 1986.<sup>11</sup>

Despite the prohibitive cost of extraction, coupled with problems finding sufficient Pacific Yew trees, Bristol-Meyers Squibb ("BMS")

2. See, e.g., Ekrem Sezik et al., *Hypoglycaemic Activity of Gentiana olivieri and Isolation of the Active Constituent Through Bioassay-Directed Fractionation Techniques*, 76 LIFE SCIENCES 1223, 1225 (2005). In the process of bioactivity screening, raw extracts of material are fractionated and tested for the desired bioactivity, with the most potent fractions being further fractionated and the process being repeated until researchers can isolate the single compound responsible for the bioactivity of the bulk sample.

3. M.C. Wani et al., *Plant Antitumor Agents. VI. The Isolation and Structure of Taxol, a Novel Antileukemic and Antitumor Agent from Taxus brevifolia*, 93 J. AM. CHEMICAL SOC. 2325, 2325 (1971).

4. *Id.*

5. See Robert A. Holton et al., *First Total Synthesis of Taxol. 2. Completion of the C and D Rings*, 116 J. AM. CHEMICAL SOC. 1599, 1599 (1994).

6. See JORDAN GOODMAN & VIVIEN WALSH, *THE STORY OF TAXOL: NATURE AND POLITICS IN THE PURSUIT OF AN ANTI-CANCER DRUG* 51–90 (2001).

7. David A. Fuchs & Randall K. Johnson, *Cytologic Evidence that Taxol, an Antineoplastic Agent from Taxus brevifolia, Acts as a Mitotic Spindle Poison*, 62 CANCER TREATMENT REP. 1219, 1219 (1978).

8. GOODMAN & WALSH, *supra* note 6, at 95. A xenograft or xenotransplantation results from transplanting cells, tissues, or organs of one species into a host of a different species. WORLD HEALTH ORG., *XENOTRANSPLANTATION*, <http://www.who.int/transplantation/xeno/en/> [<https://perma.cc/2EM5-R8H2>]. Xenografts are commonly used to study human tumors in mouse hosts. See, e.g., Ann Richmond & Yingjun Su, *Mouse Xenograft Models vs GEM Models for Human Cancer Therapeutics*, 1 DISEASE MODELS & MECHANISMS 78, 78 (2008).

9. James J. Manfredi et al., *Taxol Binds to Cellular Microtubules*, 94 J. CELL BIOLOGY 688, 688 (1982).

10. GOODMAN & WALSH, *supra* note 6, at 97–99.

11. *Id.* at 119. Phase I clinical trials study the safety of the treatment on healthy volunteers, and after safety is assured phase II trials study the efficacy of the treatment on patients with the targeted disease. FDA, *STEP 3: CLINICAL RESEARCH*, <https://www.fda.gov/forpatients/approvals/drugs/ucm405622.htm> [<https://perma.cc/4DKD-24NS>].

agreed to take over the development of Taxol in December of 1989.<sup>12</sup> BMS submitted an NDA in 1991, which the Food and Drug Administration (“FDA”) granted at the end of 1992.<sup>13</sup> BMS did not obtain a patent on the drug but was granted a five-year exclusivity period by the FDA under the Hatch-Waxman Act.<sup>14</sup> The annual sales of Taxol peaked at almost \$1.6 billion in 2000,<sup>15</sup> and Taxol (under the generic name paclitaxel) was named as one of the World Health Organization’s “Essential Medicines.”<sup>16</sup> Taxol is not unique in its origin in the natural world;<sup>17</sup> the FDA typically approves several natural product drugs for market each year.<sup>18</sup> Although Taxol was never patented, its development was both public and well documented; therefore, it provides a good factual basis for establishing if and how a molecule that follows a similar path as Taxol could obtain patent protection.

Following the Supreme Court’s decision in *Association for Molecular Pathology v. Myriad Genetics*,<sup>19</sup> (hereinafter *Myriad*) the patentability of isolated and purified natural compounds like Taxol has been cast into doubt. In *Myriad*, the Supreme Court adjudicated the dispute surrounding the validity of Myriad’s patents on the BRCA gene.<sup>20</sup> These patents gave Myriad a monopoly on testing for BRCA gene mutations, which are linked to an increased risk of breast cancer.<sup>21</sup> Traditionally inventions that ran afoul of the prohibition on patenting products of nature could still be granted a patent if they were isolated and purified from their natural source.<sup>22</sup> This Note addresses the question of whether *Myriad* completely closed the isolated and purified exception to the exclusion of patenting products of nature, and, if not, whether the decision should be read in such a way that

12. GOODMAN & WALSH, *supra* note 6, at 159.

13. U.S. FOOD AND DRUG ADMINISTRATION, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, TAXOL (PACLITAXEL) 6 MG/ML, [http://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=N&Appl\\_No=020262](http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=020262) [https://perma.cc/WF67-98ZX].

14. Complaint at 15, Bristol-Myers Squibb Co., Docket. No. C-4076 (F.T.C. April 14, 2003).

15. Jacoby, *supra* note 1.

16. WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 23 (19th ed. 2015), [http://www.who.int/medicines/publications/essentialmedicines/EML\\_2015\\_FINAL\\_amended\\_NOV2015.pdf?ua=1](http://www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1) [https://perma.cc/XQD2-FDU5].

17. See, e.g., Adis Data Information, *Fidaxomicin*, 10 DRUGS R&D 37 (2010).

18. David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs from 1981 to 2014*, 79 J. NAT. PRODUCTS. 629, 632 fig. 6 (2016).

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

20. *Id.* at 2117.

21. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L CANCER INST. (Apr. 1, 2015), <https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet> [https://perma.cc/U6KN-4JFP].

22. See, e.g., Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 163–64 (4th Cir. 1958). This Note uses the shorthand “natural product exclusion” to reference this method of patenting.

maintains the incentive structure for the discovery and commercialization of natural products like Taxol.

The line between patentable and unpatentable subject matter is established by 35 U.S.C. § 101 and elucidated by judicial interpretations of the statutory provision. Courts have cabined the expansive language of § 101, declaring abstract ideas, laws of nature, and — most importantly for this Note — products of nature unpatentable exclusions from otherwise patentable subject matter.<sup>23</sup> Historically, however, the judiciary had developed a significant exception to the natural product exclusion: that the composition of matter of a natural product, isolated and purified from nature, is eligible for patent protection.<sup>24</sup> However, the U.S. Patent and Trademark Office (“USPTO”) has read the *Myriad* decision as eliminating this exception.<sup>25</sup> There is still significant debate in the legal literature<sup>26</sup> and among practitioners<sup>27</sup> concerning whether *Myriad* must or should be read in this manner. This Note posits that sound policy requires a narrower reading of *Myriad* than the USPTO has embraced.

The closure of the isolated and purified exception dealt a significant blow to the incentivization scheme for isolated natural products. It must be noted that a prohibition on patenting natural products does not preclude a claimant from obtaining a patent on the use of a given natural product,<sup>28</sup> the patenting of new material produced using the insight gained from that natural product,<sup>29</sup> or the patenting of a meth-

23. See, e.g., *Diamond v. Diehr*, 450 U.S. 175, 186 (1981).

24. See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.D.N.Y. 1911).

25. Memorandum to the Patent Examining Corps from Andrew H. Hirshfeld, Deputy Commissioner for Patent Examination Policy, to Patent Examining Corps (Mar. 4, 2014), [https://www.uspto.gov/patents/law/exam/myriad-mayo\\_guidance.pdf](https://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf) [https://perma.cc/3HLZ-5X84] [hereinafter 2014 PTO Guidance].

26. See, e.g., David Knapp, *The Fate of Small-Molecule Natural Products After Myriad Genetics*, 43 *AIPLA Q.J.* 595 (2015); Sean Brennen, *After Myriad: A Herd of Elephants in the Room*, *PATENT DOCS* (July 3, 2013), <http://www.patentdocs.org/2013/07/after-myriad-a-herd-of-elephants-in-the-room.html> [https://perma.cc/DBE5-SDQU]; Dennis Crouch, *Twenty Thoughts on the Importance of Myriad*, *PATENTLY-O* (June 14, 2013), <http://patentlyo.com/patent/2013/06/myriad.html> [https://perma.cc/RXY9-JANW].

27. See, e.g., Stephen H. Schilling & W. Murray Spruill, *PTO Subject Matter Eligibility Guidance: An Ill-Advised Overextension of Myriad*, 33 *BIOTECHNOLOGY L. REP.* 120 (2014); Chenghua Luo & Jorge Goldstein, *Patenting Purified Natural Products by Specific Activity: Eligibility and Enablement*, *BLOOMBERG BNA LIFE SCI. LAW & INDUS. REP.* (May 29, 2015), [http://www.skgf.com/uploads/1307/doc/Patenting\\_Purified\\_Natural\\_Products.pdf](http://www.skgf.com/uploads/1307/doc/Patenting_Purified_Natural_Products.pdf) [https://perma.cc/7C6H-3L7X]; Warren D. Woessner, *“Isolated” Natural Products Still in Purgatory Post-PTO Guidance?*, *PATENTS4LIFE* (Apr. 28, 2015), <http://www.patents4life.com/2015/04/isolated-natural-products-still-in-purgatory-post-pt-guidance/> [https://perma.cc/8468-67RS].

28. See, e.g., *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003).

29. *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”).

od of production of that material.<sup>30</sup> Despite these avenues of protection, inventors have been trying to patent truly natural compositions of matter for many years<sup>31</sup> due to the high worth of composition of matter patents relative to other forms of patent protection.<sup>32</sup> Process claims, although permitted for newly discovered uses of natural products, do not provide the long-term certainty required to incentivize the multi-year, multi-billion-dollar investments into pharmaceutical research and development required to bring a product to market. Process claims are significantly more difficult to prove infringement on, as the patentee must either show that a single entity performed all steps to trigger § 271(a) direct infringement liability,<sup>33</sup> or show inducement of another party to directly infringe under § 271(b), which requires that the other party was a direct infringer under § 271(a).<sup>34</sup> Likewise, the FDA exclusivity period by itself provides insufficient incentivization. The FDA grants only data exclusivity and, absent patent protection, generic competitors could simply bear the cost of developing their own information for an NDA and enter the market. Thus, the FDA exclusivity period would delay competitors only by the length of time it takes to get FDA approval. This would be analogous to the situation before the passage of the Hatch-Waxman Act, where patentees faced competition from new entrants shortly after the patent expired.<sup>35</sup>

There have been numerous articles about the correct levels of incentivization for optimal research and development (“R&D”) investment<sup>36</sup> and alternative methods for providing these incentives,<sup>37</sup> but a fundamental problem remains: the most protected and desired class of incentives — composition of matter patents — is currently unavailable for some classes of drugs. This will bias pharmaceutical companies’ decisions regarding R&D investment towards drugs with a

30. *Cf.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119 (2013).

31. *See Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123 (denying patent application for cellular tissues of the *Pinus australis* tree, which were long filaments suitable for weaving).

32. Kevin G. Rivette & David Kline, *Discovering New Value in Intellectual Property*, 78 HARV. BUS. REV. 54 (2000), <https://hbr.org/2000/01/discovering-new-value-in-intellectual-property> (last visited May 4, 2017) (“[Patents] have the greatest effect on the commercial success and market value of companies today.”).

33. *See Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328–29 (Fed. Cir. 2008).

34. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

35. *See* Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need A Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL’Y, L. & ETHICS 293, 297–300 (2015).

36. *See generally* Vincenzo Denicolò, *Do Patents Over-Compensate Innovators?*, 22 ECON. POL’Y 681 (2007), <http://economicpolicy.oxfordjournals.org/content/economicpolicy/22/52/680.full.pdf> [<https://perma.cc/E6K5-HP2V>].

37. *See generally* Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401 (2016).

higher likelihood of effective patent protection,<sup>38</sup> to the detriment of society.<sup>39</sup> Therefore, some mechanism must be developed to correct this bias. This Note proposes one such path: revitalizing the isolated and purified exception for non-information encoding natural products.

Part II assesses the established jurisprudence surrounding 35 U.S.C. § 101 and lays out the fundamentals of the natural product judicial exclusion to the language of § 101. Part II then examines the history of the isolated and purified exception to the natural product exclusion. This exception had provided a pathway to patent significant discoveries of useful medicines extracted from the bounty of nature, but the USPTO has read *Myriad* to shut this path to subject matter eligibility.

Part III examines the most consequential decision in the landscape of the natural product exclusion and the isolated and purified exception: *Myriad*. The *Myriad* Court held that the isolated and purified natural DNA sequence for the BRCA gene Myriad claimed was not patentable. The USPTO has read this decision as permanently closing the isolated and purified exception, though Part V argues that this is not the only permissible reading, and in fact, prudent policy considerations and other related Supreme Court cases support a narrower reading of *Myriad*.

Part IV looks at the challenge *Myriad* raised: how does an applicant patent a natural product? The Part analyzes the three main inquiries the Court had to address before reaching a holding: (1) was the correct framing of the § 101 inquiry to look at the similarities and differences between the product and the naturally occurring substance, (2) was the method of claiming determinative of subject matter eligibility, and (3) did the information-carrying nature of DNA change the determination of subject matter eligibility? This Note argues that the true key was that DNA is information carrying, whereas past examples of molecules that have used the isolated and purified exception were not. This unique property of DNA upset the traditional patent balance. Part IV closes by looking at the fundamental differences between Taxol and the BRCA gene in light of the issues raised in *Myriad* in order to argue that non-information-encoding natural products should be patentable.

Part V examines possible solutions to the issues *Myriad* raised with the patenting of natural products. In light of the way the Court dealt with software patents under *Alice Corp. Pty. Ltd. v. CLS Bank*

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38. Cf. Michael Ravvin, *Incentivizing Access and Innovation for Essential Medicines: A Survey of the Problem and Proposed Solutions*, 1 PUB. HEALTH & ETHICS 110, 112 (2008).

39. Specifically, to the detriment of patients for whom nature has provided a treatment. This is pronounced in the antibiotic space, where researchers are searching for the same end result as evolutionary pressures: defeating hostile bacteria.

*Int'l*<sup>40</sup> the year after *Myriad*, there is a reading of *Myriad* that uses both the *Alice* and related *Mayo Collaborative Serv's. v. Prometheus Labs*<sup>41</sup> frameworks for subject matter eligibility to preserve the patentability of non-information-encoding molecules. The Note concludes by arguing that this method of reading *Myriad* is preferable to the USPTO's reading due to the rationales that had motivated the isolated and purified exception for over a century, which remain just as relevant to the world of drug discovery today.

## II. SECTION 101 AND PRODUCTS OF NATURE

The current iteration of 35 U.S.C. § 101 provides that “[w]hoever 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>42</sup> Lawyers reading this statute could logically conclude that a molecule present in nature would fall within this framework.<sup>43</sup> However, the courts have carved out nuanced exclusions from the broad potential scope of patent rights. These exceptions include the unpatentability of abstract ideas,<sup>44</sup> natural laws,<sup>45</sup> and, as the focus of this Note, products of nature.

### *A. Products of Nature Are Unpatentable*

The judicial exclusion from § 101's broad language for products of nature<sup>46</sup> relies on the finding that natural products do not constitute a new machine, manufacture, or composition of matter, or any new and useful improvement thereof.<sup>47</sup> Courts couched this holding in the idea that phenomena of nature, and thus natural products, are not novel, as they have always been a part, albeit undiscovered, of the storehouse of knowledge, and only *new applications* of them are patentable. The Court has thus held that:

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40. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).

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

42. 35 U.S.C. § 101 (2012).

43. It was discovered, it is useful, and it is a composition of matter.

44. *Alice*, 134 S. Ct. at 2354.

45. *See, e.g., Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).

46. These are also referred to as natural phenomenon and natural products. I will use the terms interchangeably to mean a product that exists outside of all direct human effort.

47. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1979) (“The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”). *See also* U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 706.03(a) (8th ed. July 2010) (“[A] thing occurring in nature, which is substantially unaltered, is not a ‘manufacture.’ A shrimp with the head and digestive tract removed is an example.”) (citing *Ex parte Grayson*, 51 U.S.P.Q. (BNA) 413 (Bd. App. 1941)).



[P]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.<sup>48</sup>

Appellate courts likewise have historically broken the logic underlying the exclusion of products of nature from patentability into two complementary parts:

(1) [T]hat 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 (2) 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>49</sup>

These criteria sound like pseudo-novelty and pseudo-obviousness considerations. Although such concerns are more naturally housed in 35 U.S.C. §§ 102 and 103, they have been used to justify rejecting a patent using the shorthand of the natural products exclusion.<sup>50</sup> This blended approach to the statutory criteria is likely due to the development of the natural product exclusion before the 1952 Act,<sup>51</sup> which separated the criteria of novelty, nonobviousness, and disclosure.<sup>52</sup> The Supreme Court, though, has stated that even with this muddled provenance, the determination of subject matter eligibility rests firmly within § 101 and not a more rigorous application of § 102, § 103, or

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48. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1947) (internal citations omitted).

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

50. See 1 DONALD S. CHISUM, *CHISUM ON PATENTS* § 1.02 (Matthew Bender ed. 2017) (“The phrase ‘product of nature’ is on occasion used in a different sense—as a shorthand expression of the unpatentability under the novelty and nonobviousness standards of (1) an old product derived from a new source or process or (2) a new product that differs from old ones only in terms of an incremental degree of purity.”).

51. Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 *STAN. TECH. L. REV.* 257, 264 (2013).

52. *Id.*

§ 112.<sup>53</sup> This holding overturned the earlier approach in which § 101 was practically toothless on its own<sup>54</sup> but was used as a convenient shorthand of rejecting claims that would have failed for other reasons.<sup>55</sup> As an aside, the fact that the natural product is more aptly described as discovered—rather than invented—should, in theory, bear no weight on its patentability.<sup>56</sup> The focus of the rest of this Note is on finding a navigable pathway for a natural product drug candidate like Taxol between the shoals of pseudo-novelty and pseudo-obviousness as analyzed under the §101 umbrella, and on the idea of discoveries being unpatentable despite the wording of § 101.

### *B. The Isolated and Purified Exception*

The “product of nature” exclusion evolved from a line of cases that denied patent protection to plant extracts,<sup>57</sup> naturally occurring metals,<sup>58</sup> and new combinations of existing bacteria.<sup>59</sup> To the benefit of patent holders, however, the courts<sup>60</sup> created a significant exception to this doctrine: a natural product that was isolated and purified was patent-eligible.<sup>61</sup> Both the exclusion and the exception have long lines of precedent, tracing back to the late nineteenth century.<sup>62</sup> The formative case for the isolated and purified exception was *Parke-Davis & Co. v. H.K. Mulford Co.*,<sup>63</sup> in which Judge Learned Hand held that adrenaline, isolated and purified from animal glands, was eligible for

53. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1303 (2012) (“The relevant cases rest their holdings upon [S]ection 101, not later sections”).

54. *Merck*, 253 F.2d at 162 (“But where the requirements of the [Patent] Act are met, patents upon products of nature are granted and their validity sustained.”).

55. See 1 CHISUM, *supra* note 50, § 1.02.

56. See *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting) (“That the thing was there, undiscovered, does not render it inherently anticipated. . . . Does the panel intend that no newly discovered product found in an organism can be patented? Such a ruling does not comport with either the patent statute or the incentive purposes of the patent system.”) (internal quotations omitted). *But see Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117 (2013) (“Ground-breaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”).

57. *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123.

58. *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928).

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

60. Interestingly, this doctrine was first articulated at the district court level by Judge Learned Hand, but his reasoning has been cited to and incorporated into many decisions over the years. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911).

61. See Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (“Thus, an inventor’s discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.”).

62. *Beauchamp*, *supra* note 51, at 261.

63. *Parke-Davis*, 189 F. at 95.

a patent despite it being a natural product.<sup>64</sup> The extraordinary utility of the purified product over the prior art overcame the traditional exclusion.<sup>65</sup> Using this judgment as a template, the rate of patenting of isolated and purified natural products jumped after 1911.<sup>66</sup>

*Parke-Davis* was in opposition to an earlier line of reasoning best exemplified by *Ex parte Latimer*.<sup>67</sup> In *Ex parte Latimer*, the court held that the fiber extracted from pine needles was not eligible for a patent despite its great utility.<sup>68</sup> *Ex parte Latimer* draws on a parallel and much deeper strand of cases, which hold that laws of nature are unpatentable on the grounds that they “cannot be invented or created by man; they have co-existed with eternity; and are *common stock*.”<sup>69</sup> Notably though, Federal Circuit Judge Lourie recently remarked that concerns about preempting vast swaths of scientific research are significantly less dire with regard to patents on compositions of matter compared to patents on laws of nature.<sup>70</sup> This theory of narrow preemption is likely why the courts were less hesitant to grant a patent on natural products than on laws of nature. In the classical patent bargain, “[p]atent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”<sup>71</sup> It is a trade to the public’s benefit if the monopoly is narrower and thus less harmful.<sup>72</sup>

The judicial prohibition on patenting natural products stems from two primary concerns. Under the first concern, analyzed above, courts worry about patenting natural products because the resulting monopoly would constrain further scientific inquiry into broad swaths of the natural world.<sup>73</sup> The second concern expressed over patenting natural

64. *Id.*

65. Beauchamp, *supra* note 51, at 304 (describing the reasoning of *Parke-Davis* and the related decision *Merck v. Olin Mathieson*, 253 F.2d 156 (4th Cir. 1958), “[t]he rationale of novelty-through-greater-utility carried the day”).

66. Beauchamp, *supra* note 51, at 262.

67. *Ex parte Latimer*, 1889 Dec. Comm’r Pat. 123.

68. *Id.*

69. OLIVER EVANS, EXPOSITION OF PART OF THE PATENT LAW BY A NATIVE-BORN CITIZEN OF THE UNITED STATES 12–13 (1816).

70. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (Fed. Cir. 2012), *rev’d in part sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

71. *Myriad*, 133 S. Ct. at 2109 (alteration in original) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012)).

72. Oskar Liivak, *Maintaining Competition in Copying: Narrowing the Scope of Gene Patents*, 41 U.C. DAVIS L. REV. 177, 183 (2007). This is absent any concerns about insufficient patent coverage failing to incentivize research, a topic thoroughly explored in the legal literature. *See, e.g.*, Janet Freilich, *The Uninformed Topography of Patent Scope*, 19 STAN. TECH. L. REV. 150 (2015).

73. *Mayo*, 132 S. Ct. at 1293 (“[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.”).

products is the question of novelty. Should claimants be rewarded with a monopoly if nature, not the claimants themselves, was the “first and true inventor?”<sup>74</sup> This factor has not been explicitly addressed by courts, but it underpins many of the cases concerning natural products.<sup>75</sup> The application of these policy concerns is more than a mere application of 35 U.S.C. § 102, as newly discovered natural products would meet the statutory requirements.<sup>76</sup> Courts are likely wary of granting a patent to a claimant who was the first to file but not the first to use the product of nature being claimed. However, case law permitting the patenting of different polymorphs of aspirin<sup>77</sup> suggests that as long as the claimant has not been proven to have been beaten to the discovery, and not merely the use of, the product by another, then the patent could still be granted.<sup>78</sup>

Until the era of DNA, courts imposed an unsteady truce between the practical benefits of encouraging research into natural products and the desire to deny patents to discoveries that would preclude research into vast swaths of the natural world for minimal gain.<sup>79</sup> This balance between products that fell into the isolated and purified exception, and the ban on patenting either whole organisms or natural laws with the associated preclusion of fields of research, was stable as long as inventions could be filtered into one of these categories. DNA, though, can be isolated and purified from nature. Likewise, a monopoly on a specific piece of DNA can preclude a vast field of research,<sup>80</sup> as a DNA patent is at its core concerned with the information encoded within the DNA.<sup>81</sup> This stands in contrast to the typical isolated and

74. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 23 (1829) (emphasis omitted).

75. *See, e.g., Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (“His discovery is not nature’s handiwork, but his own; accordingly, it is patentable subject matter under Section 101.”).

76. 1 CHISUM, *supra* note 50, § 1.02 (“A true product of nature could be ‘new’ as the concept of novelty is used in patent law, that is, neither previously known or used in the United States, nor patented or described in printed publication in the United States or a foreign country.”).

77. The active pharmaceutical ingredient, acetylsalicylic acid, has been in use since before the founding of the United States. *See Edmund Stone, An Account of the Success of the Bark of the Willow in the Cure of Agues*, 53 PHIL. TRANSACTIONS OF THE ROYAL SOC’Y OF LONDON 195 (1763).

78. *See, e.g., Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910).

79. *See, e.g., Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911).

80. *See David B. Resnik, DNA Patents and Scientific Discovery and Innovation: Assessing Benefits and Risks*, 7 SCI. & ENG’G ETHICS 29, 47–55 (2000).

81. Sandy M. Thomas et al., *Shares in the Human Genome—the Future of Patenting DNA*, 20 NATURE BIOTECHNOLOGY 1185, 1185 (2002) (“Others have viewed such appropriation as unethical, chiefly because they consider that human DNA is composed of pre-existing information that has been discovered and not invented.”); *see also* Jonah D. Jackson, *Something Like the Sun: Why Even “Isolated and Purified” Genes Are Still Products of Nature*, 89 TEX. L. REV. 1453, 1460 (2011) (“A gene, then, for the purposes of this Note, is best conceived of as some discrete information—expressed in a chemical compound con-

purified small molecules: patenting adrenaline<sup>82</sup> did not preclude research into other methods of treating anaphylaxis<sup>83</sup> nor into developing a more potent derivative, but patenting the BRCA gene<sup>84</sup> would stop all research into breast cancer screening tied to the gene. The Supreme Court dealt with this problem in *Myriad*, but it injected significant uncertainty into the question of whether the isolated and purified exception is still available for any small molecule.<sup>85</sup> This Note argues that there is a permissible reading of *Myriad* under which the exception is still open, and that there are good policy grounds for reading the opinion as such.

### III. REVIEW OF *MYRIAD*

On December 21, 1995, Myriad applied for patents on the BRCA gene,<sup>86</sup> the related cDNA,<sup>87</sup> and methods for analyzing the DNA to determine the risk of cancer,<sup>88</sup> as mutations in the BRCA gene have shown a significant correlation to the later appearance of breast cancer.<sup>89</sup> Myriad received these patents and began marketing a diagnostic test to detect the deleterious mutations in patients.<sup>90</sup> On May 12, 2009, the Association for Molecular Pathology (“AMP”), a non-profit dedicated to increasing innovation in and access to molecular diagnos-

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sisting of a sequence of nucleotide pairs—that is functionally significant in one or more identifiable cellular processes.”).

82. *Parke-Davis*, 189 F. at 500. Adrenalin (epinephrine) is a naturally occurring hormone used medicinally to treat anaphylaxis, among other conditions.

83. M.R. Bennett, *One Hundred Years of Adrenaline: The Discovery of Autoreceptors*, 9 CLINICAL AUTONOMIC RES. 145, 145 (1999).

84. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). The BRCA gene was associated with an increased risk of breast cancer and Myriad patented the gene to preserve its exclusive right to market testing for the gene.

85. *Id.* at 2120.

86. U.S. Patent No. 5,747,282 claim 1 is representative of both the DNA and cDNA composition of matter claims across Myriad’s patent portfolio. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 212 (S.D.N.Y. 2010), as amended (Apr. 5, 2010), *aff’d in part, rev’d in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 566 U.S. 902, 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated*, 467 F. App’x 890 (Fed. Cir. 2012), *aff’d in part, rev’d in part*, 689 F.3d 1303 (Fed. Cir. 2012).

87. cDNA is produced by transcribing RNA produced in the cell (which would normally be translated into the coded protein) back into DNA. This results in a DNA strand without any of the non-coding regions found in the chromosomal DNA. *Id.* at 198–99.

88. U.S. Patent No. 5,709,999 claim 1 is representative of the method claims across Myriad’s patent portfolio. *Id.* at 213. Both the district court and the Federal Circuit rejected the method claims, and this decision was not appealed to the Supreme Court.

89. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT’L CANCER INST. (Apr. 1, 2015), <https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet> [<https://perma.cc/U7WM-QEKK>].

90. *Hereditary Breast Cancer*, MYRIAD, <https://myriad.com/patients-families/disease-info/breast-cancer> [<https://perma.cc/TKQ4-SRZ3>].

tics,<sup>91</sup> along with a number of hospitals, doctors, and patients brought suit against Myriad, alleging that their patents were invalid under § 101.

Throughout all of the ensuing cases, there were a few questions that the courts struggled to answer and to which this Note seeks to draw attention in order to examine what the Supreme Court's ruling means for natural products like Taxol. First, what effect does the breaking of chemical bonds in chromosomal DNA to extract the claimed gene have on the patentability of that gene? Next, what should be the focus of the court's § 101 analysis when looking at "markedly different characteristics":<sup>92</sup> the differences between the chromosomal DNA and the claimed DNA, or the similarities between them (namely, the information they encode)? Third, should there be specific carve-outs in § 101 for certain items, like DNA, that have the potential to upset the entire bargain of disclosure versus monopoly upon which the patent system is built? Finally, is it material to § 101 that the value of Myriad's patents comes not from the exclusive use of the composition of matter but from the exclusive use of the information encoded in the claimed string of nucleotides?

#### A. The District Court

AMP and related parties sued Myriad and the USPTO in the Southern District of New York<sup>93</sup> seeking to invalidate Myriad's patents.<sup>94</sup> The district court granted summary judgment on the claims related to the DNA, cDNA, and methods of testing, holding them all invalid in light of § 101.

The question the court considered is whether, under *Diamond v. Chakrabarty*<sup>95</sup> where the Court held that a genetically modified bacterium was patentable, the patented DNA possessed "'markedly different characteristics' from a product of nature."<sup>96</sup> The court noted,

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91. *About AMP*, ASS'N FOR MOLECULAR PATHOLOGY, <https://www.amp.org/about/index.cfm> [<https://perma.cc/WV3Z-ULE2>].

92. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 227–28 (S.D.N.Y. 2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)), *aff'd in part, rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated*, 467 F. App'x 890 (Fed. Cir. 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).

93. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 227–28.

94. U.S. Patent No. 5,747,282; U.S. Patent No. 5,837,492; U.S. Patent No. 5,693,473; and U.S. Patent No. 5,709,999, among others.

95. 447 U.S. 303 (1980).

96. *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 227–28 (quoting *Chakrabarty*, 447 U.S. at 310).

however, that this question “fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds.”<sup>97</sup> The court thus held that “[i]n light of DNA’s unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad between native BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed in the patents-in-suit render the claimed DNA ‘markedly different.’”<sup>98</sup> In rejecting the claims, the court noted that Myriad’s focus on the differences, and not the similarities between the claimed DNA and naturally occurring DNA would be absurd given Supreme Court jurisprudence, stating that it would be:

[D]ifficult to discern how any invention could fail the test. For example, the bacterial mixture in *Funk Brothers* was unquestionably different from any preexisting bacterial mixture; yet the Supreme Court recognized that a patent directed to the mixture, considered as a whole, did no more than patent the “handiwork of nature.”<sup>99</sup>

The mere absence of proteins associated with the DNA likewise “merely constitutes a difference in purity that cannot serve to establish subject matter patentability.”<sup>100</sup> The ultimate finding of patentability under § 101 is “whether, considering the claimed invention as a whole, it is sufficiently distinct in its fundamental characteristics from natural phenomena to possess the required ‘distinctive name, character, [and] use.’”<sup>101</sup>

### *B. The Federal Circuit, Round 1*

The Federal Circuit reversed the district court regarding the patentability of DNA and cDNA, holding that both were valid subject matter under § 101.<sup>102</sup> On appeal, Myriad argued that the “district court came to a contrary conclusion by (1) misreading Supreme Court

97. *Id.* at 228.

98. *Id.* at 229.

99. *Id.* (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948)).

100. *Id.* at 230.

101. *Id.* at 229 (alteration in original) (quoting *Chakrabarty*, 447 U.S. at 309–10).

102. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, judgment vacated sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012), *opinion vacated, appeal reinstated*, 467 F. App’x 890 (Fed. Cir. 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).

precedent as excluding from patent eligibility all ‘products of nature’ unless ‘markedly different’ from naturally occurring ones; and (2) incorrectly focusing not on the differences between isolated and native DNAs, but on one similarity: their informational content.”<sup>103</sup> Echoing the language used by the district court, AMP argued that “to be patent eligible a composition of matter must also have a distinctive name, character, and use, making it ‘markedly different’ from the natural product.”<sup>104</sup> The Federal Circuit noted that, interestingly, the USPTO had chosen not to defend its historically broad practice of granting patents to isolated and purified DNA sequences. The USPTO’s position shifted, and it argued that only cDNA and other synthetically produced DNA was patent eligible, but naturally occurring DNA was not because “their nucleotide sequences exist because of evolution, not man.”<sup>105</sup>

Analyzing *Chakrabarty* and *Funk Bros.*, the court started with the premise that the “distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition’s identity compared with what exists in nature.”<sup>106</sup> The court noted that it was undisputed that Myriad’s DNA sequences “exist in a distinctive chemical form — as distinctive chemical molecules — from DNAs in the human body.”<sup>107</sup> Excising the DNA from the long strands of each chromosome where it resides is sufficient chemical manipulation “to produce a molecule that is markedly different from that which exists in the body.”<sup>108</sup> It had not simply been isolated by being purified, as was the case in *Parke-Davis*.<sup>109</sup>

The court held that Myriad’s argument regarding § 101 was correct, and the focus should be on the differences between the claim and the natural material, and not “at one similarity: the information content contained in isolated and native DNAs’ nucleotide sequence.”<sup>110</sup> Therefore, the court considered isolated and purified DNA, cleaved from the chromosomes, patentable subject matter.

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103. *Ass’n for Molecular Pathology*, 653 F.3d at 1349.

104. *Id.*

105. *Id.* at 1350.

106. *Id.* at 1351.

107. *Id.*

108. *Id.* at 1352.

109. *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

110. *Ass’n for Molecular Pathology*, 653 F.3d at 1353.



*C. The Federal Circuit, Round 2*

On remand from the Supreme Court and in light of *Mayo*,<sup>111</sup> which held that a law of nature plus routine steps is not patent eligible, the Federal Circuit again considered the patentability of DNA, cDNA, and the method claims in Myriad's patents. The court first noted that claims to isolated DNA as a composition of matter are not controlled by *Mayo*, and composition of matter claims are "expressly authorized as suitable patent-eligible subject matter in Section 101."<sup>112</sup> The court held, using almost identical language as before, that the isolated DNA was not found in nature, and, while it was prepared from nature, so are all compositions of matter.<sup>113</sup> The court again noted that Myriad argued at the district court that the focus should not have been on the similar information content of the DNA, but on the marked differences between naturally occurring DNA and the isolated and purified composition of matter it sought to patent.<sup>114</sup> AMP countered that "to be patent eligible a composition of matter must also have a distinctive name, character, and use, making it 'markedly different' from the natural product."<sup>115</sup>

The Federal Circuit, considering these arguments, held as before that "the challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different — have a distinctive chemical structure and identity — from those found in nature."<sup>116</sup> Parsing the chemical differences between chromosomal DNA and isolated DNA, the court held that "isolated DNA is not just purified DNA . . . [as it has been] manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body."<sup>117</sup> Noting the similarities between the isolated DNA and the cDNA, the court noted: "cDNAs are especially distinctive, lacking the non-coding introns present in naturally occurring chromosomal DNA. They are even more the result of human intervention into nature and are hence patent-eligible subject matter."<sup>118</sup>

The Federal Circuit considered the informational content of DNA in more depth than it had in its earlier decision. Contradicting the district court, which had effectively created a "categorical rule excluding

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111. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012).

112. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1325 (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).

113. *Ass'n for Molecular Pathology*, 689 F.3d at 1325.

114. *Id.*

115. *Id.* at 1326.

116. *Id.* at 1328.

117. *Id.*

118. *Id.* at 1329.

isolated genes from patent eligibility,”<sup>119</sup> the Federal Circuit held that “patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material.”<sup>120</sup> Taking heed of the traditional patent bargain, the court noted that allowing the patenting of isolated and purified DNA does not raise the same preemption concerns as *Mayo*, stating that “permitting patents on isolated genes does not preempt a law of nature,”<sup>121</sup> and that “[c]reating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort.”<sup>122</sup> The court also noted patents on these entities are intended to stimulate research into them and hence the isolated and purified DNA is “properly patent eligible.”<sup>123</sup>

#### D. The Supreme Court

The Supreme Court prefaced its opinion by citing *Mayo* to remark that courts have “long held that [35 U.S.C. § 101] contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.”<sup>124</sup> But the Court also stated that the “rule against patents on naturally occurring things is not without limits, however, for ‘all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,’ and ‘too broad an interpretation of this exclusionary principle could eviscerate patent law.’”<sup>125</sup>

The Court began its analysis of the Myriad patents by noting that it was undisputed that Myriad did not create or alter any of the *information* that was encoded in the genes and that the nucleotides existed in nature before Myriad discovered them.<sup>126</sup> As the Court said, “Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13,”<sup>127</sup> and the main question before the court was whether this rendered the DNA patentable under § 101.

The Court held that, unlike *Chakrabarty*’s creation of a new oil-eating bacterium, “Myriad did not create anything. To be sure, it

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119. *Id.* at 1330.

120. *Id.*

121. *Id.* at 1331.

122. *Id.* at 1332.

123. *Id.*

124. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012)).

125. *Id.* (quoting *Mayo*, 132 S. Ct. at 1293).

126. *Ass’n for Molecular Pathology*, 133 S. Ct. at 2116.

127. *Id.*

found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.”<sup>128</sup> Opining on *Funk Brothers*, the Court then stated that the bacteria there were not patent-eligible under § 101 “unless we borrowed invention from the discovery of the natural principle itself.”<sup>129</sup> The *Myriad* Court went on to say “[Kalo’s] patent claim thus fell squarely within the law of nature exception.”<sup>130</sup> The Court noted that Myriad tried to use the difficulty of discovery and vast expenditure of resources as substitutes for the basic § 101 inquiry, but the Court held that these features could not take the place of proper patent subject matter eligibility.<sup>131</sup>

The Court next turned to the key question: are the isolated segments of DNA patent-eligible?<sup>132</sup> The Court first held that even though the isolation of the genes broke chemical bonds and so, in theory, created a new molecule, the claims were “simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA.”<sup>133</sup> The Court, focusing on the true motivation for claiming the DNA and the resulting non-composition of matter language used to claim it, noted that “[i]nstead, the claims understandably focus on the genetic *information encoded* in the BRCA1 and BRCA2 genes.”<sup>134</sup> The Court went on to analyze the claims in comparison to a typical composition of matter claim:

If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad’s patent claims on entire genes (such as claims 1 and 2 of the ’282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule “invented” by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.<sup>135</sup>

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128. *Id.* at 2117.

129. *Id.* (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948)).

130. *Id.*

131. *See id.* at 2118.

132. *See id.*

133. *Id.*

134. *Id.* (emphasis added).

135. *Id.*

The Court concluded its § 101 analysis of the claimed DNA by brushing aside Myriad's argument that the USPTO's past practice of allowing gene patents should bear weight — an interesting argument for Myriad to make in light of the USPTO's brief at the Federal Circuit arguing against the patentability of DNA despite its past practice of approval.<sup>136</sup>

The Supreme Court thus unequivocally shut the door to the patenting of genes unaltered from their natural state using the broad claim language in Myriad's patent. The Court upheld the patents on cDNA, however, holding that, unlike the process by which the whole gene is extracted from the genome, using extra-cellular mechanisms to form cDNA was sufficient to remove the molecule from being considered a product of nature.<sup>137</sup>

The narrowest possible reading of the Court's holding in *Myriad* is that an applicant cannot patent DNA in its natural state using the broad claim language Myriad did. Courts have the power to read *Myriad* this narrowly,<sup>138</sup> but based upon past practice of judicial interpretation,<sup>139</sup> courts would not narrow it so. The USPTO responded to the holding by releasing guidelines that embraced an expansive view of the holding's scope. The guidelines preclude the patenting of a natural product unless the claimant demonstrates that the claimed subject matter is markedly different from what exists in nature, reaffirming *Chakrabarty*<sup>140</sup> and following the Court's treatment of cDNA.<sup>141</sup> However, in addition to forbidding the claiming of DNA in its natural state, the guidelines explicitly disallow the patenting of a non-DNA molecule isolated and purified from nature,<sup>142</sup> even though this was never addressed in *Myriad*. This Note argues, *infra* Section IV.B, that this is not a foregone conclusion, and the logic behind *Myriad*, closely read, should not preclude the patenting of all isolated and purified natural products.

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136. Brief for Appellee at 45, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2010 WL 5311467, at \*19.

137. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2119.

138. Patrick Higginbotham, *Text and Precedent in Constitutional Adjudication*, 73 CORNELL L. REV. 411, 413 (1988) ("That is, we accept that it is the rule of the case or *ratio decidendi* that binds, and the successor court has play, often considerable, in deciding what that holding is.").

139. *Cf. Mitchell v. Trawler Racer, Inc.*, 362 U.S. 539, 547 (1960) (evidencing the rare practice of confining a previous case, *Carlisle Packing Co. v. Sandanger*, 259 U.S. 255 (1922), to the narrowest of facts).

140. 2014 PTO Guidance, *supra* note 25.

141. *See infra* Section IV.B.1.

142. 2014 PTO Guidance, *supra* note 25, at 7–8.

## IV. PATENTING THINGS WITHOUT PATENTING IDEAS

With Taxol's path from tree to market in mind, the question this Note seeks to answer is how, using the current § 101 understanding, can the patent system incentivize more drugs like Taxol? The solution turns on answering the question of what exactly § 101 was designed to do. This Note concludes that § 101 was designed to permit the patenting of *things* and not *ideas*, so a permissible reading of *Myriad* leaves the isolated and purified exception alive for non-information-encoding natural products.<sup>143</sup> This is in spite of the contrary 2014 USPTO Guidance on this subject.<sup>144</sup> The desire to address pressing health problems through the discovery, isolation, purification, and commercialization of products of nature like Taxol should provide a compelling policy reason to read *Myriad* as permitting the patenting of non-information-encoding natural products.

One non-patent method to encourage research into natural products is to replicate the initial path of Taxol, with the government funding the research and development of the drug through Phase II clinical trials. Although this is possible, it would involve a massive expenditure of government resources, with a recent study pegging the R&D cost per drug at almost \$2.6 billion.<sup>145</sup> Considering that the budget of the National Institutes of Health ("NIH") was \$31.3 billion in 2016,<sup>146</sup> investigating even one natural drug per year would require a sizable budget increase. The FDA approves approximately forty-five new drug applications per year;<sup>147</sup> therefore, publicly funding R&D to the extent needed to maintain the current rate of development is not feasible from a political and budgetary perspective. Taxol should be seen

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143. For the purpose of this Note, "information-encoding" means that a molecule is capable of storing information which does not change the material's bulk properties, although the information changes the structure of the molecule. A book is a book, no matter what is written on its pages, and DNA is DNA, no matter the exact sequence of bases. Taxol, though, would not be Taxol without the correct bonding of atoms, and so can be properly classified as not information-encoding. Although the BRCA gene would not be the BRCA gene without the correct sequence (and *Jane Eyre* would likewise be different with a different arrangement of words), this is too narrow of a view of the information-encoding function of either books or genes. This is a pure line-drawing exercise and this level of generality for differentiation between similar goods is the intuitively correct and rational level.

144. See 2014 PTO Guidance, *supra* note 25, at 7 (analyzing Claim 1, which regards a hypothetical cancer-treating natural product that is purified from nature).

145. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26 (2016).

146. U.S. DEP'T OF HEALTH AND HUMAN SERV., HHS FY2016 BUDGET IN BRIEF (2016) <http://www.hhs.gov/about/budget/budget-in-brief/nih/index.html> [https://perma.cc/EEY9-CD9D].

147. David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs from 1981 to 2014*, 79 J. NAT. PRODS. 629, 632 fig.2 (2016).

as an outlier in this regard: an extraordinary case that will rarely, if ever, be repeated. The Taxol pathway for drug discovery and development is not the base upon which the country can build a drug pipeline.

A more likely (but incredibly risky) path is the one taken by Cubist Pharmaceuticals with its naturally occurring antibiotic Fidaxomicin.<sup>148</sup> Cubist obtained patents claiming “[a] polymorphic form of a compound of Formula I.”<sup>149</sup> Cubist relies on the only usable polymorph being its patented one, and this polymorph being sufficiently non-natural to pass examination.<sup>150</sup> FDA data exclusivity is insufficient protection if there is no patent protection,<sup>151</sup> so this is a risky strategy if another polymorph is discovered. The success of the few companies who take such risks in order to bring natural products to market shows that there is potential for drug development using this method, even given the current, uncertain patent landscape.<sup>152</sup>

The question thus becomes how society can incentivize more companies to look to the natural world for solutions to pressing health problems. Much has been written about the challenges of using a Western intellectual property regime allowing patents of natural products while permitting the use of traditional medicine of these natural products,<sup>153</sup> but the fact remains that patents provide a strong incentive to test and commercialize those traditional uses of natural products or to discover and develop new drugs from nature.<sup>154</sup> This leads to the heart of the issue: what does § 101 mean?

#### *A. The Meaning of 35 U.S.C. § 101*

The current judicial application of § 101 is based upon an understanding of the patent bargain.<sup>155</sup> This bargain is intensely fact-bound,<sup>156</sup> and so sweeping pronouncements about § 101 are hard to

148. Craig B. Whitman & Quinn A. Czosnowski, *Fidaxomicin for the Treatment of Clostridium difficile Infections*, 46 ANNALS PHARMACOTHERAPY 219, 220 (2012).

149. U.S. Patent No. 7,378,508.

150. See *supra* note 77 and accompanying text.

151. See *supra* Part I.

152. See, e.g., Arti K Rai & Jacob S Sherkow, *The Changing Life Science Patent Landscape*, 34 NATURE BIOTECHNOLOGY 292 (2016).

153. See, e.g., David R. Downes, *How Intellectual Property Could Be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253 (2000).

154. See Stephen R. Munzer & Kal Raustiala, *The Uneasy Case for Intellectual Property Rights in Traditional Knowledge*, 27 CARDOZO ARTS & ENT. L.J. 37, 73–74 (2009).

155. See *supra* Section II.B, discussing the Supreme Court’s view of the patent bargain in *Myriad*.

156. See Memorandum from Robert W. Bahr, Deputy Comm’r For Patent Examination Policy, to the Patent Examining Corps (May 4, 2016), <https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf> [<http://perma.cc/RUA2-8P28>] [hereinafter 2016 PTO Guidance].

come by. *Myriad* can be read to make such a sweeping ruling, but a more nuanced reading addressed in Section IV.B shows that it could be merely the restatement of the bargain tied to the facts of the case.

The text of § 101 provides an expansive slate upon which any number of meanings could be ascribed. All that is required is that “[w]hoever 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.”<sup>157</sup> A new mathematical formula could qualify for protection under the letter of the law,<sup>158</sup> as would Maxwell’s famous equations<sup>159</sup> and DNA, pre-*Myriad*. However, courts place restrictions upon this expansive grant in order to effectuate the classical patent bargain, “strick[ing] a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”<sup>160</sup> The problem with patenting mathematical formulas or laws of nature is not that they are inherently unpatentable, but that they are not worth granting the “embarrassment of an exclusive patent.”<sup>161</sup> But what makes them — and, by extension, natural products — not worth this benefit?

The difference between a mathematical process and a mechanical process is that the former is an idea and not the application of an idea. The fundamental difference between ideas and their physical manifestations has long been a concern of authors,<sup>162</sup> but the Supreme Court has also opined on this distinction.<sup>163</sup> The Court has held that granting a patent to an idea “risk[s] disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”<sup>164</sup> The owner of a patent on an idea can prevent all further developments in the relevant field because an idea, unlike a molecule or a machine, must be used in order to be improved upon. Granting a patent to an idea is too costly to innovation (or to society) to justify in the traditional patent bargain.

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157. 35 U.S.C. § 101 (2012).

158. *Cf.* *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

159. J. Clerk Maxwell, *A Dynamical Theory of the Electromagnetic Field*, 13 *PROC. OF THE ROYAL SOC’Y OF LONDON* 531 (1864).

160. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative Serv’s. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)).

161. Adam Mossof, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context*, 92 *CORNELL L. REV.* 953, 954 (2007).

162. *See, e.g.*, ALAN MOORE, *V FOR VENDETTA* 236 (2005) (“There’s no flesh or blood within this cloak to kill. There’s only an idea. Ideas are bulletproof.”).

163. *See, e.g.*, *Parker v. Flook*, 437 U.S. 584 (1978); *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014).

164. *Mayo*, 132 S. Ct. at 1294.

Sections IV.B and IV.C look at this distinction as it relates to the intersection of natural products and laws of nature in the two most important cases involving recent § 101 jurisprudence: *Myriad* and *Alice*.

### *B. The Multiple Readings of the Supreme Court's Myriad Logic*

There were several hoops the Court needed to jump through to come to the conclusion that naturally occurring DNA was not patentable. This analysis looks at the three major hoops: (1) framing the question in terms of similarities or differences, (2) whether the way the claims were written is determinative, and (3) whether the information-carrying nature of DNA changes the outcome of the § 101 analysis. This Note concludes that the Court shifted its § 101 analysis due to the information-encoding capacity of DNA, which suggests a nuance to the *Myriad* holding that preserves the traditional isolated and purified exception.

#### 1. Framing the Question: Similarities or Differences

The first step, a significant point of contention in the lower courts, was determining the frame of reference for the question of what is naturally occurring: should courts, as *Myriad* argued, begin their examination by determining the differences between the naturally occurring and claimed materials, or should courts, as AMP argued, look at the similarities in making the determination? The Court did not answer this directly. The only direct reference the Court made to this fundamental question was through a quote from Judge Bryson's dissent at the Federal Circuit, where he "then concluded that genetic 'structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive.'"<sup>165</sup>

The framing that the Supreme Court set up, that the similarities are so overwhelming that the structural differences are a mere pretense, is more akin to the obviousness analysis typically found in § 103 than the bright-line novelty rule of § 102, which would focus on the differences between the claim and what had come before. Using this framing, the Court's conclusion of the composition of matter claim was to hold that even though the isolated DNA was chemically

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165. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2115 (quoting *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (2012) (Bryson, J. concurring in part and dissenting in part)).



distinct from the chromosomal DNA, breaking the bonds on either side was insufficient to satisfy the marked differences test. The Court came to the conclusion, addressed *infra* Section IV.B.2, that Myriad's claims were not written to emphasize this difference. In light of the way the claims were written, emphasizing the similarities of the information encoded,<sup>166</sup> the Court found that the natural DNA and the claimed DNA were too similar and thus that the claim was impermissible.

In contrast to this reasoning, in analyzing the patentable cDNA, the Court relied much more on a bright-line, § 102-style standard for comparing cDNA to the natural DNA. The Court stated that cDNA is an:

[E]xons-only molecule that is not naturally occurring. Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived.<sup>167</sup>

This analysis could just as easily have been applied to the DNA: DNA retains the natural coding and non-coding regions from the chromosome from which it was extracted,<sup>168</sup> but it is just as chemically distinct from the chromosome as the cDNA is from the DNA.<sup>169</sup> The lab technician, in fact, has more of a say in the chemical makeup of the DNA, as he or she must decide which section to extract from the chromosome.<sup>170</sup> In contrast, cDNA is produced using naturally produced mRNA (which itself is naturally produced from DNA) as a starting template.<sup>171</sup> The laboratory technician simply uses a reverse

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166. *Id.* at 2118 ("Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.").

167. *Id.* at 2119 (citations omitted) (quoting Brief for Petitioners at 49, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 353961, at \*49).

168. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 184 (6th ed. 2014).

169. *See Ass'n for Molecular Pathology*, 133 S. Ct. at 2118.

170. *See Restriction Endonuclease Digestion of DNA*, in *DNA Protocols & Applications* QIAGEN, <https://www.qiagen.com/us/resources/molecular-biology-methods/dna/> [<https://perma.cc/P9BC-KV5A>].

171. *See* ALBERTS ET AL., *supra* note 168, at 470.

transcriptase to produce cDNA directly from the RNA template, wherein the only required decision is selecting the RNA template.<sup>172</sup> Thus, both DNA and cDNA have a single choice associated with their production: which section of DNA to select. Yet the Court treats these decisions differently.

Thus, the first question that the Court must contend with — whether it is the similarities that defeat § 101 eligibility for something close to a natural product, or the differences from the product in its natural state that save it — goes unanswered. This is important for the question of natural product drugs and the isolated and purified exception because if the similarities defeat eligibility, then the exception is certainly closed; the claimed products would be incredibly similar to the naturally occurring ones, save for the fact that they have been removed from their environment and purified. However, if the differences preserve eligibility, as the Court's cDNA discussion suggests,<sup>173</sup> then the isolated and purified exception can continue under the logic that the USPTO used for years. This logic holds that an isolated and purified natural product is not merely discovered; it is manufactured from the raw ingredients that nature provides, and it is a composition of matter that nature would never have made.<sup>174</sup> The question of whether it is the similarities or the differences from the natural product that are determinative was not squarely addressed, and as this Section has hopefully demonstrated, there are two contradictory, but supportable readings of *Myriad* on this issue.

The USPTO has taken the stance advocated by *Myriad*: in order to reject a claim under § 101 for reciting a product of nature, the examiner must show “why the product does not have markedly different characteristics from its naturally occurring counterpart in its natural state.”<sup>175</sup> This focus on the differences rather than the similarities is likely a pragmatic choice on the part of the USPTO: there are many things that are similar to natural products — like cDNA — that are nonetheless properly patentable. Therefore, focusing on the differences is the only way to avoid applying § 101 in an overly broad manner that would restrict the availability of patents and thus underincentivize research.

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172. *See id.*

173. *See Ass'n for Molecular Pathology*, 133 S. Ct. at 2119.

174. *Cf. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145 (2001) (holding that a hybrid plant was eligible as a “manufacture” and a “composition of matter”).

175. 2016 PTO Guidance, *supra* note 156, at 3.

## 2. Is the Method of Claiming Determinative?

As discussed *supra* Section IV.B.1, the Court looked at the language Myriad used to claim the DNA and how Myriad would ask for that language to be interpreted in determining that the claimed DNA was too similar to the natural DNA to allow patenting. The Court used claim 1 of the '282 patent as an example, which claims “[a]n isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.”<sup>176</sup> The Court noted that this was not the standard language for claiming a chemical composition and that the claim did not in any way rely on the changes that take place in the transformation of chromosomal DNA into the claimed DNA.

The Court is not necessarily correct in this statement, as there were prior examples of valid, issued claims relating to an isolated and purified natural product that read very similarly to Myriad’s claims. The most notable of these is claim 13 of Drs. Selman A. Waksman and Albert Schatz’s patent on the naturally occurring antibiotic Streptomycin, which simply claims “Streptomycin.”<sup>177</sup> The specification of Waksman and Schatz’s patent, analogous to Myriad’s, relays the fact that Streptomycin was isolated and purified, but the composition of matter claim simply lays out what the composition of matter is without relying on the changes from the natural state required to obtain the isolated and purified product.<sup>178</sup>

This conclusion — that a claim to a naturally derived composition of matter must claim and rely on the changes from the natural state in order to meet § 101 — could be read literally. This would forbid all isolated and purified claims, but it would also mandate a significant change in claim drafting style, as all compositions of matter are in some way derived from natural products.<sup>179</sup> There is no evidence of the USPTO mandating such a shift. It is logical, therefore, to conclude that the method of claiming was not determinative to the § 101 analysis but merely pointed to a deeper problem: what Myriad was trying to claim.

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176. U.S. Patent No. 5,747,282.

177. U.S. Patent No. 2,449,866.

178. In the Streptomycin patent, there were no chemical changes between the natural product and the isolated one. The patent merely relies on the discovery of the antibiotic and the manufacture of it in a purified form to meet the requirements of § 101.

179. Nicholas J. Landau, *The New Patent Policy on Natural Products Is a Game Changer for Universities and Life Sciences Companies*, BRADLEY (Sept. 26, 2014), <http://www.bradley.com/insights/publications/2014/09/the-new-patent-policy-on-natural-products-is-a-g> [<http://perma.cc/NNY8-VZAX>].

## 3. Did the Information-Carrying Nature of DNA Change the § 101 Determination?

In answering the first two questions, the Court continually hinted at the underlying facts of the case in making its determinations of law. It was not the chemical differences between the chromosomal DNA and the claimed DNA, but the similarities — namely, the information encoded — that rendered the claimed DNA unpatentable.<sup>180</sup> Likewise, although such simple claim language had been (and continues to be) commonplace, the Court relied on the fact that the claim language was not directed to the aforementioned differences. The Court finally revealed its motivation in deciding these two questions the way it did when it confronted, head-on, the question of whether the DNA's information-carrying nature rendered the DNA unpatentable.

The Court, in order to answer affirmatively, had to determine what was actually claimed in claim 1 as discussed *supra* Section IV.B.2. The Court imagined a hypothetical infringer and noted that the infringer could avoid the literal scope of the claim language by isolating and purifying the identified sequence plus an additional nucleotide. However, “Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule.”<sup>181</sup> This is the key to the Court's holding: despite the language of the claim and the differences in chemical composition from chromosomal DNA, the Court understands that Myriad is trying to monopolize the information of the BRCA gene against all who would make use of it, no matter in which physical form the information resides.<sup>182</sup> Thus, the Court reveals that the answer to this final question must be yes: the information-carrying nature of the claimed DNA influenced the Court to find a way to exclude it from patentability. The Court thus concludes its opinion: “[w]e merely hold that genes *and the information they encode* are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.”<sup>183</sup>

This inclusion, “and the information they encode,”<sup>184</sup> suggests the Court was not painting with as broad a brush as the USPTO interpreted. If this language was omitted from the holding, the Court's deci-

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180. See *supra* Section IV.B.1.

181. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2118 (2013) (emphasis in original).

182. Such as the hypothetical infringer who is working with a DNA strand containing the claimed sequence, but not limited to it.

183. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2120 (emphasis added).

184. *Id.*

sion could be much more easily read to shut the door on gene patents in particular and all isolated and purified natural products in general. However, the focus on information-carrying and the inclusion of this language suggest the Court's holding should be read more narrowly. Part V of this Note examines this reading further.

### C. *Alice* and the Refinement of § 101

Before making any conclusions regarding the scope of § 101, one additional case needs to be considered: *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*.<sup>185</sup> *Alice* is the only major Supreme Court case post-*Myriad* establishing the limits of subject matter eligibility. *Alice* dealt with the patentability of software, and it used a two-step process for determining subject matter eligibility, as established in *Mayo*.<sup>186</sup> First, a court must ask if the claims “are directed to a patent-ineligible concept.”<sup>187</sup> In *Alice*, the claims were directed toward the abstract idea of intermediated settlement, so they met this bar.<sup>188</sup> Next, the Court proceeded to ask if the claims “contain[] an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.”<sup>189</sup> The Court, referencing *Mayo*, held that a “claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’”<sup>190</sup> Importantly for the consideration of software, the Court further noted that, “*Mayo* made clear that transformation into a patent-eligible application requires more than simply stat[ing] the [abstract idea] while adding the words ‘apply it.’”<sup>191</sup> *Alice* Corporation's software patent, which merely recited the steps for an intermediated settlement and said, in effect, “do it on a computer,” failed the Supreme Court's test and was thus held ineligible for patent protection.

Although *Alice* dealt with software and is widely seen as “sound[ing] the death knell for software patents,”<sup>192</sup> its logic is also applicable to the problem the Supreme Court had over the information-carrying capacity of DNA in *Myriad*. Specifically, the application of the second step of the patentability test tells both the courts and

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185. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014).

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

187. *Alice*, 134 S. Ct. at 2355.

188. *Id.* at 2356.

189. *Id.* at 2357 (quoting *Ass'n for Molecular Pathology*, 132 S. Ct. at 1294, 1298).

190. *Id.* (alterations in original) (quoting *Ass'n for Molecular Pathology*, 132 S. Ct. at 1297).

191. *Id.* (alterations in original) (internal quotations omitted) (quoting *Mayo*, 132 S. Ct. at 1294).

192. *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1325 (Fed. Cir. 2016).

the USPTO to consider how the inventor transformed the information discovered into something new. This logic is the same logic that underpinned the isolated and purified exception. There was something unpatentable (the molecule in its natural state), and through the effort of the inventor, it was transformed into an isolated, pure manufacture. This composition of matter would never have existed in the natural world and could be sold under a patent monopoly without stifling the inquiries of other researchers into related areas.

#### *D. The Difference between Taxol and BRCA*

The *Alice* framework provides an axis upon which a court could split the otherwise parallel pathways of DNA and Taxol models of patentability. This split should be based upon the aforementioned information-carrying capacity of DNA that so perturbed the Court in *Myriad*. In so doing, courts would accomplish the policy goals of *Myriad* in preserving the traditional patent bargain while maintaining the needed incentive scheme for natural product drug discovery. Both the BRCA gene and Taxol patents fit within step one of *Alice* as they are directed towards products of nature. However, as alluded to earlier, *supra* Section IV.C, the second step of *Alice* gives different results for DNA and Taxol.

*Myriad*'s claims to the BRCA gene were directed primarily towards the information encoded in the gene and not towards the actual composition of matter.<sup>193</sup> The Court recognized this, stating that *Myriad*'s "claim is concerned primarily with the information contained in the genetic *sequence*, not with the specific chemical composition of a particular molecule."<sup>194</sup> The value in BRCA, and in all gene patents, is in the information encoded, not what the gene can do on its own. The claim fails to recite any additional features beyond the location of the information within the chromosomal DNA. Therefore, *Myriad*'s claims would have failed step two of the *Alice* test, and this result may be what the Court was working toward by focusing on the similarities between the chromosomal DNA and the claimed DNA instead of focusing on their differences.

This sits in stark contrast to other isolated and purified products of nature. There is no information encoded in Taxol, and the molecule is useful for what it does on its own. The isolation and purification of Taxol are what make it a useful composition of matter, and therefore the isolation and purification of it would constitute an additional fea-

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193. See *supra* Section IV.B.3.

194. Ass'n for Molecular Pathology v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2118 (2013) (emphasis in original).

ture as required by the second step of *Alice*. The new isolated and purified composition of matter is the product of both nature *and* human ingenuity, like so many other patentable inventions.<sup>195</sup> Furthermore, a patent on Taxol would not raise significant concerns with preempting scientific research into better cancer medication.<sup>196</sup> Thus, the bargain seems to work for Taxol: BMS gets market exclusivity on Taxol for a limited period of time, and society gets access to a new drug and the knowledge implicit in developing it.

#### V. A WAY FORWARD FOR NON-INFORMATION-ENCODING NATURAL PRODUCTS

At this point, one hopes the reader is convinced that there is still value in incentivizing the development of natural products and that the isolated and purified exception is the most effective way of doing so. The question thus becomes how to interpret the holding of *Myriad*, in light of the USPTO's understanding of it.<sup>197</sup>

As discussed in Part IV, there is a permissible reading of the holding of *Myriad* which states that the BRCA claims were invalid, not because they claimed an isolated and purified composition of matter, but because they claimed the *idea* behind the purified composition. If it was truly the composition of matter that was important to Myriad's claims, Myriad could obtain some value out of a narrowly tailored scope. The Court noted that this does not work with DNA — a narrowed scope of an idea to the point it would survive scrutiny provides no benefit to the patent holder.<sup>198</sup> This line of reasoning, although couched in the language the Court used in *Funk Brothers* for rejecting a claim as covering a product of nature, is much more easily (and far less sweepingly) expressed in the language of the abstract idea exclusion. Recognizing the valuable contribution the isolated and purified exception plays in incentivizing research into a very promising area of drug development, *Myriad* should be read with this more limited scope.

Therefore, the holding of *Myriad* should be read, in light of *Alice*, as follows: the nature of DNA is that it is an information-encoding mechanism, much like the bytes of memory in a computer. Absent

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195. See, e.g., *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

196. See, e.g., Stephen J. Clarke & Laurent P. Rivory, *Clinical Pharmacokinetics of Docetaxel*, 36 *CLINICAL PHARMACOKINETICS* 99 (2012) (describing Docetaxel, a close analog to Taxol). Cf. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1331 (Fed. Cir. 2012) *rev'd sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2118 (2013).

197. See 2014 PTO Guidance, *supra* note 25; 2016 PTO Guidance, *supra* note 156.

198. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2118.

significant human intervention, DNA is a product of nature. The isolation of DNA, although it severs the gene from the chromosome, does not fundamentally transform it into something different than DNA in its natural state, as the information contained within DNA is the key to DNA's usefulness and this information is not transformed upon isolation. Furthermore, granting a patent on DNA would rob the public of a great storehouse of knowledge and a vast field of potential research in exchange for a limited benefit. Therefore, claims that are directed towards the monopolization of the information encoded in DNA are outside of the scope of § 101, and the holding of the Federal Circuit that DNA is patentable is reversed.

Such an interpretation would provide for the survival of the isolated and purified exception because the isolation and purification of non-information-encoding molecules is a transformative function, as they are transformed from a minor component of a cell with limited to no efficacy in humans into a pharmaceutical with the potential to reshape lives. Such a transformation has been sufficient to satisfy the USPTO prior to *Myriad*,<sup>199</sup> and sound policy says that it should be sufficient if there is room under *Myriad*'s holding to accommodate it.

There are two pathways for interested parties to seek to clarify the *Myriad* holding in order to secure a patent on an isolated and purified natural product, and both require a significant expenditure of resources. The first is for the pharmaceutical industry to obtain the explicit blessing of Congress for the isolated and purified exception. The Court notes that this was sufficient in the case of patenting plants to overcome years of judicial interpretation of § 101.<sup>200</sup> However, given congressional realities, limited judicial capital, and other pressing IP issues,<sup>201</sup> this path may not be feasible. This Note nonetheless seeks to lay the foundational logic and policy arguments Congress should embrace if it seeks to re-emphasize the need for research into natural-product drugs.

The more feasible approach is for an interested party to bring a test case before the courts to argue for a clear, narrower reading of *Myriad* by the Federal Circuit. A convincing case could be made that an isolated and purified non-information-encoding small molecule does not fit under the *Myriad* holding and that the court should draw the line between true composition of matter claims, where protection for the molecule is beneficial to society, and ideas masquerading as

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199. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).

200. *Ass'n for Molecular Pathology*, 133 S. Ct. at 2118 (citing *J.E.M.*, 534 U.S. at 144–45).

201. *Legislative Solutions for Patent Reform*, ELEC. FRONTIER FOUND., <https://www.eff.org/issues/legislative-solutions-patent-reform> [https://perma.cc/A2BY-RXQR].



composition of matter claims, where such protection is not. This would be in line with the logic of *Alice*, where the Court struck down idea claims masquerading as process claims.<sup>202</sup> It would provide some assurance that the multi-year, multi-billion-dollar effort required to bring a natural drug to market would have some basis for protection under patent law. This approach has some notable downsides, such as a first mover problem (who would fund the search, development, and suit over such a test-case drug?), but it is, unfortunately, more probable than breaking through congressional intransigence. This Note hopes to serve as a good starting point for any test-case litigant to begin to craft a suitable litigation strategy.

This Note thus concludes with a plea to an enterprising lawyer: for the good of society, natural products such as Taxol should be afforded patent protection. Through legislation, litigation, or updated USPTO guidance, a small shift in the interpretation of *Myriad* could re-align the goals of the patent system in promoting an efficient trade of disclosure for monopoly without stifling further innovation in the pharmaceutical sector.

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202. See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2360 (2014).