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MYRIAD IN VIEW OF THE PREEXISTING PRODUCTS DOCTRINE: ADOPTING A STRUCTURAL APPROACH

INTRODUCTION

Modern advances in biotechnology have created analytical tension in the patent system, stretching the boundaries of the notion of patentability.[1] The conditions precedent to an invention's patentability can generally be categorized by four terms of the Patent Act of 1952: subject matter eligibility,[2] utility,[3] novelty,[4] and nonobviousness.[5] Due to the lack of statutory specificity relating to the definition of subject matter eligibility, uncertainty has developed about the patent eligibility of would-be inventions.[6] Contributing to this uncertainty, courts have recently attempted to use 35 U.S.C. § 101 as a mechanism for limiting the scope of available business method protection.[7] The murkiness of this statutory element has resulted in a conflation of its requirements with the issues of utility, novelty, and nonobviousness.[8] The

1. *See* Stephen H. Schilling, Note, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731, 732–33 (2011).

2. *See* 35 U.S.C. § 101 (2006) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."); *see also* Efthimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323, 326 (2010) ("A judicious analysis of patent jurisprudence reveals a two-step method for determining patent-eligible subject matter: an invention is patent-eligible if (1) it corresponds to a statutory category outlined in section 101 of the Patent Act, which includes processes, machines, manufactures, or compositions of matter, and (2) does not violate the product of nature doctrine, which precludes eligibility for laws of nature, natural phenomenon, mental processes, and abstract ideas." (footnote omitted)).

3. *See* Michael Risch, *A Surprisingly Useful Requirement*, 19 GEO. MASON L. REV. 57, 58 (2011) ("[T]he requirement that an invention be useful has been nearly nonexistent—essentially ignored. The level of 'utility' an applicant must currently demonstrate to obtain a patent is extremely low: the invention need only operate as described and potentially provide some de minimis public benefit." (footnote omitted)).

4. *See* 35 U.S.C. § 102.

5. *See id.* § 103.

6. *See* Parasidis, *supra* note 1, at 326.

7. *See, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218 (2010).

8. *See Patentable Subject Matter and the Supreme Court Myriad Preview*, PATENTLY-O BLOG (Aug. 3, 2011, 7:24 AM), http://www.patentlyo.com/patent/2011/08/patentable-subject-matter.html.

effects of this confusion on modern scientific progress can be seen in *Association for Molecular Pathology v. United States Patent and Trademark Office* (*Myriad I*) and its subsequent procedural history.[9]

Much has been said about the *Myriad* litigation, but confusion still exists. In 2009, a group of plaintiffs represented by the American Civil Liberties Union filed suit in federal court challenging the validity of patents held by Myriad Genetics over sequences of isolated DNA and cDNA and the methods of creating those same genetic compositions.[10] *Myriad I* was decided once at trial, affirmed in part and reversed in part on appeal by the Federal Circuit, vacated on certiorari, and again affirmed in part and reversed in part by the Federal Circuit for the same reasons as the initial Federal Circuit opinion.[11] In both Federal Circuit decisions, each judge on the three-member panel diverged as to the reason for his or her opinion. Additionally, the district court judge based his opinion on an entirely different rationale than any of the three Federal Circuit judges. The difference of opinion among the four judges underscores the confusion in patentability cases, particularly as applied in the biotechnology field. Each of the judges purported to base his or her conclusion on § 101, and each of the judges cited cases that consider the import of nineteenth-century Supreme Court precedent that articulates a rule for the patentability of purifications of preexisting products. This Note tracks the development of the purification doctrine, discusses its application to the *Myriad* litigation, and proposes an analytical approach to the doctrine that would create more predictable and consistent results in patentability cases.

The purified preexisting products doctrine was established by the Supreme Court in the nineteenth century.[12] At that time, the basic articulation of the doctrine could be conveyed as follows: a mere extraction of a pure composition from impure surroundings does not support a composition claim, but the method of extracting the pure composition from its impure surroundings could support a method claim.[13] This simple articulation of the rule was established as an offshoot of the product of nature doctrine, an important judicial rule defining a portion of § 101 subject matter eligibility.[14] The purified preexisting products doctrine does not, however, exclusively apply to extractions of products of nature. Instead, it can be applied to any

9. 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

10. *Id.* at 183–86.

11. *See infra* Part II.C–D.

12. *See* Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884); Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566 (1874).

13. *See Am. Wood-Paper*, 90 U.S. at 593–94.

14. *See* Parasidis, *supra* note 1, at 326.

known previously existing product, be it naturally occurring or man-made.[15] Over the course of time and likely in response to developments in sciences such as microbiology and pharmaceuticals, the purified preexisting products doctrine began to be applied differently by different courts.[16] Much of the confusion about the doctrine arose out of the Court's simple statement thereof. The rule statement leaves out crucial metrics for determining what qualifies as a mere extraction and what amounts to more than that. For purposes of this Note, this important distinction is framed as the difference between a mere extraction (unpatentable subject matter) and a new "kind" of composition (patentable subject matter).

This Note contends that the primary reason for confusion in the application of the doctrine is the lack of a defining characteristic that distinguishes products that are different in "kind" from one another. In view of its origins, the purification doctrine is clearly an offshoot of the product of nature doctrine, which is a subject matter eligibility issue. This Note presumes the position that the statutory elements of patentability ought to be considered separately from one another. Assuming this premise and considering the Supreme Court's articulation of the doctrine, the proposed standard for "kinds" of products is a discrete issue of subject matter eligibility. Accordingly, so as not to conflate subject matter eligibility with the other statutory elements, the standard ought to be free from considerations that overlap with statutory utility, novelty, or nonobviousness analyses. Instead, in keeping with the fundamental tenet of claim drafting, a composition's "kind" ought to be an exclusively structural determination. Ultimately, the relevant structural definition can be determined by the chemical boundaries of molecules and formula units, so that chemically distinct compositions comprise new materials in "kind" that are therefore eligible subject matter.

I. CASELAW DEFINING THE PURIFIED PREEXISTING PRODUCTS DOCTRINE

A. The Statutory Basis for the Purified Preexisting Products Doctrine

One threshold requirement of patentability is that an inventive conception be one that falls within statutorily eligible subject matter.[17] Patent examiners are instructed to first identify "what, precisely, the applicant has invented and is seeking to patent, and how the claims relate to and define that invention."[18]

15. *Compare Am. Wood-Paper*, 90 U.S. at 577, 596 (applying the doctrine to a pulp made by boiling naturally occurring wood in an alkali under pressure), *with Cochrane*, 111 U.S. at 311 (applying the doctrine to man-made, artificial alizarine).

16. *See infra* Part I.C–F.

17. 35 U.S.C. § 101 (2006).

18. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (8th ed. Rev. 8, July 2010) [hereinafter MPEP].

It is the claims that "define the property rights provided by a patent, and thus require careful scrutiny."[19] Before considering whether an inventive concept is patent-eligible subject matter, an examiner must conduct a thorough review of the prior art.[20]

Section 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."[21] In *Diamond v. Chakrabarty*, the Supreme Court recognized that Congress intended the expansive language of this statute to include "anything under the sun that is made by man."[22] According to the Court, the language of § 101, which has been carried over from the original Patent Act, authored by Thomas Jefferson in 1793, embodied the philosophy that "ingenuity should receive a liberal encouragement."[23] The Federal Circuit has likewise adopted a liberal interpretation of § 101:

> The use of the expansive term "any" in § 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in § 101 and the other parts of Title 35 . . . . Thus, it is improper to read into § 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.[24]

The plain language of 35 U.S.C. § 101 creates four categories of patentable subject matter: processes, machines, manufactures, and compositions of matter.[25] According to the *Manual of Patent Examining Procedure* ("*MPEP*"), "[t]he latter three categories define 'things' or 'products' while the first category defines 'actions.'"[26] Section 100(b) of Title 35 provides that "[t]he term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."[27] Thus, § 101 defines four discrete categories of patent-eligible subject matter.

Even though courts liberally construe § 101 so as to make it a minimal barrier to patentability, it does exclude certain concepts, namely those that are not machines, manufactures, compositions of matter, or processes.[28] "The subject matter courts have found to be outside of, or exceptions to, the four

19. *Id.*
20. *Id.*
21. 35 U.S.C. § 101.
22. 447 U.S. 303, 308–09 (1980).
23. *Id.* at 308.
24. *In re* Alappat, 33 F.3d 1526, 1542 (Fed. Cir. 1994), *abrogated on other grounds by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).
25. 35 U.S.C. § 101.
26. MPEP, *supra* note 18, § 2106.
27. 35 U.S.C. § 100(b).
28. MPEP, *supra* note 18, § 2106.

statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena."[29] "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."[30] These conceptions are "part of the storehouse of knowledge" and are "free to all men and reserved exclusively to none."[31]

Claims that include otherwise excluded subject matter might still be patentable if they are a "practical application" of the abstract idea, law of nature, or natural phenomenon.[32] For many years, the test for whether a claim was a "practical application" was the machine-or-transformation test.[33] Recently, in *Bilski v. Kappos*, the Supreme Court held that the machine-or-transformation test is not the exclusive test.[34] However, even under *Bilski*, the machine-or-transformation test offers insight into patentability,[35] and patent examiners are still instructed to assess whether a claim is directed to (1) a practical application of excluded subject matter by physical transformation, or (2) a practical application of excluded subject matter that produces useful, concrete, and tangible results.[36]

Accordingly, at the very least, one useful consideration for determining whether a patent claim that recites excluded subject matter is a "practical application" is whether it transforms or reduces an article to a different state or thing. The eligibility analysis varies based on the type of claim involved, i.e., whether the claimed invention is a method, composition, etcetera. Because the common law subject matter exclusions (abstract ideas, laws of nature, products of nature, and natural phenomena) are distinct categories, this analysis has varied depending upon which exclusion applies. In particular, a lengthy and windy jurisprudence has attempted to define products of nature.

B. Supreme Court Establishment of the Purification Doctrine

In 1874, the Supreme Court in *American Wood-Paper Co. v. Fibre Disintegrating Co.* considered the validity of a patent held by a paper

29. *Id.*

30. Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852).

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

32. *See* Diamond v. Diehr, 450 U.S. 175, 185, 187 (1981). A "practical application" of an abstract idea, law of nature, or natural phenomenon also can be referred to as a patentable process.

33. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) ("Under the Court of Appeals' formulation, an invention is a 'process' only if: '(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.'").

34. *Id.* at 3226.

35. *Id.* at 3227.

36. *See* MPEP, *supra* note 18, § 2106.

manufacturer on a pure form of cellulose pulp.[37] In its patent, the plaintiffs claimed "a pulp suitable for the manufacture of paper, made from wood or other vegetable substances, by boiling the wood or other vegetable substance in an alkali under pressure."[38] In a separate patent, the plaintiffs also claimed the process by which such a pulp was created.[39] When the patent was issued, paper manufacturers everywhere used wood- or vegetation-based cellulose pulps to make paper.[40] The plaintiff's only argument sustaining the validity of the product patent was that the pulp created "by boiling the wood or other vegetable substance in an alkali under pressure" was a purer form of cellulose than had ever before been used or created.[41]

The Court found that the patent over the pure form of paper pulp cellulose was invalid because it was a mere extract of a preexisting product.[42] Though a process for obtaining a purified extract of a preexisting material is patentable subject matter, the extract itself may not be.[43] For patents over products and chemical compounds to be valid, their "kind" must have been "unknown prior to their alleged invention."[44] Though not used by the Court, the term "kind" is chosen carefully because it is at this point in patentability analysis that issues get confused, and it is this precise term that needs definition for clarity to be restored. In *American Wood-Paper*, the product's "kind" was "a pulp suitable for the manufacture of paper, made from wood or other vegetable substances."[45] By defining the invention's "kind" as "a pulp suitable for the manufacture of paper," the Court seemed to focus on both the material properties of the product and the useful purpose of the product. In considering the utility of the product as relevant to whether it was substantially the same in "kind" as a preexisting product, the Court, whether intentionally or in haste, began what would become a long history of conflating structure and utility. The Court found that, because cellulose pulps were regularly used in the manufacture of paper at the time of the invention, a mere extraction of a purer form of such a product was not patentable subject matter.[46]

In a subsequent case, the Supreme Court affirmed and strengthened its general holding in *American Wood-Paper*. Eleven years after that decision, in *Cochrane v. Badische Anilin & Soda Fabrik*, the Court considered the validity

37. 90 U.S. (23 Wall.) 566, 593–94 (1874).
38. *Id.* at 577.
39. *Id.* at 580.
40. *See id.* at 567.
41. *Id.* at 577, 594.
42. *See Am. Wood-Paper*, 90 U.S. at 596.
43. *Id.* at 593–94.
44. *Id.* at 594.
45. *Id.*
46. *See id.* at 596.

of a patent claiming artificial alizarine produced by any method.[47] Alizarine is a natural product, contained in the root of a certain genus of tree, known to be useful as a dye.[48] The Court found that artificial alizarine was the same product in "kind" as naturally occurring alizarine because both products have the same chemical form ($C_{14}H_8O_4$).[49] The *Cochrane* holding extended the reach of the purified preexisting products doctrine beyond its origin in *American Wood-Paper* to man-made products. Furthermore, the Court seemed to show an analytical shift from defining two products as the same in "kind" based on their structural and utilitarian similarities to defining two products as the same in "kind" based on their structural similarities alone.[50] Around this time period and prior to significant development in micro-sciences, the Commissioner of Patents regularly denied patent applications for purified preexisting products.[51] However, the doctrine would only remain wholly intact for a short while longer.

C. Early Circuit Court Erosion of the Purification Doctrine

Shortly after the turn of the century, the purified preexisting products doctrine began to erode in the circuit courts, giving way to policy arguments premised on the promotion of scientific progress. In 1910, the Seventh Circuit considered *Kuehmsted v. Farbenfabriken of Elberfeld Co.*[52] There, the defendant had created an impure form of acetyl salicylic acid before the plaintiff had developed a manufacturing process for its pure form, Aspirin, for which the plaintiff obtained a patent.[53] The court upheld the plaintiff's patent despite the defendant's argument that the invention was not patentable subject matter because it was a mere purified form of a preexisting product.[54] The court found that, though the plaintiff's invention was a mere purification of the defendant's product from a structural standpoint, therapeutically, the two products had dispositive differences.[55] In so holding, the court effectively found that the two forms of acetyl salicylic acid were different in "kind"

47. 111 U.S. 293, 296 (1884).

48. *Id.* at 297.

49. *Id.* at 311.

50. This conclusion is based on the analytical process of the Court. Rather than noting that the two products served the same purpose, the Court solely highlighted the artificial alizarine's and the madder root alizarine's chemical identity. *See id.* at 311–12.

51. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 333 (2002); *see also Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 125–27 (holding that a purified pine needle fiber was not patentable).

52. 179 F. 701 (7th Cir. 1910).

53. *Id.* at 702–03.

54. *See id.* at 705.

55. *Id.*

because the two products had markedly different utility. The plaintiff's form of the product could pass through the stomach unaltered to be deconstructed in the intestines, where it could provide therapeutic value and minimize adverse results.[56] On the other hand, the defendant's product could not pass through the stomach without becoming unbounded, which proved to be injurious to many patients in a therapeutic setting.[57]

One year later, Judge Learned Hand, while sitting as judge for the Circuit Court of the Southern District of New York, issued an opinion adopting the Seventh Circuit's emphasis on utility as the dispositive factor in determining a product's "kind."[58] In *Parke-Davis & Co. v. H.K. Mulford Co.*, the validity of a patent on a purified form of adrenaline was challenged because it was said to be no more than a purification of preexisting adrenaline products.[59] Judge Hand upheld the validity of the patent on the new, purified product on the basis of its increased therapeutic value,[60] but he also pointed towards the structural differences between the purified adrenaline and the preexisting adrenaline.[61] In what appears to be a total shift from the doctrine of *American Wood-Paper* and *Cochrane*, Judge Hand found that the structural distinction between the newer form of purified adrenaline and the older impure form was sufficient to validate the newer form's patent.[62]

D. Early Strong Application of the Purification Doctrine

In 1928, the Third Circuit in *General Electric Co. v. De Forest Radio Co.* considered an infringement claim against a patent on pure tungsten.[63] As a naturally occurring material, tungsten always exists in oxide form (WO_3).[64] In this form it is highly brittle and of little value in electrical applications, but, in its pure form, tungsten becomes highly ductile and particularly valuable when used as wire in lighting systems.[65] Despite the fact that tungsten oxide and pure tungsten are two different materials and that only tungsten oxide exists in nature, the court found that exposing the naturally occurring tungsten oxide to heat treatment to create tungsten in pure form amounted to a mere discovery of

56. *Id.* at 704.

57. *Kuehmsted*, 179 F. at 704.

58. Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part and rev'd in part*, 196 F. 496 (2d Cir. 1912).

59. *See id.* at 97, 103.

60. *Id.* at 103.

61. *Id.* at 98.

62. *Id.*

63. 28 F.2d 641 (3d Cir. 1928). The relevant claim at issue read as follows: "Substantially pure tungsten having ductility and high tensile strength." *Id.* at 643.

64. *Id.* at 642.

65. *Id.*

pure tungsten.[66] Accordingly, the court found that tungsten was a product of nature and not patentable subject matter.[67]

Some commentators consider *General Electric* to follow from the *American Wood-Paper* and *Cochrane* progeny.[68] If that is the case, it represents a high-water mark for an application of the purified preexisting products doctrine focusing on the structural similarity of two products as dispositive of their sameness in "kind." However, since tungsten and tungsten oxide are actually two distinct materials with two distinct chemical structures,[69] pure tungsten is not really a purification of tungsten oxide. Instead, *General Electric* is better read as a strong application of the rule that products of nature are not patentable subject matter. The court essentially held that tungsten exists in nature, and, prior to this method of heat treatment, no one knew how to find it. The processes used in bringing out the pure tungsten are akin to a vast exploratory expedition into remote, largely inaccessible recesses of the earth which reveals new (in the sense of previously undiscovered) materials with rich utility.[70]

In the mid-to-late 1930s, the Court of Customs and Patent Appeals ("C.C.P.A.") issued holdings on a pair of cases that showed its continued support for the purified preexisting products doctrine. In *In re Ridgway*, the court considered an appeal from a patent examiner's rejection of a patent application for a pure form of alpha alumina.[71] Mirroring the language in *American Wood-Paper* and *Cochrane*, the court found that while the applicants "might be entitled to a patent on a method of purifying alpha alumina, they would not be entitled to a patent on the article alpha alumina, a natural product, merely because of the degree of purity of the article."[72] The court upheld the patent examiner's rationale that the rejection was "not necessarily based upon the fact that the applicants sought to get a patent on pure alpha alumina, but that they sought to get a patent on a nearly pure alpha alumina."[73] The court did not include in its analysis any discussion of the utility of the purer form of alpha alumina and focused on the structural similarity between the preexisting form and the form claimed in the patent application. However, the court seemed to suggest that if an altogether pure form of alpha alumina could be created, the structural differences would be significant enough to make that form of the product different in "kind" from preexisting forms of the product.

66. *See id.* at 643.

67. *Id.*

68. *See, e.g.*, Demaine & Fellmeth, *supra* note 51, at 339.

69. After all, no one would argue that O_2 (oxygen) is a mere purification of H_2O (water).

70. The C.C.P.A. also considered a similar case rejecting product claims over ductile uranium as unpatentable subject matter. *See In re* Marden, 47 F.2d 957 (C.C.P.A. 1931).

71. 76 F.2d 602, 602 (C.C.P.A. 1935).

72. *Id.* at 603.

73. *Id.*

A few years later, the same court cemented this analysis as a rigid exception to the purified preexisting products doctrine in the case of *In re Merz*.[74] Considering the patentability of purified ultramarine, a preexisting material used as a blue pigment,[75] the C.C.P.A. found that "while appellant may be entitled to a patent on a method for purifying an ultramarine either artificial or natural, he is not entitled to a patent on the article which after being produced has a greater degree of purity than the product produced by former methods."[76] However, the court also noted that this general rule has an exception: "The exception is that if the process produces an article of such purity that it differs not only in degree but in *kind* it may be patentable."[77] Building on the implication present in *Ridgway* that a totally pure version of a preexisting product may sustain a patent, the exception further focused the relevant "kind" on structural similarity, distancing the C.C.P.A. from the utility focus of the Seventh Circuit and Judge Hand.

E. Seventh Circuit's Strict Utility-Based Purification Doctrine

In 1939, the Seventh Circuit considered *Dennis v. Pitner*, where an alleged infringer of a patent over an insecticide challenged the validity of the patent based on the product of nature doctrine.[78] The inventor of the insecticide was really more of a discoverer of the product, in that the product itself was a mere extraction from the root of the South American cube plant.[79] However, the court did not shy away from the characterization of the product as a discovery and its inventor as a discoverer.[80] Instead, the Seventh Circuit embraced the notion that the patentee had discovered a natural product that could be of great benefit to mankind.[81] According to the court, the "discovery of a natural phenomenon, or of a quality or attribute of a well-known article, which discovery is of value to mankind, may be entitled to patent protection."[82] The court found the distinction between the discovery of previously unknown utility of a known product and the discovery of the utility of a novel combination of two known products that creates one new product to be untenable and irrelevant to patentability.[83] Instead, it focused on the language of the patent statute and the intentions of its drafters that its protections be

74. 97 F.2d 599 (C.C.P.A. 1938).
75. *Id.* at 600.
76. *Id.* at 601.
77. *Id.* (emphasis added).
78. 106 F.2d 142, 142–43 (7th Cir. 1939).
79. *Id.* at 143.
80. *See id.* at 144–46.
81. *Id.* at 146.
82. *Id.* at 144.
83. *See Dennis*, 106 F.2d at 144.

comprehensive.[84] The court concluded that "discovery in the field of science of a new quality or phenomenon of an old product may be . . . the proper subject of a patent."[85]

Dennis represented the high-water mark for a utility-focused analysis of the purified preexisting products doctrine. The court seemed to ignore all precedent in its interpretation of the doctrine. Nowhere in its analysis did the court even consider the structural similarity between the naturally occurring cube root and the insecticide. If applied as the law of the purified preexisting products doctrine, *Dennis* would stand for the proposition that an extraction of a preexisting product is different in "kind" from the preexisting product so long as the extraction contains some useful benefit to mankind not inherent in the preexisting product.

F. The Patent Act of 1952 and Its Effect on the Purified Preexisting Products Doctrine

In 1952, Congress passed a bill into law that overhauled the patent system. For purposes of patentability, §§ 101 and 102 of the Patent Act of 1952 substantially restated what had been the law since 1870.[86] Section 103 of the 1952 Act, however, established a new lexicon for the requirement of invention. Section 103 provides that an application is unpatentable when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[87] Thus the term "nonobvious" came to define or replace the older statutory term "invention." Rather than resolving the brewing circuit split in the purified preexisting products doctrine, the new statutory language created an opportunity for further dilution and confusion.

In the seminal case of *Merck & Co. v. Olin Mathieson Chemical Corp.*, the Fourth Circuit considered an appeal from a district court decision invalidating a patent on vitamin B-12 extracted from fermentation materials.[88] The product claims in the patent were narrowly tailored to cover only the vitamins extracted from the specified fermentates.[89] The Fourth Circuit sought to undermine the product of nature doctrine, noting "[t]here is nothing in the language of the Act

84. *Id.* at 145–46.

85. *Id.* at 146.

86. *Compare* 35 U.S.C. §§ 101–102 (1952), *with* 35 U.S.C. §§ 31–32 (1926). *See also* Eric Golas Salbert, *Duck, Duck,* Bilski*: Searching for a Law-Progress Equipoise*, 3 J. BUS. ENTREPRENEURSHIP & L. 339, 345 (2010) ("[A]lthough the current Patent Act of 1952 has been considered the second substantial revision, the provisions concerning patent-eligible subject matter appear to have undergone only minor changes." (footnote omitted)).

87. 35 U.S.C. § 103 (2006).

88. 253 F.2d 156, 157 (4th Cir. 1958).

89. *Id.* at 160.

which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability."[90] According to the court, since everything is really derived from a product of nature, no original thought should be excluded from patentability for that reason alone.[91] Instead, the court seemed to find that, on the basis of its omission in the new statutory language, the product of nature doctrine amounted to illusory fluff, devoid of any meaning or purpose. Any application of the product of nature doctrine in the past was really only a misnomer for one of the explicit statutory terms.[92]

However, the court did acknowledge the existence of the purified preexisting products jurisprudence, recognizing two ways in which patented compositions are not "new and useful compositions of matter" within the meaning of § 101 of the Act:

> (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."[93]

The court considered the doctrine as it was articulated in *American Wood-Paper*, *Cochrane*, *Ridgway*, and *Merz*, agreeing with the holding of each.[94] Despite its knowledge and acceptance of the structural interpretation of the doctrine, the court, citing *Kuehmsted*, concluded that just because "a new and useful product is the result of processes of extraction, concentration and purification of natural materials does not defeat its patentability."[95]

Ultimately, the court was persuaded by *Kuehmsted*'s utility distinction. However, rather than focus entirely on the therapeutic value of the extracted vitamin B-12, the court distinguished the patented product as a new "kind" of product on two utility-based grounds: "therapeutic and commercial worth."[96] According to the court, the inventor took the natural fermentates "from complete uselessness to great and perfected utility."[97] In its holding, the Fourth Circuit joined the Seventh Circuit and Judge Hand in a utility-based approach to distinguishing new products from the prior art, and further broadened the definition of utility from mere therapeutic value to include commercial value.

90. *Id.* at 161.

91. *See id.* at 161–62.

92. *See id.* at 162 ("To the extent that the 'product of nature' defense has validity, as urged here, it is a contention that the patented compositions are not 'new and useful compositions of matter' within the meaning of § 101 of the Act.").

93. *Merck*, 253 F.2d at 162.

94. *See id.* at 162–63.

95. *Id.* at 163.

96. *Id.* at 164.

97. *Id.*

In the 1970 case *In re Bergstrom*,[98] the C.C.P.A. relented and adopted a lax structural-based approach to purified products with the same effect, but a different form, as the utility-based approach used by the Fourth and Seventh Circuits. In the case, the C.C.P.A. considered an appeal from a decision of the United States Patent and Trademark Office ("USPTO") that rejected claims for purified forms of prostaglandins as patentable subject matter on the grounds that the claims lacked novelty.[99] The same prostaglandins claimed in the applicants' patent were present and naturally occurring in "human seminal fluid, human prostrate secretions, and secretions of the vesicular gland of sheep,"[100] but it was only after purification that it became possible "to utilize their pharmacodynamic effects without undesirable side effects or reactions."[101]

The C.C.P.A. took issue with the Patent Office Board of Appeals's position that a claimed pure material is not and cannot be novel with respect to less pure forms of the same material.[102] According to the court, "by definition, pure materials necessarily differ from *less* pure or impure materials and, if the latter are the only ones existing and available as a standard of reference . . . perforce the 'pure' materials are 'new' with respect to them."[103] Furthermore, the court found "whether the claimed pure materials have the same usefulness or assortment of properties as the impure materials of the prior art, as the board here found, is a question having no bearing on the factual and legal matter whether pure materials are new vis-à-vis impure materials within the meaning of § 101."[104] In so holding, the C.C.P.A. plainly placed the purified preexisting products doctrine within the statutory novelty requirement and expressly rejected a utility-based approach to defining a purified product as different in "kind" from the less pure form of the product. At the same time, the court distanced itself from the doctrine as it was presented in *American Wood-Paper* and *Cochrane*, finding that a mere extraction from "human seminal fluid, human prostrate secretions, and secretions of the vesicular gland of sheep" was different in "kind" from its source material.

In 1991, after the commencement of the human genome project, the first cases involving isolated and purified DNA patents were being considered by courts. In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, the defendants, who held a patent over a human protein, were being sued for use of that protein by the

98. 427 F.2d 1394 (C.C.P.A. 1970).

99. *Id.* at 1395.

100. *Id.*

101. *Id.* at 1396. "The material obtained was found to lower rabbit blood pressure." *Id.* at 1397.

102. *See Bergstrom*, 427 F.2d at 1401–02.

103. *Id.* (footnote omitted).

104. *Id.* at 1402.

holder of a patent over the purified and isolated DNA sequence capable of producing that same protein.[105] The defendants offered as their defense to the infringement suit a claim that the plaintiff's patent over the purified and isolated DNA was invalid.[106] However, it is not clear from the court's analysis whether *American Wood-Paper* or *Cochrane* were invoked by the defendants as grounds for the patent's invalidity. Though the court did recognize that neither the plaintiff nor the defendant "invented" the gene or the protein produced by the gene,[107] it found that the discovery of the isolated and purified DNA sequence, previously unknown, sustained a valid patent.[108] So, with little to no analysis, the Federal Circuit opened the door to a deluge of patent applications on isolated and purified DNA sequences, and as a direct result, in 1997, the USPTO issued a patent on isolated and purified DNA known as BRCA1.[109]

II. *MYRIAD* LITIGATION

A. Myriad*: Procedural Background*

On May 12, 2009, a group of plaintiffs, including physicians, patients, and various interested medical organizations, represented by the American Civil Liberties Union ("ACLU"), filed a complaint in the United States District Court for the Southern District of New York against the USPTO, Myriad Genetics ("Myriad"), and the Directors of the University of Utah Research Foundation.[110] The plaintiffs identified several specific BRCA1 and BRCA2 patent claims they believed constituted patents on natural human genes in violation of the product of nature doctrine.[111] Specifically, the plaintiffs identified claims 1, 2, 5, and 6 of patent 5,747,282 ("patent '282") and claim 1 of patent 5,837,492 ("patent '492").[112]

Patent '282 "relates to methods and materials used to isolate and detect a human breast and ovarian cancer predisposing gene (BRCA1)."[113] More

105. 927 F.2d 1200, 1203–04 (Fed. Cir. 1991).

106. *Id.* at 1204.

107. *Id.* at 1206.

108. *Id.* at 1206, 1219.

109. Demaine & Fellmeth, *supra* note 51, at 358–59.

110. Complaint at 1, 30, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) [hereinafter Complaint]. Note the plaintiff also makes First Amendment arguments to the effect that patenting a sequence of DNA that is innate in every or some person or persons violates such persons' freedom of speech. *Id.* at 19.

111. *Id.* at 20–21.

112. *Id.*

113. U.S. Patent No. 5,747,282, at [57] (filed June 7, 1995).

specifically, the invention relates to germline, somatic, and gene mutations in the BRCA1 gene and their use in the diagnosis of predisposition to breast, ovarian, and other cancers, as well as relating to various therapies for cancers that have a mutation in the BRCA1 gene.[114] Claims 1 and 2 relate to the isolated DNA coding of the BRCA1 gene's amino acid and nucleotide sequences respectively.[115] Claims 5 and 6 are dependent claims that relate back to claims 1 and 2 respectively and essentially require a minimum of fifteen nucleotides of each amino acid or nucleotide sequence[116] because that "number of nucleotides is usually about the minimal length required for a successful probe that would hybridize specifically with a BRCA1-encoding sequence."[117]

Patent '492 "relates to methods and materials used to isolate and detect a human breast cancer predisposing gene (BRCA2)."[118] Like patent '282, patent '492 specifically relates to germline, somatic, and gene mutations in the BRCA2 gene and their use in the diagnosis of predisposition to breast, ovarian, and other cancers, as well as relating to various therapies for cancers that have a mutation in the BRCA2 gene.[119] Claim 1 independently claims ownership of the invention of "[a]n isolated DNA molecule coding for a BRCA2 polypeptide."[120]

The plaintiffs also identified several BRCA1 and BRCA2 claims they thought failed as claiming nothing more than naturally occurring genetic mutations. The plaintiffs alleged that Myriad merely observed variants in BRCA1 and BRCA2 genes present in individuals and obtained patents on those naturally occurring mutations.[121] Specifically, the plaintiffs challenged the validity of claim 1 of patent 5,693,473 ("patent '473"), claim 7 of patent '282, and claims 6 and 7 of patent '492.[122]

Issued a few months before patent '282, patent '473 also deals with "methods and materials used to isolate and detect a human breast and ovarian

114. *Id.*

115. *Id.* at col. 153 ll. 55–61.

116. *Id.* at col. 153 ll. 66–67 to col. 154 ll. 55–56.

117. *Id.* at col. 20 ll. 38–40.

118. U.S. Patent No. 5,837,492, at [57] (filed Apr. 29, 1996).

119. *Id.*

120. *Id.* at col. 167 ll. 15–17. It is not clear why the plaintiffs did not follow parallel tracks when alleging the invalidity of the '282 claims relating to natural human genes and the '492 claims relating to natural human genes. Claims 1 and 2 of both the '282 patent and the '492 patent correspond to the same essential claims as they relate to BRCA1 and BRCA2 respectively. However, the plaintiffs challenged the validity of claims 1 and 2 of '282 while challenging only the validity of claim 1 of patent '492 on the same grounds. Likewise, the plaintiffs challenged claims 5 and 6 of patent '282 but did not challenge the virtually identical claim 5 of patent '492. The plaintiffs provide no reason for the patent '492 omissions in their complaint. *See* Complaint, *supra* note 110, at 30.

121. Complaint, *supra* note 110, at 21.

122. *Id.*

cancer predisposing gene (BRCA1)."[123] However, whereas '282 claims BRCA1 in its pure, non-mutated form, '473 is more limited in scope to specific alterations to the natural BRCA1 sequence. Claim 1 of '282 is the broadest independent claim, relating to all the alterations to the BRCA1 sequence described in a series of tables found in the detailed description.[124] Narrower independent and dependent claims not challenged by the plaintiffs also claim subsets of claim 1 that amount to human genes with natural mutations.[125]

Claims 7 of patent '282 and claims 6 and 7 of patent '492 also lay out specific genetic mutations to the BRCA1 and BRCA2 genes respectively. Claim 7 of '282 identifies and claims three instances of amino acid variance at specific nucleotide positions.[126] In claim 6 of '492, Myriad set out an independent claim to any mutated form of the BRCA2 gene that creates a susceptibility to cancer, and the dependent claim 7 narrows the scope of claim 6 to a particular mutation identified by a mutated nucleotide sequence set out in the patent.[127]

In support of its summary judgment argument that all of the composition claims at issue do, in fact, fall under the § 101 definition of composition of matter, Myriad relied on the development of the isolated and purified products doctrine.[128] Myriad contended that the plaintiffs' argument depended on a complete demolition of all of the caselaw in the isolated and purified products doctrine since *Parke-Davis* and *Bergstrom*.[129] Myriad also made a similar argument that the plaintiffs simply ignored the clear imposition of the USPTO's guidelines that affirmed the patentability of genetic inventions.[130] According to Myriad:

> The composition-of-matter claims—covering isolated *BRCA1/2* nucleic acids—are patent-eligible because they do not exist in pure form in nature. In

123. U.S. Patent No. 5,693,473, at [57] (filed June 7, 1995).

124. *See id.* at col. 159 ll. 57–62.

125. *Id.* at col. 159 ll. 63–67, col. 160 ll. 57–58, col. 162 ll. 1–16.

126. U.S. Patent No. 5,747,282 col. 154 ll. 57–67 (filed June 7, 1995) ("(a) [A] DNA having the nucleotide sequence set forth in SEQ ID NO:1 having T at nucleotide position 4056; (b) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having an extra C at nucleotide position 5385; (c) a DNA having the nucleotide sequence set forth in SEQ ID NO: 1 having G at nucleotide position 5443; and, (d) a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having 11 base pairs at nucleotide positions 189–199 deleted.").

127. U.S. Patent No. 5,837,492 col. 167 ll. 30–36 (filed Apr. 29, 1996).

128. *See* Myriad Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Opposition to Plaintiffs' Motion for Summary Judgment at 3, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (No. 09 Civ. 4515), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) [hereinafter Defendants' Memorandum of Law].

129. *Id.* at 3–4.

130. *Id.* at 4.

> addition, they differ in kind from native (naturally occurring) *BRCA1/2* genes. Specifically, the claimed isolated nucleic acids have new properties and functions not found in the native genes, resulting in "ample practical differences" from the native genes.[131]

In its brief analysis, it further argued that "isolated DNA molecules are distinct from any substance found in the human body—indeed, in all of nature."[132] This is because "[i]solated DNA acquires new properties not shared by its native (naturally occurring) counterpart," and "[t]hese new properties impart isolated DNA molecules with new characteristics and new utilities."[133] These isolated DNA molecules can be used in ways that are not possible for native DNA; they can be used as a probe "to target and bind to a particular portion of DNA" or as primers "to bind to (or 'hybridize' with) a DNA target."[134]

B. Myriad*: Scientific Background*

Some discussion of the pertinent science of molecular biology is in order. For the purposes of this Note, the trial court's discussion of the subject, which is largely consistent with the appellate court's explanations of genetics, will provide the basis for the overview. The court began its discussion with Gregor Mendel and his first recognition of the notion of genetic material.[135] Though Mendel recognized the notion of genetics in the nineteenth century, it was not until 1944 that scientists discovered that the carrier for genetic material was deoxyribonucleic acid ("DNA").[136] The double-helix structure was identified by James Watson and Francis Crick, and Crick later proposed three assertions that make up "the central dogma" of genetic science: "(1) information is encoded in a segment of DNA, i.e., a gene; (2) transmitted through a molecule called RNA; and then (3) utilized to direct the creation of a protein, the building block of the body."[137] The court noted that since the work of Watson and Crick, "understanding of the DNA contained within our cells has since grown at an exponential rate and has included the landmark completion of the first full-length sequence of a human genome, containing 25,000 genes, as a

131. *Id.*

132. *Id.* at 7.

133. Defendants' Memorandum of Law, *supra* note 128, at 8.

134. *Id.*

135. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad I), 702 F. Supp. 2d 181, 192 (S.D.N.Y. 2010), *rev'd in part and aff'd in part*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).

136. *Id.* at 192–93. The process by which scientists recognized that DNA was the carrier for genetic material involved transferring DNA extracted from one strain of bacteria to another and recognizing the attribution of genetic characteristics of the first strain in the second. *Id.* at 193.

137. *Id.* at 193.

result of the work performed by the Human Genome Project from 1990 to 2003."[138]

The court then turned its discussion away from the development of modern genetic science to the current state of the field.[139] "DNA is a chemical molecule composed of repeating chemical units known as 'nucleotides,'" which are either adenine ("A"), thymine ("T"), cytosine ("C"), or guanine ("G").[140] "DNA typically exists as a 'double helix' consisting of two intertwined strands of DNA that are chemically bound to each other."[141] The double helix structure occurs because of "base pairing," where A on one side of the double helix binds to T on the other side of the double helix, and in the same manner G on one side of the double helix binds to C on the opposing side.[142] Each of these base pairs is known as a nucleotide, and the terms "genetic sequence," "nucleotide sequence," or "DNA sequence" all refer to linear arrangements of these nucleotides.[143] Noticeably distinguishable, a gene is "composed of several, typically contiguous, segments of DNA."[144] Genes contain "the information used by the body to produce . . . proteins."[145] They are further comprised of both exons, the segments of the DNA sequences necessary for the creation of a protein, and introns, segments of DNA not required to create a protein.[146] "DNA encodes proteins by way of three nucleotide combinations, termed 'codons,' that correspond to one of twenty amino acids that constitute the building blocks of proteins."[147] The human body contains roughly 25,000 genes which comprise the human genome,[148] and the series of nucleotide sequences within the human genome and the order of the nucleotides within each sequence are entirely naturally occurring.[149]

138. *Id.*

139. *See id.* According to the court, its characterization of the field "represents the standard undisputed knowledge of those in the field of molecular biology." *Id.*

140. *Myriad I*, 702 F. Supp. 2d at 193.

141. *Id.* at 193–94 (footnote omitted). A helix is a shape that essentially takes the form of the red ribbon on an old-fashioned, white and red barber's pole. A double helix takes the shape and orientation of the corresponding white ribbon of a barber's pole.

142. *Id.* at 194.

143. *Id.*

144. *Id.*

145. *Myriad I*, 702 F. Supp. 2d at 194. The genetic production of proteins is known as encoding. *Id.*

146. *Id.*

147. *Id.* Since "there are only twenty different amino acids but 64 possible codons that can be derived from combinations of the four DNA nucleotides, most amino acids are encoded by more than one DNA codon." *Id.*

148. *Id.*

149. *Id.*

Molecular biologists refer to the normal sequence of a human gene as the gene's "wild-type."[150] Variations from the "wild-type" genes are called mutations, which can take the form of single misplaced nucleotides or misplaced gene sequences hundreds of nucleotides long.[151] Some of these mutations correlate with known effects on the human body in the form of particular diseases.[152]

DNA "is not typically found floating freely in cells of the body, but is packaged into chromosomes."[153] Chromosomes are made up of chromatin, a mixture of genomic DNA that is bound to proteins.[154] From this chromosomal environment, DNA can be extracted, and from the extracted DNA, a particular segment of the DNA, the "purified DNA," can be excised.[155] Purified DNA and synthesized DNA, the DNA that has been created in a laboratory, can be used as a "probe," "a diagnostic tool that a molecular biologist uses to target and bind to a particular segment of DNA, thus allowing the target DNA sequence to be detectable using standard laboratory machinery."[156] Likewise, DNA that has been purified or synthesized may function as a "primer" "to sequence a target DNA, a process used by molecular biologists to determine the order of nucleotides in a DNA molecule, or to perform polymerase chain reaction ('PCR') amplification, a process which utilizes target-DNA specific primers to duplicate the quantity of target DNA exponentially."[157] These probes or primers bind with corresponding nucleotide sequences in the target DNA, if such a nucleotide sequence exists therein.[158] Because of these phenomena in molecular biology, the purified BRCA sequences derive their utility from their ability to bind with the native BRCA sequences should they exist within the native DNA.[159]

RNA, like DNA, "is composed of a combination of four different nucleotides, three of which are the same bases incorporated into DNA."[160] However, instead of T, RNA comprises uracil ("U") as a fourth nucleotide.[161] RNA forms the basic messenger material through which the processes of "transcription" and "translation" can form the protein that corresponds with the

150. *Myriad I*, 702 F. Supp. 2d at 195.
151. *Id.*
152. *Id.*
153. *Id.* at 196.
154. *Id.* at 195.
155. *Myriad I*, 702 F. Supp. 2d at 196.
156. *Id.* at 196–97.
157. *Id.* at 197.
158. *Id.*
159. *Id.*
160. *Myriad I*, 702 F. Supp. 2d at 197.
161. *Id.*

exons in the DNA.[162] During transcription, RNA forms a temporary copy of a DNA sequence.[163] This temporary copy is called a "pre-messenger RNA" or "pre-mRNA".[164] "In a process known as 'splicing,' the introns are physically cut out of the pre-mRNA by the cell and the remaining RNA segments containing the exons are rejoined, or 'ligated,' together in consecutive order to form the final 'messenger RNA,' or 'mRNA.'"[165] During translation, the mRNA sequence is used "as a template for the assembly of a protein."[166]

Complementary DNA ("cDNA") "is typically generated by scientists in a laboratory."[167] It is "generated from mRNA during a process known as 'reverse transcription,'" and takes the form of the bases corresponding to those in the mRNA, which is also the same form as the protein coding sequences encoded by the original DNA (without introns).[168] cDNAs do occur in nature in the form of pseudogenes.[169] All cDNA, whether it is synthetically created or a naturally occurring pseudogene, has distinct differences from native DNA.[170] Because the cDNA is formed out of RNA that had already gone through the transcription process, it lacks the introns present in native DNA and therefore does not have to go through RNA splicing to produce proteins.[171] Furthermore, cDNA may be unable to produce proteins without regulatory sequences and

162. *See id.* ("During transcription, a discrete segment of DNA unwinds itself inside the cell and the bases of the DNA molecule act as 'clamps' that hold the bases of the newly forming RNA molecule in place while the chemical bonds of its sugar-phosphate backbone are formed. Each nucleotide in the DNA strand corresponds to a nucleotide to be incorporated into the newly forming RNA molecule: adenine on the DNA molecule binds to and thereby acts as a clamp for RNA nucleotide uracil, thymine for adenine, guanine for cytosine, and cytosine for guanine."(citation omitted)).

163. *Id.*

164. *Id.*

165. *Myriad I*, 702 F. Supp. 2d at 197–98. "Pre-mRNAs can also undergo a process known as 'alternative splicing,' in which different combinations of exons from the same pre-mRNA molecule are ligated together to yield different final mRNA products." *Id.* at 198.

166. *Id.* at 198 ("In a process that parallels the transcription of DNA, the mRNA bases, along with other proteins in the cell, serve as clamps to hold the corresponding amino acids in place while the chemical bonds between the individual amino acids are formed. The three-nucleotide codons originally found in DNA and copied into mRNA determine which amino acids are incorporated into the protein and the order in which they are incorporated." (citation omitted)).

167. *Id.*

168. *See id.* ("During reverse transcription, each base of the mRNA serves as a clamp for its complementary nucleotide to be incorporated into the new cDNA molecule while the chemical bonds between the nucleotides of the cDNA strand are formed. Much like transcription, uracil on the mRNA binds to and thereby acts as a clamp for the nucleotide adenine, adenine for thymine, guanine for cytosine, and cytosine for guanine. The synthesis of cDNA from very long mRNA molecules, such as *BRCA1* and *BRCA2*, often does not result in a cDNA strand that is as long as the mRNA chain." (citations omitted)).

169. *Id.*

170. *Myriad I*, 702 F. Supp. 2d at 198.

171. *Id.* at 198–99.

may have additional nucleotide sequences not present in the corresponding native DNA that formed as a result of the additional "'poly A tail' sequence found in mRNA."[172] Likewise, cDNA is also more stable than mRNA and "requires both transcription and translation to produce protein, rather than simply translation, as is the case with mRNA."[173] cDNA can be used the same way as isolated DNA (as a probe or primer), or cDNA can be used to learn more about a protein.[174]

C. Myriad I*: Southern District of New York Decision*

After considering the opposing sides' arguments, the trial court described the validity of the composition claims issue as "whether or not claims directed to isolated DNA containing naturally-occurring sequences fall within the products of nature exception to § 101."[175] The court identified several cases that it included in its product of nature discussion that have not yet been broached in this paper.[176] These cases, which include *American Fruit Growers, Inc. v. Brogdex Co.*,[177] *Funk Brothers Seed Co. v. Kalo Inoculant Co.*,[178] and *Diamond v. Chakrabarty*,[179] established the product of nature doctrine generally.[180] Although the court used these cases distinctly from the purification cases and thereby established the invalidity of the composition claims,[181] it is worth briefly discussing the way in which these cases formed the structure of the court's explanation of the product of nature doctrine. According to the court, *American Fruit Growers* stood for the proposition that a product fails to satisfy the § 101 subject matter eligibility requirements "unless it 'possesses a new or distinctive form, quality, or property' compared to the naturally-occurring article" from which it is derived.[182] To the extent that the court discussed *American Fruit Growers*, *Funk Brothers*, and *Chakrabarty* as a separate and distinct basis for concluding that the composition claims were invalid, they will not be discussed here. Instead, attention will be paid to the bulk of the court's analysis involving the purification doctrine.

172. *Id.* at 199.

173. *Id.*

174. *See id.* ("[A] scientist seeking to learn more about a protein of interest may transfer a cDNA encoding the protein into a recipient cell that does not normally express that protein. If the cDNA is operatively linked to particular 'promoter' sequences that initiate transcription from the cDNA, the recipient cell will then express the protein of interest.").

175. *Myriad I*, 702 F. Supp. 2d at 220.

176. *See id.* at 222–23.

177. 283 U.S. 1 (1931).

178. 333 U.S. 127 (1948).

179. 447 U.S. 303 (1980).

180. *See Myriad I*, 702 F. Supp. 2d at 222–23.

181. *See id.* at 232.

182. *Id.* at 222 (quoting *American Fruit Growers*, 283 U.S. at 11).

In laying out the doctrine, the court looked to *American Wood-Paper* and *Cochrane*.[183] Likewise, the court found that *General Electric*, *In re Marden*, and *Ex Parte Latimer* were pertinent.[184] In recounting each of these cases, the court concluded that earlier courts had all held that the purifications of the preexisting products discussed therein were not subject matter eligible under § 101 because they violated the product of nature doctrine.[185]

The court also considered cases proffered by Myriad, including *In re Bergstrom*, which the court dismissed for not having been decided by the Supreme Court,[186] and *In re Kratz*.[187] According to the court, both of these cases "presented issues of novelty and anticipation rather than the question of patentable subject matter."[188] It found that the *Bergstrom* court "in effect treated the rejection as if it had been made under § 102, observing in the process that '[t]he word "new" in § 101 is defined and to be construed in accordance with the provisions of § 102.'"[189] Likewise, the court found that, although the *Kratz* court discussed whether the composition was a naturally-occurring compound, "the court treated the appeal as a question of novelty and anticipation pursuant to § 102."[190]

However, the court gave stronger consideration and spent more effort in its analysis of Myriad's use of *Parke-Davis*. According to the district court, the "question before the court in *Parke-Davis* was one of novelty (a modern-day § 102 question), not of patentable subject matter (the § 101 question before this Court)."[191] Likewise, the court found that it was "[o]nly after concluding that the claimed purified adrenaline was novel over the prior art" that Judge Hand "offer[ed], as dicta, the statement to which Myriad cites: '[b]ut, even if it were merely an extracted product without change, there is no rule that such products are not patentable.'"[192] The court concluded that "the accuracy of this statement at the time was written [sic] is dubious in light of *American Wood-Paper* (to which Judge Hand did not cite)," and "it is certainly no longer good law in light of subsequent Supreme Court cases."[193] Likewise, "Judge Hand's suggestion that a claimed invention was patentable since it was a 'new thing commercially and therapeutically,'" is at odds with subsequent caselaw

183. *See id.* at 223–24.
184. *See id.* at 224.
185. *See Myriad I*, 702 F. Supp. 2d at 223–24.
186. *Id.* at 224.
187. *Id.* at 226–27.
188. *Id.* at 226.
189. *Id.*
190. *Myriad I*, 702 F. Supp. 2d at 227.
191. *Id.* at 225.
192. *Id.* (quoting Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd in part and rev'd in part*, 196 F. 496 (2d Cir. 1912)).
193. *Id.* at 226.

"establishing that 'it is improper to consider whether a claimed element or step in a process is novel or nonobvious, since such considerations are separate requirements' when evaluating whether a claim is patent-eligible subject matter."[194]

Finally, the court considered and dismissed Myriad's arguments premised on *Merck*. The court found the holding in *Merck* to be entirely consistent with the cases it relied upon in this case.[195] Because the purified substance there "was more than a 'mere advance in the degree of purity of a known product,"' the Southern District concluded that the *Merck* court must have found that the product there was markedly different from any product already in existence.[196] Accordingly, after considering all of these cases in the lineage of the purification doctrine, the court concluded that "purification of a product of nature, without more, cannot transform it into a patentable subject matter"; instead, "the purified product must possess 'markedly different characteristics' in order to satisfy the requirements of § 101."[197]

It is worth briefly noting some differences between the court's interpretations of the purified preexisting products jurisprudence and the discussion of those same cases here. The trial court was cautious to portray *Parke-Davis* as holding on § 102 novelty, quickly dismissing the therapeutic and commercial value tests.[198] Noting a clear line between § 101 subject matter eligibility and § 102 novelty issues, the court was able to easily distinguish these cases from *Myriad I*. However, as discussed earlier, *Parke-Davis* is really best read as standing for the proposition that two products, one preexisting and the other a purification of the former, are different in "kind" when having substantially different commercial or therapeutic value.[199] The rationale behind the court's choice to focus on the delineation between subject matter eligibility and novelty as opposed to subject matter eligibility and utility presents itself in its analysis of the composition claims in *Myriad I*.

At the outset of its application of the purified preexisting products doctrine to the composition claims, the court criticized Myriad's argument that focused solely on the structural differences in the native and isolated DNA.[200] Referring to the useful property of DNA as an information carrying composition, the court noted that "Myriad's focus on the chemical nature of DNA, however, fails to acknowledge the unique characteristics of DNA that

194. *Id.* (quoting Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1343 (Fed. Cir. 2009), *vacated*, 130 S. Ct. 3543 (2010)).

195. *See Myriad I*, 702 F. Supp. 2d at 227.

196. *See id.*

197. *Id.*

198. *See supra* notes 191–94 and accompanying text.

199. *See supra* notes 58–62 and accompanying text.

200. *Myriad I*, 702 F. Supp. 2d at 228.

differentiate it from other chemical compounds."[201] The court found that the structural differences between native and isolated DNA were unimportant to determining whether the two substances are markedly different; instead, the court focused on the "utility associated with DNA in its isolated form" as the "defining characteristic."[202]

The court did, however, acknowledge the structural differences between Myriad's composition claims and native DNA, recognizing that native DNA is diluted with chromosomal proteins not present in the isolated DNA and that inside native DNA is found introns also nonexistent in the isolated form.[203] Likewise, the court conceded the fact that isolated DNA attained certain functional differences from native DNA, particularly its utility as a probe or primer or sequencing target.[204] However, the court found all of these differences to be secondary because the purification of native DNA does not alter its nucleotide sequence.[205] Instead, to the court, the marked element distinguishing the two compositions was their utility as information carriers, and, since the two compositions carry the same basic chemical information, Myriad failed to "establish the existence of differences 'in kind' between native and isolated DNA that would establish the subject matter patentability of what is otherwise a product of nature."[206]

D. Myriad II *and* Myriad III*: Federal Circuit's Decisions*

Upon review of the district court decision, a split Federal Circuit opinion written by Judge Lourie came to a different conclusion.[207] Unlike the lower court, the Federal Circuit characterized the distinction between a product of nature and an invention of patentable subject matter as turning on "a change in the claimed composition's identity compared with what exists in nature."[208] Discussing the facts of the *Myriad* litigation in light of this standard, the court noted "[i]t is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body."[209] According to the court, "*BRCA1* and *BRCA2* in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native

201. *Id.*
202. *Id.* at 229.
203. *See id.* at 229–30.
204. *See id.* at 230.
205. *See Myriad I*, 702 F. Supp. 2d at 231–32.
206. *Id.* at 232.
207. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad II), 653 F.3d 1329 (Fed. Cir. 2011), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012).
208. *Id.* at 1351.
209. *Id.*

chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA."[210]

The court next sought to address the distinct structural identity of isolated DNA in purification terms:

> [I]solated DNA is not purified DNA. Purification makes pure what was the same material, but was previously impure. Although isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body.[211]

The court went on to explain that "a covalent bond is the defining boundary between one molecule and another," and the differences in these chemical bonds between native and isolated DNA "separate one chemical species from another."[212] In analysis that should prove helpful to determining the boundaries of the purification doctrine, the court distinguished between chemical alteration and physical alteration.[213] Accordingly, the court concluded that the purification doctrine does not necessarily preclude isolated DNA from being patentable subject matter, and distanced itself from the rationale of the district court, noting the genes' "informational content is irrelevant to that fact."[214] In so doing, the court, although refusing to adopt the purification jurisprudence as its basis, effectively returned to a strong structural approach to the purification doctrine. Moreover, the court sought to remove any consideration of utility from subject matter eligibility analysis and focused strictly on the structural properties of the claimed composition.

Judge Moore reached the same conclusion but differed slightly from the majority in her approach. According to Judge Moore, the chemical difference between native and isolated DNA does not alone make the native DNA so markedly different to place the isolated DNA within the realm of subject matter eligibility.[215] Instead, Judge Moore looked to *Funk Brothers* to support the assertion that "an invention which 'serve[s] the ends nature originally provided' is likely unpatentable subject matter, but an invention that is an 'enlargement of the range of . . . utility' as compared to nature may be patentable."[216] Accordingly, Judge Moore engaged in the analytical effort of

210. *Id.* at 1352.

211. *Id.*

212. *Myriad II*, 653 F.3d at 1352–53.

213. *Id.* at 1354.

214. *Id.* at 1353.

215. *Id.* at 1359 (Moore, J., concurring).

216. *Id.* at 1359–60 (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948)).

ferreting out a "new utility which makes the molecules markedly different from nature."[217]

Judge Moore, unlike the district court, found sufficient new utility to place the isolated DNA within eligible subject matter, noting the "ability to use isolated DNA molecules as the basis for diagnostic genetic testing is clearly an 'enlargement of the range of . . . utility' as compared to nature."[218] However, on this point, the concurring opinion distinguished between claims over two classes of isolated DNA: the first, short strands used as primers, and the second, longer strands not used as primers.[219] Because the shorter strands of native DNA could easily be used as a primer and the same nucleotide sequence in native form could not, Judge Moore found that claims covering those shorter strands could easily be reconciled with the utility requirement she had articulated earlier.[220] "Longer strands of isolated DNA, in particular isolated strands which include most or all of the entire gene, are a much closer case."[221] Actually, Judge Moore was unable to identify any purely utility-based benefits of longer strands of isolated DNA sufficient to show an "enlargement of the range of . . . utility," and, instead, she relied on more pragmatic reasons to uphold the claims' validity.[222] Judge Moore pointed to the USPTO's history of allowing claims on purified natural products and isolated DNA, and she concluded that, as a matter of judicial restraint, the court ought not to overturn such precedent and create uncertainty in scientific communities.[223]

In the dissenting opinion, Judge Bryson advocated for a subject matter eligibility standard that considers both structural differences and differences in utility.[224] While acknowledging the presence of certain chemical differences between native and isolated DNA, Bryson refused to concede that those minimal differences are sufficient to make the isolated DNA a materially different composition.[225] According to Bryson, the "only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are found in nature."[226] Though Bryson recognized that the two forms have

217. *Myriad II*, 653 F.3d at 1365 (Moore, J., concurring).

218. *Id.*

219. *Id.* at 1364–65.

220. *Id.* at 1365.

221. *Id.* at 1366.

222. *Myriad II*, 653 F.3d at 1366–67 (Moore, J., concurring).

223. *Id.* at 1367.

224. *See id.* at 1378 (Bryson, J., dissenting) ("In sum, the test employed by the Supreme Court in *Chakrabarty* requires us to focus on two things: (1) the similarity in structure between what is claimed and what is found in nature and (2) the similarity in utility between what is claimed and what is found in nature.").

225. *Id.* at 1375.

226. *Id.*

chemically different structures due to separation of previous covalent bonds, he concluded "there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken."[227] In fact, Judge Bryson implied that only a matter of degree distinguishes separating a molecule from a larger chemical structure and separating a leaf from a tree.[228]

Since the chemical distinction alone does not make the isolated DNA subject matter eligible, Judge Bryson then turned his attention to the second prong of his proffered test for subject matter eligibility: utility. Like the district court, Bryson focused on DNA's informational properties as the primary point of utility.[229] According to Bryson, the isolated DNA, when compared to the native DNA, "retains the character and function of the product as found in nature" and "does not result in the creation of a human invention."[230] Supporting his utility-focused analysis with cases such as *Parke-Davis*, the judge concluded that "[w]hat is claimed in the BRCA genes is the genetic coding material, and that material is the same, structurally and functionally, in both the native gene and the isolated form of the gene."[231]

However, shortly after the Federal Circuit decided *Myriad II* on subject matter eligibility grounds, the Supreme Court issued a ruling that changed the analytical framework of 35 U.S.C. § 101, at least with respect to method claims.[232] In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court found that even though an application of a law of nature to a known process may be patentable, "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"[233] If the application of a law of nature merely substitutes a newly discovered law of nature into a well-known combination of steps in a process that applies a

227. *Myriad II*, 653 F.3d at 1375 (Bryson, J., dissenting).

228. *See id.* at 1377.

229. *See id.* at 1377–78.

230. *Id.* at 1377.

231. *Id.* at 1378.

232. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, writing for a unanimous Court, Justice Breyer found claims directed at a method of assessing a proper drug dosage to be ineligible under § 101. 132 S. Ct. 1289, 1294 (2012). The claims at issue recited only:

> (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.

Id. at 1290–91.

233. *Id.* at 1293–94.

similar or related law of nature, such application is normally unpatentable.[234] It is important to note that in *Prometheus*, the Court was concerning itself with method claims, which are subject to considerations that are quite distinct from composition claims.[235] Despite the obvious differences between composition claims and method claims, in response to its decision in *Prometheus*, the Supreme Court vacated the Federal Circuit's decision in *Myriad II* and remanded it for Federal Circuit review in light of *Prometheus*.[236]

In response to the *Prometheus* decision, the USPTO issued a white paper that directed examiners on how to interpret the Supreme Court's rather open-ended instruction.[237] As a first question, in order to determine the applicability of the *Prometheus* analysis, the USPTO requires its examiners to consider whether "the claimed invention [is] directed to a process, defined as an act, or a series of acts or steps."[238] Thus, in the USPTO's estimation, the Supreme Court was uniquely concerned with process claims and was interested only in bolstering the threshold for whether a process claim is a "practical application" of a law of nature. At a fundamental level, this means that, according to the USPTO, *Prometheus* should have no bearing on the composition claims in the *Myriad* litigation.

On remand to the Federal Circuit, the same three-judge panel heard arguments as to the applicability of *Prometheus*.[239] Applying *Prometheus* to the claims at issue, the court found that the method claims were invalid in view of the Supreme Court's decision.[240] Ultimately, however, the three judges were not swayed by the Supreme Court on the composition claims. Judge Lourie found that "[*Prometheus*] does not control the question of patent-eligibility of [composition] claims."[241] Further distancing himself from the Court's

234. *See id.* at 1297–98.

235. Accordingly, the Court also was concerned with policy arguments that are applicable to laws of nature and less apt with respect to products of nature. "The Court has repeatedly emphasized . . . a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature." *Id.* at 1301. This is because the Court recognized that laws of nature are "the basic tools of scientific and technological work," and as such deserve special protection. *Id.* These policies apply with unique force to laws of nature because a monopoly over a law of nature can inhibit innovation and scholasticism in ways that tend to be beyond the reach of mere products of nature.

236. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794, 1794 (2012).

237. U.S. PATENT & TRADEMARK OFFICE, 2012 INTERIM PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS OF PROCESS CLAIMS INVOLVING LAWS OF NATURE, *available at* http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf.

238. *Id.* at 2.

239. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad III), 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012).

240. *Id.* at 1333.

241. *Id.* at 1325.

Prometheus decision, Judge Lourie continued: "While [*Prometheus*] and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules."[242] Since *Prometheus* did not apply, Judge Lourie was free to apply the same rationale that he had in his earlier decision.[243]

Judge Moore noted that, following the direction of the Court in *Prometheus*, the question of eligibility of the composition claims could be decided on the basis of two principles: "(1) laws of nature/manifestations of nature are not patentable; (2) a composition of matter with 'markedly different characteristics' from that found in nature with the potential for significant utility is directed to patentable subject matter."[244] Finding that *Prometheus* did not control the outcome of the case, in a truncated opinion, Judge Moore found that the composition claims were eligible subject matter on the same grounds as in her vacated opinion.[245] She also once again expressed her opinion that, if given a blank canvas, she would possibly come to a different conclusion.[246] But in her view, the scientific community's reliance upon longstanding precedent allowing patents on isolated DNA compelled her to exercise judicial restraint.[247]

Judge Bryson concurred in part and dissented in part. Like the other members of the panel, Judge Bryson did not construe *Prometheus* as deciding this case.[248] He did however believe that some of the underlying principles upon which *Prometheus* was decided could be applied here.[249] "Just as a patent involving a law of nature must have an 'inventive concept' that does 'significantly more than simply describe . . . natural relations,' a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product."[250] Relying on *Prometheus* for the principle that there ought to be a meaningful threshold to subject matter eligibility, Judge Bryson again found that claims directed to isolated DNA are not patent-eligible subject matter because they fail to recite a useful difference from naturally occurring DNA compositions.[251]

242. *Id.* at 1326.
243. *See id.* at 1326–33.
244. *Myriad III*, 689 F.3d at 1340 (Moore, J., concurring).
245. *See id.* at 1339–48.
246. *Id.* at 1343.
247. *Id.* at 1344–45.
248. *Id.* at 1354 (Bryson, J., concurring in part and dissenting in part).
249. *Myriad III*, 689 F.3d at 1354 (Bryson, J., concurring in part and dissenting in part).
250. *Id.* at 1355 (citation omitted).
251. *See id.*

III. PROPOSING A BRIGHT-LINE STANDARD FOR THE PURIFICATION DOCTRINE

Although neither the District Court nor the Federal Circuit was inclined to analyze the patentability of the isolated DNA sequences using solely purified preexisting products jurisprudence, the doctrine, if properly articulated, could provide clear, helpful guidance in this context as well as in other emerging micro-science contexts. At this point, it is worth reviewing the status of the doctrine prior to the Federal Circuit's first consideration of the validity of patents claiming purified and isolated DNA sequences.

In *American Wood-Paper* and *Cochrane,* the Supreme Court set out the rule that a mere extraction of a preexisting product is not patentable if the extract does not amount to a new "kind" of product.[252] While *Cochrane* seemed to shift the *American Wood-Paper* definition of "kind" to a purely structural one, the Seventh Circuit, later joined by Judge Hand and the Fourth Circuit, defined two products as being different in "kind" when they have different therapeutic and commercial values.[253] In *Bergstrom*, the C.C.P.A. seemed to adopt a more structural approach, but one where only slight structural differences are required to show that two products are different in kind.[254] So, along one axis, discord developed in defining when two products are the same in "kind," with the disagreement centered on the precise definitions or factors relevant to a product's "kind." However, augmenting the confusion with respect to the doctrine, on an entirely separate axis, disagreement seems to have developed in regard to the statutory basis for the purified preexisting products doctrine. Traditionally, the doctrine was rooted in and a natural extension of the product of nature doctrine, but the Fourth Circuit expressly denied the existence of such a doctrine, making it an issue of novelty.[255] Likewise, by focusing so intently on utility as the distinguishing characteristic of a product's "kind," the Seventh Circuit, whether intentionally or by implication, analyzed purified preexisting products under the statutory term "utility."[256] This multidimensional conflict within the doctrine has created an untenable system that is of little value in providing guidance to courts or other patent authorities in determining the eligibility of claims over extractions or purifications of known products.

A. Determining the Statutory Basis for the Purification Doctrine

Before addressing the ultimate issue of defining the term "kind" for purposes of the purified preexisting products doctrine, the statutory basis for the doctrine should be determined. Confusion as to which statutory element the

252. *See supra* Part I.B.
253. *See supra* notes 52–62, 88–97 and accompanying text.
254. *See supra* notes 98–104 and accompanying text.
255. *See supra* notes 88–92 and accompanying text.
256. *See supra* notes 78–85 and accompanying text.

purified preexisting products doctrine applies can reasonably be attributed to confusion surrounding the product of nature doctrine generally. Since nothing in the statute explicitly requires that each statutory category be considered independently, occasionally courts, in response to the natural analytical overlap between the categories, blur what should be the bright lines between them. Having never appeared in the statutory lexicon, the product of nature doctrine is a judicial creation,[257] making it all the more susceptible to being analyzed outside of its proper context.

Assuming the premise that each statutory element is separate and distinct, the rule for purified preexisting products ought to be analyzed as a discrete issue of subject matter eligibility, novelty, nonobviousness, or utility. As discussed earlier, courts have lacked consistency with respect to their analytical approach to the doctrine, explicitly assigning it to statutory novelty and implicitly conflating it with statutory utility.[258] This inconsistency has predictably led to confusion in the application of the doctrine. To develop an approach to purified products that produces consistent, predictable, and fair results, the statutory basis for the doctrine must be resolved.

Ultimately based on the following considerations, the appropriate statutory basis is § 101 subject matter eligibility. The source of the purified preexisting products doctrine is the product of nature doctrine, and, though it applies to purifications of products of nature and man-made preexisting products,[259] it is best classified as an offshoot thereof. The product of nature doctrine is generally understood as a judicial creation to be analyzed as a matter of subject matter eligibility.[260] It limits the scope of patent-eligible materials by excluding those products that exist in nature.[261] *American Wood-Paper* and *Cochrane*, the only Supreme Court discussion of the purification doctrine, simply expand the scope of excluded products from precise products of nature to include mere extractions of products of nature. Thus, Supreme Court authority is clear on the source of the purification doctrine, and, without a fundamental shift in patent law, wherein the requirement of subject matter eligibility is done away with, or alternatively the destruction of the product of nature doctrine as advocated by the Fourth Circuit in *Merck*,[262] the statutory authority for the purified preexisting products doctrine should remain the § 101 subject matter eligibility requirement.

257. *See* Parasidis, *supra* note 1, at 333–34.
258. *See supra* notes 255–56 and accompanying text.
259. *See supra* note 15 and accompanying text.
260. *See* MPEP, *supra* note 18, § 2106.
261. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).
262. *See supra* notes 88–92 and accompanying text.

B. Defining a "Kind" of Composition

Assuming the premises that the purification doctrine properly resides within the § 101 subject matter eligibility statutory requirement and that each statutory element should be considered independently, the commercial and therapeutic value tests advocated for by the Seventh and Fourth Circuits lead to an improper conflation of statutory elements. Whether a composition or other patented invention has the proper utility is an issue that ought to be analyzed exclusively as a matter of the utility element of patentability. Since the statute expressly provides that a patentable invention must have utility,[263] considering the utility of the extraction or purification of a composition in determining whether it is a mere purification results in a conflation of the statutory elements. Commercial and therapeutic values are merely nominally different expressions of utility, and, since the purification doctrine is analytically distinct from the statutory utility analysis, any discussion of utility within the purification doctrine is analytically improper. Even though the Supreme Court in *American Wood-Paper* left some ambiguity as to whether a purification is different from its source composition in "kind" because of its structural differences or functional differences,[264] recognition of the statutory source of the purification doctrine compels the conclusion that the Court intended the doctrine to distinguish between patentable and unpatentable purifications on the basis of their structural similarity to their source materials.

Since the purified preexisting products doctrine, as articulated in *American Wood-Paper* and *Cochrane*, was established as an offshoot of the product of nature doctrine, a component part of § 101 subject matter eligibility and not § 101 utility,[265] it ought to be considered as a distinct requirement from utility. This conclusion is also supported by the general principles of claim drafting. The USPTO has recognized that inventions should be described in the claims structurally rather than functionally and that, particularly in biotechnology patent applications, a mere functional description of an invention will not support a valid patent.[266] The *Manual of Patent Examining Procedure* expressly adopts a requirement that biotechnology claims be described structurally.[267] In so doing, the USPTO has adopted essentially a structural

263. *See* 35 U.S.C. § 101 (2006).

264. *See supra* notes 45–46 and accompanying text.

265. *See supra* note 14 and accompanying text.

266. *See* MPEP, *supra* note 18, § 2163 ("The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.").

267. *Id.*

definition for "kinds" of compositions. This USPTO imperative, in combination with the statutory basis for the purified preexisting products doctrine, strongly supports a categorical definition for "kinds" of compositions as determined by said compositions' structure.

However, this conclusion still leaves the doctrine no more easily applied than subsequent to the Supreme Court's decision in *Cochrane*. Some tangible, structural standard must be articulated to distinguish between mere purifications and new products that are different in "kind" from any preceding compositions. To prevent arbitrary application, an appropriate standard should be based on readily identifiable physical indicia and should signify a genuinely meaningful difference between the new and old compositions. Recall that in *American Wood-Paper*, the Supreme Court considered the distinction between a pure mixture and an impure mixture insignificant for the purposes of gauging subject matter eligibility.[268] By extension then, removing an independent substance from a mixture[269] and creating a pure form of that substance does not create a composition that is different in "kind" from the previously existing composition. In both cases, the preexisting compositions contained the claimed composition in a discrete chemical form, so as a practical matter there is not a meaningful difference between the discrete material as it existed within the mixture and as it exists in pure form.

Moving from weaker to stronger connections between materials, intermolecular forces between molecules provide the next logical break point worth considering. Generally, intermolecular forces fall into one of six categories: dipole-dipole, ion-dipole, dipole-induced dipole, ion-induced dipole, London dispersion forces, and hydrogen bonding.[270] These forces are extremely weak relative to intramolecular forces,[271] and the point of their bonding marks the separation point between two discrete molecules. The connection created thereby is generally insufficient to bond two or more portions of the same molecule.[272] However, hydrogen bonding is different in that regard. Molecules, including molecules of common compositions like

268. *See supra* note 46 and accompanying text.

269. From a thermochemical perspective, as compared with chemical reactions that result in new chemical compounds, mixture and separation causes a near negligible enthalpy change. *See* PETER ATKINS & JULIO DE PAULA, ATKINS' PHYSICAL CHEMISTRY 51 (8th ed. 2006). Thus, it is changes in chemical identity as measured by new or broken chemical bonds that account for the enthalpy change of chemical reactions.

270. *See* Todor K. Gounev, *Lecture 3 Notes*, CHEMISTRY 211/212: GENERAL CHEMISTRY, http://g.web.umkc.edu/gounevt/Weblec212Silb/L3(12.3-12.4).pdf (last visited Mar. 14, 2013).

271. *See* THANDI BUTHELEZI ET AL., CHEMISTRY: MATTER AND CHANGE 411 (2008).

272. *See* Jim Clark, *Intermolecular Bonding—van der Waals Forces*, UNDERSTANDING CHEMISTRY, http://www.chemguide.co.uk/atoms/bonding/vdw.html (last updated Sept. 2012).

water, are formed by way of hydrogen bonding.[273] Intermolecular forces, then, provide little categorical guidance because they do not form a bond that holds together one or more parts of a discrete composition.

Finally, consider briefly intramolecular bonding as the relevant break point for a new composition in "kind." Intramolecular forces occur in one of three forms: ionic bonding, covalent bonding, and metallic bonding.[274] The extent to which atoms and ions are bound together into one discrete compound is generally controlled by these forces.[275] If at any point one of these bonds is broken, the derivative pieces are two or more different chemical entities from their source material.[276] It is this consequence of intramolecular forces that make them an appropriate starting point for establishing a categorical distinction between materials that are different in "kind."

However, the categorical definition cannot rest on the presence or absence of ionic, covalent, and metallic bonding alone because, as discussed above, hydrogen bonding can form the basis of distinct chemical compounds in the same way that these intramolecular forces do.[277] Furthermore, unfortunately for the sake of the simplicity of the patent system, discrete materials are not always defined by molecular boundaries. Materials such as salts and crystals are not technically molecules,[278] but instead are series of two- or three-dimensional patterns of chemical structure.[279] However, these complexities of material science coupled with the most basic of human perception can form a workable definition. Generally, whether considering molecules, ions, ionic compounds, salts, crystals, or any other material, a minimal chemical form that defines the material is ascertainable. That is to say that if a container of a discrete chemical compound is processed, the processing mechanisms can chip away material until a point is reached where what remains is that very same material, but if any more were to be removed, it would result in a new material of a different chemical structure. It is that chemical structure that ought to define a material's "kind."[280]

273. *See* Walt Volland, *Intermolecular Forces Dipole-Dipole, London Forces, Hydrogen Bonding Versus Covalent Bonds*, http://www.800mainstreet.com/08/0008-0012-interforce.html (last updated Nov. 3, 2011).

274. BUTHELEZI ET AL., *supra* note 271, at 411.

275. *Id.*

276. Atkins distinguishes between two separate forms of discrete chemical entities, covalently bonded molecules and ionically bonded formula units. ATKINS & DE PAULA, *supra* note 269, at 362. For the purposes of this Note, discrete compositions or discrete chemical substances refer to either molecules or formula units.

277. *See supra* note 273 and accompanying text.

278. These are what Atkins refers to as formula units. *See* ATKINS & DE PAULA, *supra* note 269, at 960.

279. *See* BUTHELEZI ET AL., *supra* note 271, at 212–13.

280. In terms of Atkins' definitions, a composition's "kind" is the chemical structure that makes up a discrete molecule or formula unit. *See supra* note 276.

There are, of course, limitations to this categorical definition. In fact, Judge Bryson, who wrote the dissenting opinions in *Myriad II* and *III*, found that assigning value to the presence or absence of chemical bonding was arbitrary.[281] As shown above, however, the chemical bond that creates and maintains distinct chemical structure is anything but arbitrary. It is the very thing that defines discrete materials and ought to provide definitively whether compositions are different in "kind" from previously existing compositions. However, *In re Marden* found that purification of a natural chemical element that only existed in nature outside of its pure elemental form would not sustain a composition patent.[282] This poses a more problematic hurdle to the effective administration of this proposed definition, but ultimately this issue is better addressed as an exception to the purification doctrine. As a sub-issue of the product of nature doctrine, courts ought to continue to find that fundamental elements that exist in nature in non-elemental form are not patentable subject matter. Even though the element, in its pure form, is a distinct chemical structure from preexisting materials, chemical elements are too foundational to all scientific notions of materials and too prevalent throughout nature to be considered patentable subject matter.

CONCLUSION: APPLICATION OF THE PROPOSED BRIGHT-LINE RULE TO *MYRIAD*

Accordingly, a mere extraction of a preexisting product that is not different from the preexisting product in "kind," where "kind" is defined as a new discrete chemical structure, is not patentable subject matter. This discrete chemical structure can be ascertained by chipping away at a material until a point is reached where what remains is that very same material, but if any more were to be removed, it would result in a new material of a different chemical structure. By adopting this definitional approach to the purification doctrine and providing an articulable standard for subject matter eligibility, courts could help create certainty in the patent system without upsetting the analyses of the other three elements of patentability. This is but one step in creating a more workable patent system. Ultimately, a standard for each separate element of patentability should be clearly defined, creating a system where each statutory element has a discrete meaning and distinct purpose in the larger patentability system. By adopting such an approach, the courts would create predictability and consistency that would promote the progress of science and the useful arts.

281. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad III), 689 F.3d 1303, 1350–51 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part), *cert. granted sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012).

282. *See In re* Marden, 47 F.2d 958, 959 (C.C.P.A. 1931). On its surface, *Marden* seems to undermine the definition of "kind" previously adopted because a pure elemental form of an atom is a discrete chemical entity from the molecule or formula unit from which it came.

Applying this standard to the *Myriad* facts makes quick work of the subject matter eligibility issue. Since even the trial court's decision and Judge Bryson's dissent acknowledged that each of the claimed compositions was for a new chemical structure,[283] the claims should not fail on subject matter eligibility grounds because what is claimed is a composition that is different in "kind" from the natural composition from which it is based. Because isolated DNA is a distinct material from native DNA, it ought to at least pass the threshold question of subject matter eligibility. This is not to conclude on the whole issue of patentability, and, to an even greater extent, this conclusion is not intended to provide a policy judgment on the efficacy of gene patents. Instead, the purpose of this analysis is to draw attention to the confused state of patentability by highlighting one judicial creation within one statutory element and pointing out the confusion created therefrom. By adopting a more categorical approach to the statutory elements and attempting to define the judicial creations of each, courts can bring much needed clarity to the patent system and generally promote the progress of science.

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283. *See supra* notes 203, 224–28 and accompanying text.

* J.D., Saint Louis University School of Law, anticipated May 2013; B.S., Missouri University of Science and Technology, May 2010. The clarity of thought presented in this Note is owed to the guidance of Professor Efthimios Parasidis, the instruction of my parents, the support of my wife, and the skilled and capable editing of Nick Cejas and the rest of the *Saint Louis University Law Journal*'s editorial board and staff.