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WILL NANOTECHNOLOGY PRODUCTS BE IMPACTED BY THE FEDERAL COURTS' "PRODUCT OF NATURE" EXCEPTION TO SUBJECT-MATTER ELIGIBILITY UNDER 35 U.S.C. 101?

LAURA W. SMALLEY

ABSTRACT

In 2013, the Supreme Court in *Myriad* held that DNA is a "product of nature" that is not patentable merely because it is isolated from the human body. The year before, the Supreme Court in *Prometheus* held that diagnostic tests that incorporate little more than a "law of nature" is not patent eligible. These two decisions altered the landscape of patent eligible subject matter under Section 101 of the patent statute. They not only impact the patent eligibility of isolated DNA or diagnostic tests, but they may also have far wider-ranging impact on other technological fields, including biotechnology and nanotechnology. This article delves into the history of cases leading up to these two decisions as a way to determine the exact scope of the decisions. In particular, the article looks at the parallel development of the "product of nature" and "law of nature" doctrines, and examines its culmination in *Myriad* and *Prometheus*. The article then looks at whether and to what extent the patentability of nanotechnology will be impacted. Nanotechnology is "the science of manipulating materials on an atomic or molecular scale." By its very nature, nanotechnology incorporates products of nature and laws of nature. But the technology also creates new benefits and uses that may deserve patent protection. This article looks at both the current state of the law and policy reasons that must be considered in determining the patent eligibility of inventions in the field of nanotechnology.

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I. INTRODUCTION

Nanotechnology literally means "the science of manipulating materials on an atomic or molecular scale."[1] While what constitutes "nanotechnology" varies depending on the context, the United States National Nanotechnology Initiative defines the field as "science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometers."[2] The United States Patent and Trademark Office's ("USPTO") definition of nanotechnology-related patents (those involving "nanostructure") conforms to that of the National Nanotechnology Initiative's,[3] as does the definition of nanotechnology used by many foreign patent offices.[4]

This article looks at whether nanotechnology is patent-eligible. The current Patent Act defines patent-eligible subject matter as any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ."[5] While the courts have interpreted the Patent Act's definition of subject matter broadly, the Supreme Court has created certain categories of patent-ineligible subject matter, including laws of nature, natural phenomena, and abstract ideas.[6] These judicially created categories of patent-ineligible subject matter ostensibly were

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[1] *Nanotechnology Definition*, MERRIAM-WEBSTER ONLINE DICTIONARY, http://www.merriam-webster.com/dictionary/nanotechnology (last visited Mar. 1, 2013).

[2] *What is Nanotechnology?*, NATIONAL NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/nanotech-101/what/definition (last visited Dec. 18, 2013).

[3] *Nanotechnology Class Definition*, U.S. PAT. & TRADEMARK OFFICE, http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm (last visited Mar. 1, 2013) (defining a "nanostructure" as "an atomic, molecular, or macromolecular structure" that has "at least one physical dimension of approximately 1-100 nanometers" and possesses "a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure[']s nanoscale physical size").

[4] *See Patenting Nanotechnology: Exploring the Challenges*, WORLD INTELLECTUAL PROPERTY ORGANIZATION (Apr. 2011), http://www.wipo.int/wipo_magazine/en/2011/02/article_0009.html#7.

[5] 35 U.S.C. § 101 (2012).

[6] *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) ("The laws of nature, physical phenomena, and abstract ideas have been held not patentable."); Diamond v. Diehr, 450 U.S. 175, 185 (1981) ("Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.").

created to prohibit patent claims from preempting broad principles such as physical laws ($E = mc^2$) or other manifestations of nature.[7]

Recent Supreme Court decisions and other scholarship have addressed whether medical diagnostic methods are patentable subject matter under Section 101 of the Patent Act or whether they are unpatentable "laws of nature."[8] These cases elucidate principles that are helpful to understanding how the courts will treat nanotechnology inventions, particularly as to how the courts will apply the "natural law" exception to Section 101. The recent Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* addressed the "law of nature" exception, holding that the correlation between blood metabolite levels and drug dosage was a law of nature, and that the additional steps purporting to apply that law failed to transform it into patent-eligible subject matter.[9] According to the Supreme Court, additional steps that "involve well-understood, routine, conventional activity previously engaged in by researchers in the field," cannot transform a law of nature into patent-eligible subject matter.[10]

After *Prometheus*, the Federal Circuit Court of Appeals decided *Association for Molecular Pathology v. U.S. Patent and Trademark Office.*[11] The court held that isolated DNA is patentable and that the rationale of *Prometheus* does not control a claim to a composition of matter.[12] The Supreme Court's subsequent decision in *Myriad* reversed the Federal Circuit in part, holding that naturally occurring DNA segments are not patentable.[13] In determining the subject matter eligibility of DNA and complementary DNA ("cDNA"), the Supreme Court based its decision on whether the patentee "create[d]" a "new . . . composition of matter."[14] It did not overtly rely on *Prometheus*' "inventive concept" analysis, although the Court noted that "separating [a] gene from its surrounding genetic material is not an act of invention."[15] The Court held that cDNA was patent eligible because the cDNA molecule is not "naturally occurring."[16] It did not address whether, once the natural genetic sequence was known, creating cDNA required an "inventive concept."[17] It remains to be seen whether an "inventive concept" is required for a composition of matter to be patent eligible, or whether obviousness, rather than § 101, will control the inquiry on whether nature-based products are patentable.

The rules articulated in *Prometheus* and *Myriad* may ultimately be applicable to nanotechnology. Compositions of matter that fall into the category of nanotechnology may already exist in nature or be a small-scale version of something

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[7] *Chakrabarty*, 447 U.S. at 309.

[8] *See infra* Part III.

[9] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1297 (2012).

[10] *Id.* at 1294.

[11] *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (*Myriad III*), *cert. granted*, 133 S. Ct. 694 (2012) (mem.), *aff'd in part and rev'd in part*, 133 S.Ct. 2107 (2013).

[12] *Id.* at 1309, 1339–40.

[13] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2117, 2120 (2013).

[14] *Id.* at 2109–10.

[15] *Id.* at 2117–18.

[16] *Id.* at 2119.

[17] *Id.*

that already exists in nature. For example, carbon nanotubes are naturally created in soot, but are the subject of thousands of patents.[18] Further, the usefulness of nanotechnology inventions often comes from the unique properties of matter at the nanoscale, such as increased magnetism, conductivity, reactivity, or reflective ability.[19] The "product of nature" doctrine, as articulated in *Prometheus* and *Myriad*, may have substantial effects on the patenting of nanotechnology-related inventions because many such inventions involve discovering and harnessing the properties of material at the nanoscale or processes involving the use of nanoscale materials. This article explores the implication of recent Federal Circuit and Supreme Court precedent on nanotechnology.

II. BACKGROUND ON THE PRODUCT OF NATURE DOCTRINE

The "product of nature" doctrine is one aspect of a judicially created doctrine excluding certain subject matter, such as mental processes and abstract ideas, from the broad statutory definition of patent-eligible subject matter.[20] The exclusion of that subject matter is not constitutionally required. The Intellectual Property Clause of the United States Constitution permits Congress "[t]o promote the Progress of Science and useful Arts" by granting "to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[21] Given that "discover" means "to be the first to find or find out about; to learn about or encounter for the first time; to find after study or search; to reveal or make known,"[22] the use of the term "Discoveries" does not foreclose protection for products of nature.[23]

Likewise, the "product of nature" doctrine itself is not mandated by the language of the Patent Act, neither presently nor for most of the existence of the patent system of the United States. Under Section 1 of the 1790 Patent Act, a patent could be granted to an inventor who had "invented or *discovered* any useful art, manufacture, engine, machine, or device, or any improvement therein."[24] While the Patent Act of

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[18] Julie A. Burger et al., *Nanotechnology and the Intellectual Property Landscape, in* NANOSCALE: ISSUES AND PERSPECTIVES FOR THE NANO CENTURY 239, 245 (Nigel M. de S. Cameron & M. Ellen Mitchell eds. 2007).

[19] *What It Is and How It* Works, NATIONAL NANOTECHNOLOGY INITIATIVE, http://www.nano.gov/nanotech-101/what (last visited Jan. 1, 2014).

[20] 35 U.S.C. § 102 (2012).

[21] U.S. CONST. art. I, § 8, cl. 8.

[22] *Discover Definition*, COLLINS ENGLISH DICTIONARY, *available at* http://www.collinsdictionary.com/dictionary/english/discover (last visited Jan. 1, 2014).

[23] *See* John F. Duffy, *Why Business Method Patents?*, 63 STAN. L. REV. 1247, 1274 (2011) (noting that the three judicially created exceptions to patent-eligibility are not required in the text of 35 U.S.C. § 101).

[24] Patent Act of 1790, 1 Stat. 109, 109, § 1 (Apr. 10, 1790) (emphasis added).

1793 eliminated the reference to discoveries,[25] the 1836 Patent Act again included the term "discovery" in the definition of patentable subject matter.[26]

The basic definition of patentable subject matter was not amended again until 1952, when 35 U.S.C. § 101 was promulgated along with separate statutory requirements for novelty and non-obviousness (which were already requirements under existing case law).[27] The 1952 Patent Act ("Patent Act") defines the term "invention" as "invention or *discovery*," and states that a patent may be granted to a person who "invents or *discovers* any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . ."[28] Again, the term "discovery" connotes material that is already in existence and simply found, not created. The judicial creation of a "product of nature" exception is not necessarily based on the language of the Patent Act or the Constitution, but based on policy considerations noted by the judiciary.[29]

Congress' use of expansive terms in describing patent-eligible subject matter, modified by the comprehensive term "any," plainly contemplates that the patent laws "would be given wide scope."[30] The Act's broad language notwithstanding, courts have long recognized a limitation that patents cannot issue for "laws of nature, natural phenomena, and abstract ideas."[31]

A. Early Decisions Based on Lack of Novelty.

The theory behind the "product of nature" exception was first addressed in terms of novelty, rather than as an exclusion from patentable subject matter. This

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[25] Patent Act of 1793, 1 Stat. 318, 318, § 1 (Feb. 21, 1793) (providing that a patent may be granted to one who "invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter, not known or used before the application").

[26] *See* Patent Act of 1836, 5 Stat. 117, 119, § 6 (July 4, 1836) ("[H]aving discovered or invented any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others before his or their discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer.").

[27] U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (8th ed. Rev. 9, Aug. 2012) [hereinafter MPEP].

[28] 35 U.S.C. § 101 (emphasis added).

[29] *In re* Beineke, 690 F.3d 1344, 1351 (Fed. Cir. 2012). The Federal Circuit, Court of Appeals confirmed that the Plant Patent Act does not protect a "discovery" per se. *Id.* The term "discovery," as used in the legislative history and the Act, referred to the "discovery" resulting from the plant breeder's own work and not a "chance find" or discovery. *Id.* While the Plant Patent Act was amended in 1954 to provide protection for "*newly found seedlings, other than* a tuber propagated plant or *a plant found in an uncultivated state,*" it was limited to seedlings found on land in a cultivated state, which could be assumed to have been cultivated from inception. *Id.* at 1353 (citing 35 U.S.C. § 161) (emphasis in original). A plant simply discovered on uncultivated land does not constitute a discovery within the terms of the Plant Patent Act, consistent with the requirements for utility patents under the Patent Act of 1954. *Id.* at 1345.

[30] Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010) (citing Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).

[31] *Id*. at 3238 (citing Diamond v. Diehr, 450 U.S. 175, 185 (1981).

approach could be seen in the Supreme Court's two early decisions in *American Wood-Paper* and *Cochrane*.

1. American Wood-Paper Co. v. The Fibre Disintegrating Co.

In *American Wood-Paper Co. v. The Fibre Disintegrating Co*.,[32] the Supreme Court addressed a reissued patent for paper pulp produced from wood. Pulp, out of which paper is made, is a fibrous material consisting of "cellulose."[33] Prior to the patent at issue, pulp had been manufactured from straw, wood, and other vegetable substances, and was not pure.[34] Further mechanical and chemical treatment had been required to achieve the proper consistency and dimensions for felting.[35]

The original 1853 patent (to Watt and Burgess) had been granted for pulp produced by a three-step chemical process of producing pulp ready for washing and bleaching.[36] Before the patented process began, wood and vegetable substances were reduced to very fine shavings or cuttings and then boiled in a solution of caustic alkali.[37] The shavings were washed and pressed, and then exposed to the action of chlorine until a portion of the shavings fell into a dark pulpy mass upon being placed in a caustic alkali solution.[38] The shavings were again washed to remove the hydrochloric acid that had formed as a result of the exposure to chlorine and then placed in a weak solution of caustic alkali.[39] The resulting pulp was again washed to remove the alkali and then could be bleached by known processes.[40] The patent claimed "the pulping and disintegrating of shavings of wood and other similar vegetable matter for making paper, by treating them with caustic alkali, chlorine simple, or its compounds with oxygen and alkali, in the order substantially as described."[41] As noted by the Court, there was no process prior to 1853 by which pulp was produced so that it was ready for washing or bleaching by a single operation; generally, successive mechanical operations were used.[42]

Two patents reissued in 1863, one for "an improved manufacture of paper and paper pulp from wood" (the process) and the other for "paper and paper pulp" (the product).[43] The product patent 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, substantially as described."[44] The process patent claimed "the process of treating wood or other vegetable substance, by

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[32] Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 566 (1874).
[33] *Id.*
[34] *Id.*
[35] *Id.* at 568.
[36] *Id.*
[37] *Id.* at 570.
[38] *Id.* at 571.
[39] *Id.*
[40] *Id.*
[41] *Id.* at 572.
[42] *Id.* at 568.
[43] *Id.* at 569.
[44] *Id.* at 577.

boiling it in alkali under pressure, as a process, or preparatory process, for making pulp for the manufacture of paper from such woods or other vegetable substances substantially as described."[45] The specification described the use of chlorine in the process.[46]

The district court had held the product patent invalid as claiming matter that was not new and the process patent as claiming a "different invention from the original."[47] The Supreme Court affirmed the district court's holding as to the process patent and addressed the novelty of the product patent, determining that, if the substance produced is not new, it is not patentable *as a substance* even if made by a new process.[48] The Court held that the product, unlike the process, was not novel because it had existed prior to 1853.[49] Although the patentees argued that the prior art was not pure cellulose, and that therefore the claimed product was "different and new," the Supreme Court questioned "[w]hether a slight difference in the degree of purity of an article produced by several processes justifies denominating the products different manufactures," but declined to decide the issue.[50] The product claimed in the patent was a pulp suitable for the manufacture of paper, and the pulp produced by the prior art processes was apparently "equally suitable."[51]

The fact that the claimed product was in a more final stage than the intermediate condition found in the prior art was immaterial to the Court's decision, because both products had the same consistency and fiber length properties once processed.[52] The claimed product was therefore "in no sense new" and void "for want of novelty in the manufacture patented."[53] As one legal scholar noted:

> the Court made clear (without distinguishing between naturally occurring and non-naturally occurring but pre-existing things) that simply increasing the purity of pre-existing pulp (by isolating the naturally occurring cellulose from more of the "impurities" of naturally occurring wood) did not thereby create a new *thing* (a new manufacture), even if wood pulp was a distinct thing from the cellulose that comprised it.[54]

Although the Court was not addressing the patentability of a true "product of nature," the principle articulated in *American Wood Pulp* is that purification or

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[45] *Id.* at 580.

[46] *Id.* at 579.

[47] *Id.* at 592.

[48] *Id.* at 593 (noting that in such instances, the process, but not the product, may be patentable).

[49] *Id.* at 594.

[50] *Id.*

[51] *Id.*

[52] *Id.* at 595–96.

[53] *Id.* at 596.

[54] Joshua D. Sarnoff, SHAKING THE FOUNDATIONS OF PATENTABLE SUBJECT MATTER 89 (Apr. 2, 2008) (preliminary discussion draft) (on file with American University Washington College of Law), *available at* http://www.wcl.american.edu/pijip/go/research-and-advocacy/ip-policy-and-law-reform (emphasis in original).

further refinement of an existing product is not a novel product—and therefore not patentable—even if the process of creating that product is novel.

2. Cochrane v. Badische Anilin & Soda Fabrik

A second Supreme Court case addressing the "product of nature" problem presents the issue again as one of novelty rather than the scope of patent-eligible subject matter. *Cochrane v. Badische Anilin & Soda Fabrik* addressed a reissue patent for an "improvement in dyes or coloring matter from anthracine."[55] The reissue patent claimed a "[new and useful improvement] . . . *for preparing alizarine from anthracine*," which was in essence the production of a synthetic form of alizarine.[56] The patent holder sued, claiming that the reissue patent was infringed by making and selling the invention, or dyes produced with it.[57] The accused infringer claimed that it sold alizarine lawfully made in Germany and imported into the U.S. that was made by a newer, improved process than that described in the reissue patent.[58] The accused infringer also argued that the reissue patent was invalid because "'alizarine is a natural product, having a well-known definite constitution; that it is not a composition of matter, within the meaning of the statute, but has been well-known in the arts . . . for the purpose of dyeing . . . .'"[59] The infringers claimed that the patented product had the same chemical formula as the natural product.[60]

The lower court held the reissue patent valid and infringed.[61] The Supreme Court considered the technical literature on alizarine, which is a red coloring obtained from rose madder with the chemical formula $C_{14}H_8O_4$.[62] The patentees discovered a method of creating synthetic alizarine by various reactions that, according to the literature, had the same composition and properties as vegetable alizarine.[63] The reissue patent claimed a process (an improved process over the initial patent) and a product denominated artificial alizarine.[64] The court noted that the specification of the original patent clearly intended the invention "to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process . . . ."[65] The Supreme Court concluded that the product to be produced by the new process was intended to have the same chemical formula as natural alizarine.[66] The Court held that because the defendant's product was made by a different process

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[55] Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 294, 294 (1884) (emphasis in original).
[56] *Id.* at 294, 296.
[57] *Id.* at 296.
[58] *Id.*
[59] *Id.* at 297.
[60] *Id.* at 298.
[61] *Id.* at 297.
[62] *Id.* at 299.
[63] *Id.* at 300, 304.
[64] *Id.* at 308.
[65] *Id.*
[66] *Id.* at 311–12.

and could not be identified as the product of the process of the reissue patent, the defendant did not infringe.[67] To the extent the reissue patent claimed the product alizarine with the chemical formula $C_{14}H_8O_4$, it was an old article; the new process for creating the chemical was patentable, but the product itself could not be patented because, although synthetic, it had the same composition as the well-known natural substance.[68] This Supreme Court decision established that a composition of matter with the same chemical composition as a natural product cannot be patented regardless of how it is derived.

B. Emergence of a "Product of Nature" Doctrine and a "Purification" Doctrine.

The "product of nature" doctrine emerged from a combination of Supreme Court, Patent Office, and Circuit Court decisions. These cases moved away from the earlier Supreme Court cases of deciding patent-eligibility on the basis of novelty. Instead, the courts began to carve out a patent-ineligible "product of nature" category, where the courts looked at whether the claimed product was distinguishable from a product found in nature. The courts were in disagreement, however, about how to apply the "product of nature" doctrine, or whether to even apply it at all. Many circuit courts, for example, found that "purified" "products of nature" were patentable under the "purification doctrine."

1. Ex Parte Latimer

The first specific reference to the "product of nature" doctrine is in *Ex parte Latimer*, a decision rejecting a patent for fiber consisting of the cellular tissues of pine needles.[69] At the time of the case, in 1889, Section 1 of the Patent Act provided that a patent could be granted for "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter, not known or used by others . . . at the time of [the] application . . . ."[70] The applicant in *Latimer* claimed a "new article of manufacture" comprising the "cellular tissues of the *Pinus australis* eliminated in full lengths from the silicious, resinous, and pulpy parts of the pine-needles and subdivided into long, pliant filaments adapted to be spun and woven . . . ."[71] The applicant obtained a patent for the process, but the patent examiner rejected it, finding the physical characteristics of the claimed product indistinguishable from any other fiber.[72]

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[67] *Id.* at 310.
[68] *Id.* at 311.
[69] *Ex Parte* Latimer, 1889 Dec. Comm'r Pat. 123, 123 (1889).
[70] Patent Act of 1836, 5 Stat. 117, 119 § 6 (July 4, 1836).
[71] *Ex Parte* Latimer, 1889 Dec. Comm'r Pat. at 123.
[72] *Id.* at 124.

The Commissioner of Patents affirmed, upholding the primary examiner's rejection.[73] While the decision in *Latimer* hints that the patent could have been rejected based on lack of novelty, the Commissioner denied the attempt to patent the fiber material by disavowing the concept that one could patent a "natural product" such as "an element or a principle . . . which nature has produced and which nature has intended to be equally for the use of all men."[74] The decision further noted that the differences between the useful properties of the fiber extracted from the pine tree and the useful properties of other fibers were not due to the method of processing but to the natural properties of the pine tree fiber.[75] Further, the fiber was unchanged from its "natural construction" by chemical combination and was therefore not something "new or different from the fiber in its natural state."[76] The product of nature doctrine was therefore first formulated to preclude patent protection for a "product whose physical characteristics are indistinguishable from those of its naturally-occurring counterpart," despite any novelty inherent in the process used to produce the product, the "unprecedented status" of its discovery, or the product's utility.[77]

2. American Fruit Growers, Inc. v. Brogdex Co.

American Fruit Growers, Inc. v. Brogdex Co. is also instructive on the "product of nature" doctrine, even though it does not directly address the doctrine. The Supreme Court addressed what constituted a "manufacture" for purposes of the patent statutes.[78] The Supreme Court held that a rind of an orange with a small amount of borax added did not constitute a "manufacture" as that term is used in § 101, because the "[a]ddition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article . . . ."[79] The Supreme Court did not consider an orange with skin impregnated by borax patentable because the process did not create an article having a new or distinctive form or property than the naturally occurring orange.[80]

3. Kuehmsted v. Farben Fabenfabrik of Elberfeld Company

Despite the Supreme Court and the Patent Office's prohibitions on patenting natural products, certain circuit court cases in the early twentieth century permitted

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[73] *Id.* at 125–26.

[74] *Id.*

[75] *Id.* at 126.

[76] *Id.*

[77] John M. Conley & Robert Makouski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents* (*Part I*), 85 J. PAT. & TRADEMARK OFF. SOC'Y 301, 322 (2003).

[78] Am. Fruit Growers v. Brogdex Co., 283 U.S. 1, 10–11 (1931).

[79] *Id.* at 11.

[80] *Id.*

patents on what are in essence synthetic or purified "products of nature." In *Kuehmsted v. Farben Fabenfabriken of Elberfeld Company*,[81] the Seventh Circuit Court of Appeals affirmed the validity of a patent covering acetyl salicylic acid (aspirin) made by heating salicylic acid with acetic anhydride and then recrystallizing the product.[82] The accused infringer claimed that the product had the identical formula as the prior art substance.[83] The Seventh Circuit rejected the argument that the formula of the accused product and the prior art were identical because the substances could be physically and therapeutically different due to impurities detectable upon a qualitative analysis.[84] The patent was not barred because the prior art product could be treated to create the claimed aspirin product and that recrystallized product differed from the prior art. In use, the salicylic acid in the patented product did not dissolve in the stomach therefore avoiding the side effects of the prior art product and rendering the patented product "effective and safe in its therapeutical results . . . ."[85] The Seventh Circuit therefore held that the patented product—in essence a purification of a prior product—was a "medicine indisputably beneficial to mankind—something new in a useful art, such as our patent policy was intended to promote."[86] The validity of the patent did not hinge on the fact that it was derived from a substance containing the claimed compound and that it was the result of purification because the prior art was "at best, a chemical compound in an impure state."[87] This result may, in part, be dictated by the state of chemical analysis at the time and/or the proof adduced in the lower court—the appellate court recognized differences in the two products simply because they performed differently, despite the lack of actual differences in the composition of the two products.[88]

4. Parke-Davis & Co. v. H.K. Mulford & Co.

Two years later, the Second Circuit (based upon a district court opinion authorized by Learned Hand) refused to invalidate a patent for purified adrenaline in a controversial opinion, *Parke-Davis & Co. v. H.K. Mulford & Co.*[89] The patentee discovered how to purify adrenaline from the adrenal glands and claimed, in essence, any substance that had the "physiological characteristics of the glands and is substantially pure."[90] The accused infringer argued that because the product was simply a purified form of a substance existing in the body, it was not a new "composition of matter" and therefore not patentable.[91] The district court held that

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[81] Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 F. 701, 705 (7th Cir. 1910).
[82] *Id.*
[83] *Id.* .
[84] *Id.* at 703–04.
[85] *Id.* at 704.
[86] *Id.* at 705.
[87] *Id.*
[88] *Id.* at 701.
[89] Parke-Davis & Co. v. H.K. Mulford & Co., 196 F. 496, 497 (2d Cir. 1912).
[90] Parke-Davis & Co. v. H.K. Mulford & Co., 189 F. 95, 101–02 (S.D.N.Y. 1911).
[91] *Id.* at 103.

the patent did not disclose adrenaline in a salt form and that no prior art disclosed isolated adrenaline in anything but that form.[92] In dicta, Learned Hand also noted that the result would have been the same even if the patented product "were merely an extracted product without change, [because] there is no rule that such products are not patentable."[93] The patentee was the first to make pure adrenaline available for use by removing it from gland tissue when "it became for every practical purpose a new thing commercially and therapeutically," and the product was therefore patentable even if seen as a simple "purification."[94] This decision, which has lent support for decades to the premise that a purified natural substance can be patented,[95] has been criticized as based on an erroneous interpretation of law, ignoring *Ex Parte Latimer* and perhaps misunderstanding the *American Wood Paper* decision.[96]

5. General Electric Company v. De Forest Radio Company

In contrast, intervening cases involving purified elements unequivocally held that "products of nature" were not patentable, whether or not the purified form of the material existed in nature. For example, in *General Electric Company v. De Forest Radio Company*, the court addressed the claim to "[s]ubstantially pure tungsten having ductility and high tensile strength."[97] The Third Circuit's 1930 decision upheld the determination that the patent was invalid, although pure tungsten, as described in the claims, had not been found in nature.[98] As an element, tungsten's properties were natural by definition,[99] and "a patent cannot be awarded for a discovery or for a product of nature, or for a chemical element."[100] Based on the holding in *General Electric,* the Court of Customs and Patent Appeals ("CCPA") consistently rejected patents on products seen merely as purified forms of a natural substance, including ductile uranium,[101] ductile vanadium,[102] purified ultramarine,[103] and purified vitamin C,[104] finding that the claimed inventions were "product[s] of

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[92] *Id.*

[93] *Id.*

[94] *Id.* The case cited *Union Carbide Co.*, in which the court found that crystalline calcium carbide was patentable because it had different physical properties than the amorphous product known in the prior art and those properties made it better suited for commercial use. Union Carbide Co. v. Am. Carbide Co., 181 F. 104 (2d Cir. 1910).

[95] Jon M. Harkness, *Dicta on Adrenalin(e): Myriad Problems with Learned Hand's Product-of-Nature Pronouncements in* Parke-Davis v. Mulford, 93 J. PAT. & TRADEMARK OFF. SOC'Y, 363, 364 (2011).

[96] *Id.* at 389, 390–91.

[97] Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 643 (3d Cir. 1928).

[98] *Id.* at 647.

[99] *Id.* at 643.

[100] *Id.* at 642 (citing U.S. Indus. Chem. Co. v. Theroz Co., 25 F.2d 387 (4th Cir. 1928)).

[101] *In re* Marden (*Marden I*), 47 F.2d 957, 957 (C.C.P.A. 1931).

[102] *In re* Marden (*Marden II*), 47 F.2d 958, 958 (C.C.P.A. 1931).

[103] *In re* Merz, 97 F.2d 599, 599 (C.C.P.A. 1938).

[104] *In re* King, 107 F.2d 618, 618 (C.C.P.A. 1939).

nature" and that the inventor was not entitled to a patent on such a product or any of its inherent qualities.[105]

6. In re Merz

In *Merz*, the CCPA articulated the general rule that one cannot patent a product that simply has a greater degree of purity than the same product produced by different methods.[106] To patent the product, the inventor must show that the process used "produces an article of such purity that it differs not only in degree but in kind . . . ."[107] Therefore, to obtain a patent, the general rule at that time required the inventor to demonstrate that the product was, in effect, new, and had a new (and not simply improved) use.[108]

7. In re Williams

Despite the strict barrier established by cases such as *General Electric, American Wood Fiber*, and *Cochrane*, the rule stated in *Parke-Davis*, permitting patents on purified natural products, seems to have carried the day in the CCPA case of *In re Williams*.[109] In *In re Williams*, the CCPA reversed the Patent and Trademark Office's rejection of claims to the laevo rotary form of lactone.[110] In essence, the laevo rotary form was a purified form of a racemic mixture that contained both the laevo rotary form and the dextro rotary form of the compound.[111] While the rejection of the claims by the patent examiner was based on lack of novelty and obviousness, rather than a claim that the compound was not patent-eligible subject matter, *Williams* expanded the ability to claim a purified product, holding that "a pure compound may, under certain conditions, be patentable over the same compound in an impure form . . . ."[112] Even though the racemic nature of the "impure" compound was clearly inherent in the compound, the CCPA believed that the "pure" form was not only novel, in that it did not exist before the patentee created it, but was also non-obvious because the prior art did not demonstrate that those skilled in the art knew the compound was racemic, or that it was obvious to one skilled in the art that the compound was racemic.[113] This decision flies in the face of prior precedent, including *Ex Parte Latimer* and *General Electric*, which stand for the

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[105] *Marden I*, 47 F.2d at 957. *See also Marden II*, 47 F.2d at 958; *Merz*, 97 F.2d at 600; *King*, 107 F.2d at 620 (noting that vitamin C was considered a known compound without naming it a "product of nature").

[106] *Merz*, 97 F.2d at 601.

[107] *Id.*

[108] *Id.*

[109] *See* Conley & Makowski, *supra* note 77 at 325.

[110] Application of Williams, 171 F.2d 319, 319 (C.C.P.A. 1948).

[111] *Id.* at 319–20.

[112] *Id.* at 320 (citing *Merz*, 97 F.2d at 601).

[113] *Id.*

proposition that simply discovering a natural property of a substance and using purification to realize that property are not patentable.[114]

8. Funk Brothers Seed Co. v. Kalo Inoculant Co.

The Supreme Court addressed the patentability of natural products again in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[115] The patent claimed an inoculant for leguminous plants comprising a plurality of selected, mutually non-inhibitive strains of different bacteria.[116] The ability of leguminous plants to withdraw nitrogen from the air is dependent on the presence of certain bacteria that infect the roots of the plants, yet no species of that particular bacteria genus will infect the roots of all species of leguminous plants.[117] Methods of selecting strains and producing a bacterial culture from those strains had been known in the art, but the claimed invention was the first inoculant to contain six rather than one species of bacteria.[118] In general, different strains of the bacterium inhibited one another.[119] The inventor discovered certain strains of each of the six species that did not inhibit each other and provided a mixed culture usable with multiple types of plants.[120]

The Supreme Court held that the disclosed subject matter was not an "invention or discovery"—in other words, not patent-eligible subject matter under the Patent Act.[121] The inventor did not create the effects of the bacteria; their properties were works of nature and "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes."[122] To be patentable, the invention must be an application of a natural phenomenon to a new and useful end.[123] The combination of the six species of bacteria did not produce a new bacteria, change the old bacteria, or increase the utility of the bacteria.[124] This case, while not differing in effect from prior Supreme Court cases such as *American Wood Fiber*, clearly analyzed the issue of patent subject matter eligibility separately from novelty.[125]

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[114] Ex parte Latimer, 1889 Dec. Comm'r Pat. 123, 123 (1889); Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 642 (3d Cir. 1928).

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

[116] *Id.* at 128 n.1.

[117] *Id.* at 128–29.

[118] *Id.* at 130.

[119] *Id.* at 129.

[120] *Id.* at 128–30.

[121] *Funk*, 33 U.S. at 131–32.

[122] *Id.* at 130.

[123] *Id.*

[124] *Id.* at 131.

[125] *Id.* at 131 (citing Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 90, 91 (U.S. 1941)) (stating that "a product must be more than new and useful to be patented; it must also satisfy the requirement of invention or discovery").

9. Merck & Co., Inc. v. Olin Mathieson Chemical Co.

While *Funk Brothers* seemed to emphasize that a natural phenomenon cannot constitute patentable subject matter, the "purification" concept continued to expand in patent law. In *Merck & Co., Inc. v. Olin Mathieson Chemical Co.*, patent claims directed to Vitamin B-12–active composition were determined to constitute patentable subject matter.[126] Vitamin B-12 existed in the liver of cattle, which was used to treat pernicious anemia since 1926.[127] Prior to the claimed invention, certain liver compounds were prepared that had the effect of treating pernicious anemia, although the treatments were expensive and often hard to tolerate.[128] The nature of the substance with the beneficial effect, including whether it was a hormone or vitamin, was unknown.[129] Employees of Merck, based on prior research assigned to the drug manufacturer, eventually isolated a pure, red, crystalline material derived from fermentates, which clinical tests confirmed to be the anti-pernicious anemia factor, and the employees subsequently named it Vitamin B-12.[130] Merck also isolated the pure, red, crystalline material from the liver of cattle.[131] The patent claims were directed to the composition, vitamin B-12 derived from fermentates, which the Court noted had a "very great therapeutic and commercial importance" and was "cheaply and abundantly produced."[132]

In addressing whether the compound was patentable as a product of nature, the Fourth Circuit noted that "[t]here is nothing in the language of the Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useable composition of matter," noting that all patentable materials are "products of nature in the sense that nature provides the basic source materials."[133]

The Fourth Circuit distinguished cases such as *Funk Brothers*, *General Electric*, and *Marden* as rejecting patents on products of nature that did not meet the requirements (novelty and non-obviousness) of the Patent Act, rather than as establishing a *per se* rule that products of nature could not be patent eligible.[134] In other words, it held that products of nature (i.e., substances that already existed in nature) could be patent eligible if they were novel and non-obvious. The Fourth Circuit reasoned that the B-12 active compositions at issue were unlike the cellulose claimed in *American Wood Fiber* and the synthetic alizarine claimed in *Cochrane* because, prior to Merck's work, "[n]o one had produced even a comparable product" to the claimed B-12 active composition and "[t]he active substance was unidentified and unknown."[135] This holding is inherently contradictory because if the substance already exists, but was simply unidentified and unknown, it is not "new" but simply "discovered."

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[126] Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958).
[127] *Id.* at 158.
[128] *Id.*
[129] *Id.*
[130] *Id.* at 159–60.
[131] *Id.* at 160.
[132] *Id.*
[133] *Id.* at 161–62.
[134] *Id.* at 162.
[135] *Id.* at 162–63.

The Circuit Courts of Appeals were seemingly beginning to hold, in contradiction to Supreme Court precedent, that discovering and isolating an active compound that already exists in nature can be a novel composition of matter. Relying on the aspirin (*Kuehmsted*) and adrenaline (*Park-Davis*) cases, these courts were establishing that purification of an existing substance could produce a patentable, new product if the difference was not only in degree, but in kind—in other words, the difference between a substance that is therapeutically and commercially useful and one that is not.[136]

C. Diamond v. Chakrabarty *and the Rise of Biotech Patents.*

The Supreme Court's decision in *Diamond v. Chakrabarty*,[137] which recognized the patent-eligibility of genetically engineered bacteria, did not explicitly rein in the "purification principle" articulated by the district courts. The claimed bacterium was a new strain into which two stable energy-generating plasmids were introduced to give the bacterium enhanced "hydrocarbon degradative" properties—in other words, the bacterium could break down multiple components of crude oil.[138] The claims directed to the product (the bacterium itself) were rejected by the examiner as a "product of nature."[139] The Supreme Court, however, determined that the man-made bacterium was a "manufacture" or "composition of matter" within the meaning of § 101 of the Patent Act.[140]

Notably in contrast to its more recent decisions, the Supreme Court stated that the terms of the Patent Act should be given wide scope due to the use of the term "any" in § 101, and that the courts should not "read into the patent laws limitations and conditions which the legislature has not expressed."[141] Given the broad language used by Congress, statutory subject matter was intended to encompass "anything under the sun that is made by man."[142] The Supreme Court distinguished the claimed man-made bacterium from unpatentable "laws of nature, physical phenomena, and abstract ideas" such as "a new mineral discovered in the earth or a new plant found in the wild" because the bacterium at issue was not a previously unknown natural phenomenon, but a "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity . . . . "[143] Unlike the bacterium in *Funk Brothers*, the new bacterium in *Chakrabarty* had "markedly different characteristics from any found in nature and [was] one having the potential for significant utility."[144] The crucial distinction between the claimed products in *Funk Brothers* and *Chakrabarty* was "between products of nature . . . and human-made invention."[145]

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[136] *Id.* at 163.
[137] *Diamond v. Chakrabarty*, 447 U.S. 303, 303–04 (1980).
[138] *Id.* at 305.
[139] *Id.* at 306.
[140] *Id.* at 309–10.
[141] *Id.* at 308.
[142] *Id.* at 309 (citing S. REP. NO. 82–1979, at 2399 (1952)).
[143] *Id.* at 309–10 (internal citations omitted).
[144] *Id.* at 310.
[145] *Id.* at 313.

After the Supreme Court's decision in *Chakrabarty*, the USPTO issued guidelines on patentable subject matter for living subject matter.[146] The USPTO believed that the Supreme Court had enunciated a very broad interpretation of the terms "manufacture" and "composition of matter" as used in § 101, and that it had not limited its decision to genetically engineered living organisms.[147] The USPTO believed that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[148] The guidelines stated that "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use'" is patentable subject matter and the "production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties or combinations whether by hand labor or by machinery," is a "manufacture" under § 101.[149] The USPTO indicated that it would decide the questions as to patentable subject matter under 35 U.S.C. § 101 on a case-by-case basis following the test set forth in *Chakrabarty*.[150]

Later, in 2001, the USPTO issued new utility examination guidelines, which involved purified products of nature.[151] The revised guidelines set forth that isolated DNA molecules satisfy § 101 if there "is a specific, substantial, and credible utility" for those molecules.[152] The new guidelines noted that patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice, citing the Pasteur patent for yeast and the Takamine patent for adrenaline[153] (which was upheld as valid by the Second Circuit Court of Appeals in *Parke-Davis*).[154]

After the *Chakrabarty* decision, and during the time the patent office guidelines were issued, the biotechnology industry, including the fields of genetics, drugs, and vaccines, expanded rapidly.[155] Commentators have stated that *Chakrabarty* "opened the floodgates for protection of biotechnology-related inventions."[156]

While early biological engineering companies were founded before the decision in *Chakrabarty*, such as Cetus (1971), Genentech (1976), and Amgen (1980),[157] subsequent growth in the industry has been astounding. For example, "as of December 31, 2003, there were 1,473 biotechnology companies in the United States," and "the U.S. revenues for the biotechnology industry had increased from $8 billion in 1992 to $39.2 billion."[158] By December 31, 2008, there were 1502 U.S.

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[146] *See* MPEP, *supra* note 27, § 2105.

[147] *Id.*

[148] *Id.*

[149] *Id.*

[150] *Id.*

[151] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

[152] *Id.* at 1093.

[153] *Id.*

[154] Parke-Davis & Co. v. H.K. Mulford & Co., 196 F. 496, 500 (2d Cir. 1912).

[155] Douglas Robinson & Nina Medlock, Diamond v. Chakrabarty*: A Retrospective on 25 Years of Biotech Patents*, 17 INTELL. PROP & TECH. J. 12, 12 (2005).

[156] *Id.*

[157] Eugene Russo, *Learning How to Manipulate DNA's Double Helix Has Fuelled Job Growth in Biotechnology During the Past 50 Years*, 421 NATURE 456, 456 (2003).

[158] Robinson & Medlock, *supra* note 155, at 13.

biotechnology companies with 195,000 employees,[159] although that figure decreased to 98,560 by the end of 2011.[160] The U.S. biotechnology industry spent $17.9 billion on research and development in 2003,[161] which increased to $30 billion in 2008.[162] Technologies developed by the industry include not only recombinant DNA technology, which was the original focus of the biotech industry in the 1970s, but monoclonal antibodies, cloning, protein engineering, biosensors, tissue engineering, stem cell technology, and vaccines.[163]

The number of patent applications and issued patents on biotechnology-related inventions has risen dramatically since *Chakrabarty*,[164] climbing from 2,160 in 1989 to 7,763 in 2002.[165] Biotechnology patents issued over the last twenty-five years "have covered a wide range of technologies and products from medicine and diagnostics for treating diseases to agriculture and environmental products for feeding the world's growing population and safeguarding the environment."[166]

The Supreme Court did not revisit the patentability of a "product of nature" in the thirty years since *Chakrabarty* until its *Prometheus* decision in March 2012.[167] Although the Federal Circuit had upheld the validity of several gene patents,[168] none of its cases until *Prometheus* directly addressed the question of whether such compositions encompass patentable subject matter under 35 U.S.C. § 101 or cannot be patented because they are "products of nature."[169]

III. BACKGROUND ON THE "LAW OF NATURE" EXCEPTION IN PROCESS PATENTS

The law on the patentability of so-called "products of nature" developed in tandem with the patentability of "abstract ideas" or "natural principles" inherent in the patentability of processes.[170] The discussion of patentability of "abstract ideas" or "natural principles" is an exception to subject-matter eligibility similar to the "law of

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[159] ERNST & YOUNG, BEYOND BORDERS GLOBAL BIOTECHNOLOGY REPORT 2008 30 (2008) [hereinafter BEYOND BORDERS 2008].

[160] ERNST & YOUNG, BEYOND BORDERS GLOBAL BIOTECHNOLOGY REPORT 2012 27 (2012) [hereinafter BEYOND BORDERS 2012].

[161] Robinson & Medlock, *supra* note 155, at 13.

[162] BEYOND BORDERS 2008, *supra* note 159, at 30.

[163] BIOTECHNOLOGY INDUSTRY ORGANIZATION, GUIDE TO BIOTECHNOLOGY 2008 2, 19–21, 36–37, 83 (2008).

[164] Robinson and Medlock, *supra* note 155, at 13.

[165] *Id.*

[166] *Id.*

[167] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1303–04 (2012).

[168] *See, e.g.*, *In re* Deuel, 51 F.3d 1552, 1560 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781, 783–85 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200, 1219 (Fed. Cir. 1991).

[169] *See* Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1293 (Fed. Cir. 2010) (noting that the Federal Circuit and the United States Supreme Court has never "directly decided the issue of the patentability of isolated DNA molecules"). Although the Federal Circuit had upheld the validity of several gene patents, no case directly addressed "the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101." *Id.*

[170] *See Prometheus*, 132 S. Ct. at 1293–94, 1300 (noting that abstract ideas, mathematical and scientific principles, and laws or products of nature are not patentable subject matter).

nature" doctrine. Below is a discussion of the development of this doctrine in relation to process patents.

A. Early Cases on the Patentability of Process Patents

1. Tilghman v. Proctor

In the early cases discussing the patentability of processes, it appeared that the novelty could stem, to a certain extent, from the natural principle involved, such as the operation of temperature and pressure. For example, in *Tilghman v. Proctor*, the Supreme Court found patentable a process for the "manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure."[171] The apparatus used was admittedly not novel.[172] Further, although the specification described a specific apparatus, the claims were not limited to that apparatus, because the process, not the apparatus, was claimed.[173] The inventor "discovered that fat can be dissolved into its constituent elements by the use of water alone under a high degree of heat and pressure."[174] While the invention was based on the chemical principle that "the elements of neutral fat require to be severally united with an atomic equivalent of water in order to separate from each other and become free," the Supreme Court characterized the invention as "a particular mode of bringing about the desired chemical union between the fatty elements and water" albeit not confined to a particular machine, finding that it was "not for a mere principle."[175] The claims did not preclude the use of other methods to separate fatty acids in glycerin from fatty bodies, such as sulfuric acid distillation or steam distillation.[176] Although arguably stating a "natural law" in the claims—that fat subjected to water at high temperature and pressure will dissolve into fatty acids—the Supreme Court did not hold the patent invalid on the basis that it was simply a natural law or that it preempted the broader, natural principle that high temperature and pressure tend to break chemical bonds.[177]

2. O'Reilly v. Morse

Another early case had sustained the validity of a process for creating vulcanized rubber by treating rubber with heat.[178] The classic Goodyear

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[171] Tilghman v. Proctor, 102 U.S. 707, 709 (1880).
[172] *Id.* at 718.
[173] *Id.* at 720–22.
[174] *Id.* at 721.
[175] *Id.* at 729.
[176] *Id.*
[177] *Id.* at 730, 734.
[178] Providence Rubber Co. v. Goodyear, 76 U.S. 788, 794 (1869). The claim was to "the curing of caoutchouc, or India-rubber, by subjecting it to the action of a high degree of artificial heat, substantially as herein described, and for the purposes specified." *Id.*

vulcanization patent wholly preempted the "natural phenomenon" that subjecting rubber to a high degree of heat when mixed with sulfur and a mineral salt would make it more durable and useful.[179] In *O'Reilly v. Morse*,[180] the Supreme Court sustained the validity of a patent for a process of using electromagnetism to produce distinguishable signs for telegraphy.[181] One of the claims, however, which covered the use of "electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances," was disallowed because the claim was not tied to any particular process or machinery.[182] The Supreme Court later explained that "the use of magnetism as a motive power, without regard to the particular process with which it was connected in the patent, could not be claimed, but that its use in that connection could."[183] On the other hand, Alexander Graham Bell's invention, the use of electric current to transmit vocal or other sounds, did not purport to claim electrical current in its natural statute but claimed "putting a continuous current, in a closed circuit, into a certain specified condition, suited to the transmission of vocal and other sounds, and using it in that condition for that purpose."[184] Stated differently, the claim was not "one for the use of electricity distinct from the particular process with which it is connected in his patent."[185] The early cases allowed "natural" principles when tied to a specific process or machine.

3. Gottschalk v. Benson

The Supreme Court readdressed what constituted a patentable "process" again in *Gottschalk v. Benson*.[186] Decided in 1972, the case involved a patent for a method of converting binary-coded decimal numerals into pure binary numerals for use with general purpose computers of any type.[187] The method was an algorithm—a set of rules for solving a problem in a finite number of steps.[188] In this case, although the computer performed the conversion, it could also be done "mentally" by a person.[189] The Supreme Court held that the claimed method was not patentable because "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."[190] The Supreme Court primarily took issue, it seems, with the breadth of the claims, stating that the process claims were "so abstract and sweeping" they covered both "known and unknown uses" of the conversion process, "performed through any existing machinery or future-devised machinery or without

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[179] *Id.* at 795.
[180] O'Reilly v. Morse, 56 U.S. 62, 86 (1853).
[181] *Id.* at 136.
[182] *Id.* at 86, 112–13.
[183] Dolbear v. Am. Bell Tel. Co., 8 S. Ct. 778, 782 (1888).
[184] *Id.*
[185] *Id.*
[186] Gottschalk v. Benson, 409 U.S. 63, 64 (1972).
[187] *Id.*
[188] *Id.* at 65.
[189] *Id.* at 67.
[190] *Id.* at 67.

any apparatus."[191] The Supreme Court distinguished between processes that are abstract and ones that transform an article to a different state or use a particular machine.[192] While not limiting patentable claims to processes either tied to a particular machine or that transformed articles or materials into a different state, the Supreme Court found that the claimed process had no use except with a general purpose computer and thus patenting the process would "wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."[193]

4. Parker v. Flook

Parker v. Flook expanded upon the principles set forth in *Benson* in addressing a process patent using an algorithm.[194] The Court held that the only novel feature of the claimed process was the mathematical formula, and that limiting the claims to a particular application of that formula did not render an unpatentable law of nature patentable.[195] Adding post-solution activity that was conventional or obvious (Flook's activity consisted of adjusting the alarm limit) could not "transform an unpatentable principle into a patentable process . . ."[196]

Other than citing examples of inventions containing mathematical algorithms or natural processes that were patentable, *Flook* did not provide substantive guidance as to when claims containing a law of nature constituted patentable subject matter. The decision simply stated that "[t]he process itself, not merely the mathematical algorithm, must be new and useful" and stated that the process must be considered for purposes of determining whether it was patent-eligible as if the algorithm were in the prior art.[197] *Flook* seemed to institute a "point of novelty" test requiring that the novelty of an invention lie outside the "law of nature" or algorithm utilized.[198] This test was soon rejected, but would bob its head up now and then, until being adopted in *Prometheus.*[199]

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[191] *Id.* at 68.
[192] *Id.* at 69.
[193] *Id.* at 71–72.
[194] Parker v. Flook, 437 U.S. 584, 585–86, 594–96 (1978).
[195] *Id.* at 589–91.
[196] *Id*. at 589–90.
[197] *Id.* at 591–92.
[198] *Id*. at 589, 590–91.
[199] *See, e.g.*, Crocs, Inc., v. Int'l Trade Comm'n, 598 F.3d 1294, 1303 (Fed. Cir. 2010) (noting that when "determining whether an accused product infringes a patented design, this court applies the 'ordinary observer' test, without any 'point of novelty' perspective."); Egyptian Goddess, Inc., v. Swisa, Inc., 543 F.3d 665, 678 (Fed. Cir. 2008) (rejecting the point of novelty test); Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1384 (Fed. Cir. 2009) (finding the point of novelty test as problematic because "it might cause the court to focus 'on whether the accused design has appropriated a single specified feature of the claimed design, rather than on the proper inquiry, i.e., whether the accused design has appropriated the claimed design as a whole.'").

B. The Machine or Transformation Test for Process Patents

1. Diamond v. Diehr

In a case that is difficult to reconcile with *Flook*—*Diamond v. Diehr*—the Supreme Court found a patent on a process for curing synthetic rubber subject-matter eligible.[200] The process claimed in *Diehr* functioned by continuously updating a mathematical calculation of the time to left cure, as a function of temperature and pressure, in order to determine when the machine should open the mold.[201] Of course, the mathematical equation used in that process was, standing alone, a scientific principle and abstract, but was incorporated in a process that used a mold to shape the raw material under heat and pressure and then cure the rubber in the mold.[202] The claims involved the transformation of an article—raw, uncured, synthetic rubber—into "a different state or thing."[203] That the claimed method used the Arrhenius equation, a previously known scientific principle, did not render it patent-ineligible because the claims were not an attempt to patent a mathematical formula, but were "drawn to an industrial process."[204] Further, the claims did not preempt the use of the equation, but only sought to "foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process."[205]

Diehr, in essence, began to crystallize the so-called machine or transformation test, noting that the patent eligibility of a process depended on whether it was tied to a particular machine or transformed an article "to a different state or thing."[206] While *Diehr* reiterated the general rule that laws of nature, natural phenomena, and abstract ideas are not eligible for patent protection,[207] it specifically rejected the "point of novelty" test set forth in *Flook*, stating that process claims must be considered "as a whole" and that it is "inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."[208]

Diehr noted that a process itself could be patentable even though all of the steps were already known in the art.[209] Indeed, the point of novelty approach outlined in *Flook* presents several sticky problems, including the fact that the novelty in many inventions lies in underlying scientific principles.[210] It should also be noted that in *Flook* and *Diehr*, the natural law or abstract concept ideas were being applied to process claims, not claims to particular "manufacture[s]" or "composition[s] of matter," which present different policy issues.[211]

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[200] Diamond v. Diehr, 450 U.S. 175, 177 (1981).
[201] *Id.* at 177–78.
[202] *Id.*
[203] *Id*. at 184.
[204] *Id.* at 192–93.
[205] *Id.* at 187.
[206] *Id.* at 184.
[207] *Id.* at 185.
[208] *Id.* at 188.
[209] *Id.*
[210] *See* Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253, 1278 (2011).
[211] *See Diehr*, 450 U.S. at 185–87.

As of the early 1990s, however, *Chakrabarty* and *Diehr* (and to a certain extent *Flook* and *Benson*) had broadly interpreted § 101, especially in terms of "products of nature," which are generally claimed as compositions of matter or manufacture and as "natural law" principles integrated into process claims.[212] *Chakrabarty* noted that the comprehensive terms of § 101, including the word "any," demonstrated that Congress wanted the patent laws to be given a wide scope.[213] *Diehr* warned against reading "limitations and conditions" that Congress had not expressed into § 101.[214] The Supreme Court expansively read the statutory term "composition of matter" as one that "has been construed consistent with its common usage to include 'all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.'"[215] Likewise, a "manufacture" under § 101 was interpreted "in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.'"[216] A "manufacture" or "composition of matter" was patent eligible if it demonstrated "the hand of man," or in other words, was "a product of human ingenuity 'having a distinct name, character [and] use.'"[217]

2. Bilski v. Kappos

In 2010, the Supreme Court seemed, if anything, to adopt and expand the holding of *Diehr* in *Bilski v. Kappos*,[218] which the blog *Patently-O* characterized as "business as usual."[219] The Federal Circuit's decision in *Bilski* formally presented and applied the machine-or-transformation test, holding that a claimed process is patent-eligible under § 101 if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[220] The Federal Circuit required one of those two tests to be met for claims to a method to be considered patent-eligible subject matter.[221]

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[212] *See, e.g.*, Diamond v. Chakrabarty, 407 U.S. 303, 308 (1980) ("In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."); *Diehr*, 450 U.S. at 184 (holding that "a physical and chemical process for molding precision synthetic rubber falls within the § 101 categories of possibly patentable subject matter.").

[213] *Chakrabarty*, 447 U.S. at 308.

[214] *Diehr*, 450 U.S. at 182.

[215] *Chakrabarty*, 447 U.S. at 308 (quoting Shell Dev. Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957)).

[216] *Id.* at 308 (quoting Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931)).

[217] *Id.* at 309–10.

[218] Bilski v. Kappos, 130 S. Ct. 3218, 3229, 3230–31 (2010).

[219] Dennis Crouch & Jason Rantanen, *Bilski v. Kappos*, PATENTLY-O (June 28, 2010), http://www.patentlyo.com/patent/2010/06/bilski-v-kappos-business-methods-out-software-still-patentable.html.

[220] *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).

[221] *Id.* at 961–62.

In its modification of the Federal Circuit's decision in *Bilski*, the Supreme Court reiterated the broad nature of § 101—which makes its later pronouncement in *Myriad* puzzling—stating that, "[i]n choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."[222] The Supreme Court again reiterated the exclusions from patent eligible subject matter for "laws of nature, physical phenomena, and abstract ideas" noting that these were "not required by the statutory text" but have "defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years."[223] In light of the broad reach of the definition of statutory subject matter under the Patent Act, the Supreme Court held that the Federal Circuit's reliance on the "machine or transformation test," in determining what constituted a "process" for purposes of § 101, was too rigid in light of the mandate that the "courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'"[224] The Supreme Court held that the "machine or transformation" test was not the exclusive test for patent eligibility of a process, but simply a "useful and important clue" to whether a process constitutes statutory subject matter under § 101.[225] Ironically, in light of its later decision in *Prometheus*, the Supreme Court noted that limiting patent eligibility to those inventions that meet the "machine-or-transformation test" may create "uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals"[226] (and such uncertainty has arisen in the past few years, attributable in part to recent Supreme Court precedent). Although *Bilski* defined patentable-subject matter broadly, it held that the patent claims at issue, which were directed to the concept of hedging risk and the application of that concept to energy markets, were invalid as an attempt to patent abstract ideas according to the holdings in *Benson*, *Flook*, and *Diehr*.[227]

C. Post-Bilski *"Law of Nature" Cases*

After *Bilski*, the Federal Circuit addressed a wide variety of "natural law" or "abstract idea" cases and attempted to apply Supreme Court precedent addressing the scope of § 101.[228] An expected result from the vague opinion in *Bilski*, the scope of § 101 has not been clarified by subsequent precedent.[229]

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[222] *Bilski*, 130 S. Ct. at 3225 (citing Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980)).

[223] *Id.* at 3225.

[224] *Id.* at 3225–26 (citing Diamond v. Diehr, 450 U.S. 175, 182 (1981)).

[225] *Id.* at 3327.

[226] *Id.* at 3227; *see also* CLS Bank Int'l. v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1314 (Fed. Cir. 2013).

[227] *Bilski*, 130 S. Ct. at 3229–30.

[228] *See, e.g.*, *CLS Bank*, 717 F.3d at 1276–84 (finding that "the asserted claims drawn to methods, computer-readable media, and systems are not patent eligible and hence invalid under § 101."); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066–70 (Fed. Cir. 2011)

1. Research Corporation Technologies v. Microsoft Corporation

In *Research Corporation Technologies v. Microsoft Corporation*, the Federal Circuit addressed the patentability, under § 101, of method patents related to digital image half-toning.[230] Half-toning techniques bridge the gap between color-specific arrays of pixels created by a computer and computer displays, and printers that can only use a limited number of primary colors to display digital images.[231] Half-toning simulates a continuous tone image through the use of dots, allowing computers to "present many shades and color tones with a limited number of pixel colors."[232] The technique places "the dots of primary colors in a formation that gives the viewer the illusion of many more shades of gray or varying colors."[233] As the Court explained, "Digital halftoning technology thus allows computer displays and printers to render an approximation of an image by using fewer colors or shades of gray than the original image."[234] The challenged invention was essentially software (presumably consisting of algorithms) involving an "improved blue noise mask . . . stored in a computer's memory, to carry out a pixel-by-pixel comparison of the mask to the digital image."[235] The Federal Circuit found that the subject matter of the patent was a "'process' for rendering a half-tone image," which qualified as patent-eligible subject matter "under both the categorical language of section 101 and the process definition in section 100," subject only to the Supreme Court's three exceptions to subject matter eligibility.[236] The Federal Circuit found that the claimed process was not too "abstract," holding that the invention presented "functional and palpable applications in the field of computer technology," including a "method of and apparatus for the halftone rendering of grayscale images in which a digital data processor is utilized in a simple and precise manner to accomplish the halftone rendering."[237] Relying on the Supreme Court's reasoning in *Diehr*, the Federal Circuit found that the patentees were not seeking to patent a mathematical formula, but instead sought patent protection for the process of half-toning in computer applications, and therefore the claims were directed toward patent-eligible subject matter.[238]

(finding the methods of evaluating and improving safety of immunization schedules "reasonably meet the threshold of § 101 eligibility").

[229] *See* MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1259 (Fed. Cir. 2012) ("Our opinions spend page after page revisiting our cases and those of the Supreme Court, and still we continue to disagree vigorously over what is or is not patentable subject matter.").

[230] Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 865–66 (Fed. Cir. 2010).

[231] *Id.* at 862–63.

[232] *Id.* at 863.

[233] *Id.*

[234] *Id.*

[235] *Id.* at 864.

[236] *Id.* at 868.

[237] *Id.* at 868–69.

[238] *Id.* at 869.

2. Ultramercial LLC v. Hulu LLC

In *Ultramercial, LLC v. Hulu, LLC*,[239] the court characterized the "abstractness" exception to subject-matter eligibility as having "presented a different set of interpretive problems, particularly for the § 101 'process' category."[240] It further noted that "[b]oth members of the Supreme Court and this Court have recognized the difficulty of providing a precise formula or definition for the judge-made ineligible category of abstractness."[241] The Federal Circuit held that the claimed invention, a patent for a method of monetizing and distributing copyrighted products over the Internet, was not so manifestly abstract as to render it ineligible for patent protection.[242] In noting that "[a]lthough abstract principles are not eligible for patent protection, an application of an abstract idea may well be deserving of patent protection[,]" the Federal Circuit stated that "inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act."[243] The patents at issue, it held, disclosed a practical application of the idea that advertising can be used as a form of currency, disclosing "a particular method for monetizing copyrighted products" consisting of specific steps.[244] Although "the broadly claimed method . . . d[id] not specify a particular mechanism for delivering media content to the consumer . . . [the] breadth and lack of specificity d[id] not render the claimed subject matter impermissibly abstract."[245] When the Supreme Court later vacated this decision for further consideration in light of *Prometheus*,[246] the Federal Circuit affirmed its original holding, finding that the subject matter of the patent was a "'process' within the language and meaning of 35 U.S.C. § 101."[247] It noted that, because patents are presumed valid, lack of patent-eligible subject matter under § 101 must be proven by clear and convincing evidence.[248] The crucial distinction is whether the claim is an "*application* of an abstract idea" (and therefore patent-eligible) or "*to* the abstract idea itself" (and therefore not patent-eligible).[249]

3. CyberSource Corp. v. Retail Decisions, Inc.

The Federal Circuit has found other method patents ineligible under § 101, however. In *CyberSource Corp. v. Retail Decisions, Inc.*, the court addressed a claim to a "process for verifying the validity of credit card transactions over the Internet" and a "computer readable medium containing program instructions for executing the

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[239] Ultramercial, LLC v. Hulu, LLC, 657 F.3d 1323, 1326 (Fed. Cir. 2011).
[240] *Id.*
[241] *Id.* at 1327.
[242] *Id.* at 1329–30.
[243] *Id.* at 1327, 1328 (citations omitted).
[244] *Id.* at 1328.
[245] *Id.* at 1329.
[246] *See* WildTangent, Inc. v. Ultramercial, LLC, 132 S. Ct. 2431, 2431 (2012).
[247] Ultramercial, LLC v. Hulu, LLC, 722 F.3d 1335, 1337 (Fed. Cir. 2013).
[248] *Id.* at 1338.
[249] *Id.* at 1343 (emphases in original).

same process."[250] The Federal Circuit has held that the method claim was not tied to a particular machine (the "Internet"), because even if the Internet could be considered a machine, it did not perform the steps of the claimed method and the claims did not require use of the Internet because the infringer could obtain the data from other sources, including databases.[251] Although under *Bilski*, the claimed method need not be tied to a particular machine, the court found that the patent did not "recite patent-eligible subject matter because it [wa]s drawn to an unpatentable mental process."[252] The claim was not limited in scope to any particular fraud detection mechanism, and therefore the method could be performed by the human mind.[253] Specifically, the claim extended to "any method of detecting credit card fraud based on information relating past transactions to a particular 'Internet address,'"[254] including methods that could be performed by the human mind.[255]

The other challenged claim—a "Beauregard" claim "to a computer readable medium (e.g., a disk, hard drive, or other data storage device) containing program instructions for a computer to perform a particular process"[256]—was likewise found not patent-eligible because it was directed to "a method for detecting credit card fraud"[257] rather than "'drawn to a specific' computer readable medium."[258] The court stated, "[T]he incidental use of a computer to perform the mental process . . . [steps] d[id] not impose a sufficiently meaningful limit on the claim's scope . . . [to] make the otherwise unpatentable method patent-eligible under § 101."[259] Both claims were in essence a method consisting of "only the general approach of obtaining information about credit card transactions utilizing an Internet address and then using that information in some undefined manner to determine if the credit card transaction is valid."[260] Both claims were therefore invalid under § 101 because they claim unpatentable mental processes or abstract ideas.[261]

4. Dealertrack, Inc. v. Huber

In *Dealertrack, Inc. v. Huber*, the Federal Circuit addressed the patent eligibility of a "computer-aided method and system . . . for processing credit applications over electronic networks."[262] In essence, the method proposed a "'central processor,' which receives credit application data from dealers, processes the data to conform to the individual application forms of different banks, forwards the completed applications

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[250] CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366, 1367 (Fed. Cir. 2011).
[251] *Id.* at 1370.
[252] *Id.* at 1371.
[253] *Id.* at 1372.
[254] *Id.*
[255] *Id.* at 1372.
[256] *Id.* at 1373.
[257] *Id.* at 1374.
[258] *Id.* at 1374–75.
[259] *Id.* at 1375.
[260] *Id.* at 1376.
[261] *Id.* at 1376–77.
[262] Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1317 (Fed. Cir. 2012).

to banks selected by the dealer, receives answers from the banks, and forwards those answers back to the dealer."[263] The Federal Circuit held that the claims were "invalid as being directed to an abstract idea preemptive of a fundamental concept or idea that would foreclose innovation in this area."[264] The claims described the concept of "processing [application] information through a clearinghouse," which, if allowed, would "wholly preempt the clearinghouse concept."[265] The claims were not limited to a specific application or algorithm, nor tied to a specific machine.[266] Limiting the claims to a particular application (the car loan application process), could not render the method patent eligible, because under *Bilski* and *Diehr* limiting the claims to a "particular technological environment," without more, was insufficient.[267]

5. Fort Properties, Inc. v. American Master Lease, LLC

In *Fort Properties, Inc. v. American Master Lease, LLC*, the Federal Circuit likewise held that a method patent, for creating real estate investment instruments adapted for performing tax-deferred exchanges, was impermissibly abstract.[268] The claims disclosed "an investment tool not requiring the use of a computer" as a method involving several conceptual steps.[269] The Federal Circuit held that the invention's "intertwinement with deeds, contracts, and real property" did not transform the abstract method "into patentable subject matter merely because of connections to the physical world . . . ."[270] The claims with an additional limitation "requir[ing] the computer to 'generate a plurality of deedshares'" were likewise not directed to patent eligible subject matter because the use of the computer did not "impose meaningful limits on the claim's scope."[271] Here, the invention did not "require[] intricate and complex computer programming," nor did it have a "specific application to the Internet and a cybermarket environment" or represent "advances in computer technology."[272] The computer limitations were simply "insignificant post-solution activity."[273]

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[263] *Id.*
[264] *Id.* at 1333.
[265] *Id.*
[266] *Id.* at 1333–34.
[267] *Id.* at 1334.
[268] Fort Props., Inc. v. Am. Master Lease LLC, 671 F.3d 1317, 1323–24 (Fed. Cir. 2012).
[269] *Id.* at 1322.
[270] *Id.*
[271] *Id.* at 1323.
[272] *Id.*
[273] *Id.*

6. Comparing *CLS Bank International v. Alice Co.* with *Bancorp Services LLC v. Sun Life Assurance Co.*

The differences between different Federal Circuit panels on the scope of the "abstract idea" exception to subject matter eligibility and the difficulty in establishing clear standards is best shown by the different holdings and rationales in two Federal Circuit decisions in the same month: *CLS Bank International v. Alice Corporation Pty.*[274] and *Bancorp Services, LLC. v. Sun Life Assurance Company of Canada (U.S.).*[275] In both cases, the Federal Circuit addressed the patentability of inventions implemented by computers. In *CLS Bank,* the Federal Circuit addressed the patentability of "a computerized trading platform for exchanging obligations in which a trusted third party settles obligations between a first and second party" in a manner that eliminates "settlement risk."[276] The method claims included, *inter alia*, steps for: (1) creating shadow credit and debit records; (2) obtaining from the exchange institutions a start-of-the-day balance for both the shadow credit record and shadow debit record; (3) adjusting the shadow credit and/or shadow debit record for completed transactions; (4) allowing only those transactions that do not result in the value of the shadow debit being less than the value of the shadow credit; and (5) instructing the exchange institutions as to exchange credits or debits to the credit record and debit record of the respective parties.[277] There were also system and product (media) claims that implemented the claimed method.[278]

The Federal Circuit noted that the "[t]he abstractness of the 'abstract ideas' test to patent eligibility has become a serious problem, leading to great uncertainty and to the devaluing of inventions of practical utility and economic potential"[279] and that "the dividing line between inventions that are directed to patent ineligible abstract ideas and those that are not remains elusive."[280] The Court tried to establish a test for what is an "abstract idea" stating that "a claim drawn to a *specific way* of doing something with a computer is likely to be patent eligible whereas a claim to *nothing more than the idea* of doing that thing on a computer may not [be]."[281] Further, patent eligibility must be determined based on the claims as a whole.[282] The Federal Circuit held that if "it is not manifestly evident that a claim is directed to a patent ineligible abstract idea, that claim must not be deemed for that reason to be inadequate under § 101."[283] Likewise, it is inappropriate to hold that claims are directed to an "abstract idea" under § 101 "[u]nless the single most reasonable understanding is that a claim is directed to nothing more than a fundamental truth

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[274] CLS Bank Int'l v. Alice Corp. Pty., 685 F.3d 1341, 1355, *reh'g en banc granted, opinion vacated*, 484 F. App'x 559 (Fed. Cir. 2012).

[275] Bancorp Servs., LLC v. Sun Life Assurance Co. of Canada, 687 F.3d 1266, 1281 (Fed. Cir. 2012).

[276] *CLS Bank*, 685 F.3d at 1343.

[277] *Id.* at 1343–44.

[278] *Id.* at 1344–45.

[279] *Id.* at 1348–49.

[280] *Id.* at 1349.

[281] *Id.* at 1351 (emphases in original).

[282] *Id.* at 1351–52.

[283] *Id.* at 1352.

or disembodied concept . . . ."[284] The rationale for the Federal Circuit's decision was that the "implicit" exception for abstractness created by the Supreme Court should not be permitted to override Congress's intent in creating broad patent subject matter eligibility in § 101 of the Patent Act.[285] In accordance with this limited view of the "abstract idea" exception, the Federal Circuit held that the method, system and product claims at issue were patent-eligible subject matter,[286] finding that the claims as a whole were directed to more than a fundamental truth or disembodied concept, because they required computer implementation and were limited to a specific application of the business concept.[287]

A few weeks later, a different panel of the Federal Circuit held in *Bancorp Services* that claims to a system for administering and tracking the value of separate-account life insurance policies, issued pursuant to corporate-owned life insurance and bank-owned life insurance were not patent-eligible.[288] The method at issue disclosed "formulae for determining the values required to manage a stable value protected life insurance policy."[289] As construed by the Federal Circuit, the dependent claims "requir[ed] that the method be 'performed by a computer.'"[290] The Federal Circuit concluded that the claims at issue covered "no more than abstract ideas and therefore do not recite patent-eligible subject matter."[291]

Although computers offer capabilities and utilities that can constitute patent-eligible subject matter, they are basically "electronic device[s] for performing mathematical or logical operations."[292] The use of a computer to implement an otherwise patent-ineligible process therefore cannot "circumvent the prohibition against patenting abstract ideas."[293] To confer subject-matter eligibility, the use of the computer must be integral to the claimed invention and "impose meaningful limits on the scope of those claims."[294] Here, the use of a computer did not render the claims patent-eligible because the computer was used only for performing calculations and it did not limit the scope of the claims in any way.[295] The method for determining the values at issue was "a matter of mere mathematical computation" and claimed nothing more than an "abstract idea of managing a stable value protected life insurance policy by performing calculations and manipulating the results."[296] This situation contrasts that in *CLS Bank*, where computer limitations played "a *significant part* in the performance of the invention," and the claims were "limited to a *very specific application* of the [inventive] concept."[297] Yet as in *CLS*

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[284] *Id.*
[285] *Id.* at 1352 n.3.
[286] *Id.* at 1356.
[287] *Id.* at 1353–56.
[288] Bancorp Servs., LLC. v. Sun Life Assurance Co. of Can., 687 F.3d 1266, 1280–81 (Fed. Cir. 2012).
[289] *Id.* at 1270.
[290] *Id.* at 1271.
[291] *Id.* at 1277.
[292] *Id.*
[293] *Id.* at 1278.
[294] *Id.*
[295] *Id.*
[296] *Id.* at 1280.
[297] *Id.* at 1280–81 (emphases in original).

Bank, the Federal Circuit did note the importance of construing the claims before performing an analysis of subject matter eligibility under § 101, although it construed the claims in this case where the district court declined to do so.[298]

The Federal Circuit granted *en banc* review in the *CLS* case and affirmed the decision that the asserted system claims are not directed to eligible subject matter under 35 U.S.C. § 101.[299] No single opinion of the Court had a majority,[300] so the *CLS* decision fails to provide clear guidance in analyzing the "abstract ideas" exception to patent-eligible subject matter under § 101. While the subject-matter eligibility exception for "abstract ideas" does not directly impact the "product of nature" exception, the Federal Circuit's (and perhaps the Supreme Court's) opinion on whether such exceptions should be narrowly or broadly construed, and whether § 101 should be a threshold determination, will affect any "product of nature" analysis. *CLS* did not state that subject matter eligibility need always be addressed first, but one of the plurality opinions stated that "district courts may exercise their discretion to begin elsewhere when they perceive that another section of the Patent Act might provide a clearer and more expeditious path to resolving a dispute."[301]

7. Classen Immunotherapies v. Biogen IDEC

After *Bilski*, the Federal Circuit also ruled on the patentability of diagnostic method claims in *Classen Immunotherapies v. Biogen IDEC*.[302] Initially, the district court granted summary judgment of invalidity of the asserted claims because they claimed an abstract idea,[303] and that decision was perfunctorily affirmed on appeal by the Federal Circuit.[304] What is, in hindsight, a curious decision in light of its later decision in *Prometheus*, the Supreme Court vacated *Classen* in light of *Bilski* and remanded the case to the Federal Circuit.[305] Upon consideration of *Bilski*, the Federal Circuit determined that the patent claims, directed toward a method of lowering the risk of chronic immune-related disorders, were patent-eligible subject matter, although the only physical step in the claimed method was administering the vaccine, and many of the steps constituted no more than a "correlation" between vaccines and chronic immune disorder.[306] Judge Newman dissented, stating, "The immunization step of the #739 patent, like updating the alarm limit in *Parker v. Flook*, is nothing more than post-solution activity" that cannot "transform the unpatentable principle—that a correlation exists between vaccination schedules and

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[298] *Id.* at 1280.

[299] CLS Bank Int'l v. Alice Corp. Pty. Ltd., 717 F.3d 1269, 1273 (Fed. Cir. 2013).

[300] *Id.* at 1292 n.1 (Rader, J., concurring-in-part and dissenting-in-part).

[301] *Id.* at 1284.

[302] Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1068–69 (Fed. Cir. 2011).

[303] Classen Immunotherapies, Inc. v. Biogen IDEC, No. WDQ-04-2607, 2006 WL 6161856, at *6 (D. Md. 2006), *aff'd*, 304 Fed. App'x. 866 (Fed. Cir. 2008), *cert. granted, judgment vacated*, 130 S. Ct. 3541 (2010), *aff'd in part, vacated in part, rev'd in part*, 659 F.3d 1057 (Fed. Cir. 2011).

[304] *Classen*, 304 Fed. App'x. at 867.

[305] *Classen*, 130 S. Ct. at 3541.

[306] *Classen,* 659 F.3d at 1068–69.

incidence of chronic immune disease—into a patentable process."[307] This decision, particularly the dissent, foreshadows *Prometheus*,[308] although it would have been difficult at the time to predict the result because *Bilski* seemed to broaden what the subject-matter eligible and seemed careful not to disturb prior precedent.

IV. COMBINING THE "PRODUCT OF NATURE" AND "LAW OF NATURE" DOCTRINES IN *PROMETHEUS* AND *MYRIAD*

A. The Supreme Court's Decision in Prometheus

In 2012, the Supreme Court again addressed what constitutes a "law of nature" in a decision that may have far reaching implications on the patentability of articles of "manufacture" or "compositions of matter" that are arguably products of nature. In *Mayo v. Prometheus*,[309] the Supreme Court addressed whether a method for calibrating a proper dosage of drugs was patent-eligible. While the decision recited the oft-repeated adage that, "Although 'laws of nature, natural phenomena, and abstract ideas' are not patentable subject matter . . . 'an *application* of a law of nature . . . to a known structure or process may [be],'"[310] it noted that, to be patentable, an invention must be tied to a concrete application of the law of nature in question.[311]

The method claim at issue involved the use of thiopurine drugs to treat autoimmune diseases.[312] These drugs are metabolized by the body, producing metabolites in the bloodstream.[313] Because patients metabolize the drug differently, it has been difficult for physicians to determine whether the dosage for a particular patient "is too high, risking harmful side effects, or too low, and . . . likely ineffective."[314] The patent claims at issue disclosed a process to identify correlations between metabolite levels and potential harm.[315] The claims included: (1) an "administering" step, requiring the drug to be administered to the patient; (2) a "determining step," requiring the level of the metabolite in the patient's blood to be measured; and (3) a "wherein step" essentially describing the level of metabolite concentrations above which harmful side effects are likely and below which the drug dosage is likely ineffective.[316] The Supreme Court held that the claims at issue "set

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[307] *Id.* at 1079 (Moore, J., dissenting).

[308] *See id.* at 1076–81; *see also* Mayo Collaborative Servs. v. Prometheus Labs. Inc., 132 S. Ct. 1289, 1305 (2012) (holding that the method claims of a diagnostic process using thiopurine drugs were ineligible patent subject matter, because the correlations between the administered drug and the concentrations of certain metabolites in the blood of the patient were laws of nature).

[309] *Prometheus*, 132 S. Ct. at 1294.

[310] *Id.* at 1293–94.

[311] *Id.* at 1294.

[312] *Id.*

[313] *Id.* at 1295.

[314] *Id.*

[315] *Id.*

[316] *Id.*

forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[317]

The Supreme Court noted that it has long held that § 101, which defines patent-eligible subject matter, contains an "important implicit exception" for "laws of nature, natural phenomena, and abstract ideas."[318] Natural phenomena, such as new minerals or wild plants, or natural laws, such as the law of gravity, are "manifestations of . . . nature, free to all men and reserved exclusively to none"[319] and "are the basic tools of scientific and technological work."[320]

To be patentable, a process using a natural law must contain an "'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."[321] The Supreme Court held that the claimed processes lacked an inventive concept (other than the natural law itself) because the steps of the process (administering the drug and determining the level of metabolite in the blood) involved "well-understood, routine, conventional activity previously engaged in by researchers in the field."[322] The Supreme Court held that the relationship between the concentration of metabolites in the blood and the effectiveness of the drug was a law of nature because it was a consequence of a natural process—the way thiopurine compounds are metabolized by the body.[323] The other steps were nothing more than "conventional or obvious" "[pre]-solution activity" insufficient "to transform a[] . . . law of nature into a patent-eligible" process.[324]

In rendering its decision, which in essence resurrected the "point of novelty" test, the Supreme Court attempted to harmonize its prior decisions in *Diamond v. Diehr*[325] and *Parker v. Flook*,[326] two process cases that involved natural laws and that were, for all practical purposes, irreconcilable.[327] The Supreme Court, in interpreting *Diehr*, claimed that, while the process in *Diehr* involved the use of a mathematical equation, "the additional steps of the process integrated the equation into the process as a whole."[328] The Court's statement that *Diehr* "nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional,"[329] is not supported by the record, however. As noted in

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[317] *Id.* at 1296.

[318] *Id.* at 1293.

[319] *Id.* (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[320] *Id.*

[321] *Id.* at 1294.

[322] *Id.*

[323] *Id.* at 1297.

[324] *Id.* at 1298.

[325] Diamond v. Diehr, 450 U.S. 175, 192–93 (1981) (holding that the claim fell within the § 101 categories of patentable subject matter because the claim was not merely "an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products").

[326] Parker v. Flook, 437 U.S. 584, 594–95 (1978) (finding that the method, which included a mathematical formula for updating alarm limits during the catalytic conversion process, was not patentable).

[327] *Prometheus*, 132 S. Ct. at 1298.

[328] *Id.*

[329] *Id.* at 1299.

the *Diehr* opinion, the patent examiner specifically rejected the claims as non-patentable subject matter because the steps carried out in the computer were non-statutory subject matter, and the remaining steps—installing rubber in the press and the closing of the press—were "conventional and necessary to the process and cannot be the basis of patentability."[330] Nevertheless, *Prometheus* characterized the process steps in *Diehr* as adding "something" significant and "transform[ing] the process into an inventive application of the formula."[331]

By contrast, *Prometheus* characterized the process in *Flook* as an unpatentable formula for computing an updated alarm system because the claims lacked an explanation of how the variables would be selected, a disclosure of the chemical processes at work, or a means of adjusting the alarm limit.[332] The Supreme Court characterized the claims in *Flook* as directed to non-statutory subject matter because the other steps in the process did not limit the claim to a particular application.[333] Further, the process contained no "inventive concept" other than the algorithm because the chemical processes involved, the practice of monitoring the process variable, and the uses of alarm limits were all "well known."[334] While the Supreme Court tried to reconcile its prior decisions in *Flook* and *Diehr*, *Prometheus* adopts the *Flook* "point of novelty" test, and requires that if a process includes a natural law or abstract concepts, the other steps in the process must be non-obvious or more than routine for the process to be patent-eligible.[335]

Arguably, *Prometheus* only applies to process or method claims, and not to "manufacture" or "composition of matter" claims. Extended to its logical conclusion, however, *Prometheus* could have a substantial effect on such claims, because if a "product of nature" is subjected to nothing more than "routine, conventional" activity and claimed as a manufacture or composition of matter, it could be ruled non-eligible subject matter even if it does not exist in nature and only exists through the "hand of man."[336]

B. The Supreme Court's Decision in Myriad

Despite hopes to the contrary, the final word on the scope of the "product of nature" exception to patent-eligibility was not forthcoming in the cases addressing the patentability of isolated DNA, which is typically claimed as a composition of matter.[337] Initially, the Federal Circuit upheld the patentability of DNA and isolated DNA in *Association for Molecular Pathology v. United States Patent and Trademark*

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[330] *Diehr*, 450 U.S. at 180–81.

[331] *Prometheus*, 132 U.S. at 1299.

[332] *Id.*

[333] *Id.*

[334] *Id.*

[335] *Id.* at 1299–300.

[336] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980) (finding that the micro-organism constitutes patentable subject matter because his claim is "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter").

[337] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116, 2117, 2219–20 (2013).

Office based on the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers*, which the Federal Circuit believed controlled the analysis.[338] The Supreme Court initially vacated that decision and directed the Federal Circuit to reconsider its decision based on *Prometheus*.[339]

On remand, the Federal Circuit again held that that cDNA and isolated DNA constitute patent-eligible subject matter, with each of the panel members (Judges Lourie, Bryson, and Moore) adhering to their previous opinions in the case.[340] The Federal Circuit held that *Prometheus* does not control the determination of whether claims to a "composition of matter," such as isolated DNA, are patent-eligible subject matter because "compositions of matter" are "expressly authorized as suitable patent-eligible subject matter in § 101."[341] Instead, "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 . . . ."[342]

The Federal Circuit held that isolated DNA molecules are not products of nature because they are not found in nature, but are "obtained in the laboratory and are man-made, the product of human ingenuity."[343] The use of materials found in nature is not determinative because all compositions of matter, including chemical and biological inventions, are made from natural materials.[344] The primary distinction between products of nature and patentable compositions of matter, like the distinction between the unpatentable mixed bacteria cultures in *Funk Brothers* and the patentable, engineered bacteria in *Chakrabarty*, is that the patentable composition of matter has "markedly different characteristics" from the unpatentable product of nature.[345] Isolated DNA, the Federal Circuit found, was "markedly different" from genomic DNA due to the "distinctive chemical form" of the former compared to DNA found in the human body, because the covalent bonds of the isolated DNA have been severed and the isolated molecule is a "fraction of a naturally occurring DNA molecule."[346] By contrast, "isolated DNA is a tangible, man-made composition of matter defined and distinguished by its objectively discernible chemical structure."[347]

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[338] Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office, 653 F.3d 1329, 1350 (Fed. Cir. 2011), *vacated and remanded*, 132 S. Ct. 1794, *aff'd in part and rev'd in part*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), *aff'd in part and rev'd in part*, 133 S.Ct. 2107 (2013).

[339] *See* Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office, 689 F.3d 1303, 1308 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), *aff'd in part and rev'd in part*, 133 S.Ct. 2107 (2013).

[340] *Id.* at 1333, 1336 (Moore, J., concurring-in-part), 1348 (Bryson, J., concurring-in-part and dissenting-in-part).

[341] *Id.* at 1325.

[342] *Id.* at 1326.

[343] *Id.* at 1325.

[344] *Id.*

[345] *Id.* at 1327–28. The court distinguished older cases such as *American Wood-Paper* and *Cochrane* as having been decided on novelty, not patent subject matter eligibility, grounds. *Id.* at 1326 n.10.

[346] *Id.* at 1328.

[347] *Id.* at 1330.

Judge Moore's concurrence stated that *Funk Brothers* and *Chakrabarty* "do not stake out the exact bounds of patentable subject matter."[348] "Instead, each applies a flexible test to the specific question presented in order to determine whether the claimed invention falls within one of the judicial exceptions to patentability."[349] Those cases teach that an invention that enlarges the range of utility compared to the natural substance or that has "markedly different characteristics with the potential for significant utility" constitutes patent-eligible subject matter.[350] The cases relating to purified substances, which held that purifications of, for example, adrenaline and B-12, were patentable, whereas purifications of naturally-occurring elements, such as uranium, were not, followed a similar inquiry—whether the purified substance was in effect new with the potential for significant utility or had the same inherent characteristics as the material found in nature.[351]

Judge Moore held that *Prometheus* did not control the inquiry but "is nonetheless instructive regarding the scope of the law of nature exception" and that its "discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims)."[352] Reading *Funk Brothers* and *Chakrabarty* together with *Prometheus*, she determined the following principles: "(1) laws of nature/manifestations of nature are not patentable; [but] (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."[353] She held that the claimed cDNA did not exist in nature and had a distinct character and use from the natural RNA or DNA sequences in the body and therefore was patent eligible.[354] Further, shorter length DNA sequences were likewise patentable because the ability to use those isolated molecules as primers for a screening process or as probes represented new and significant utility as compared to the naturally-occurring DNA.[355] Longer strands of DNA, although literally different from the gene occurring in the chromosome, do not have an "'enlarge[d] . . . range of . . . utility' as compared to nature."[356] Judge Moore refused to expand the judicial exceptions to patentability to exclude the longer length DNA from patentable subject matter because of "settled expectations" and extensive property rights arising from DNA that has been patented, pursuant to PTO policy, for decades.[357]

Judge Bryson dissented and stated his position that isolated DNA is not patent-eligible subject matter.[358] He noted that Myriad was not the first to map the gene at issue, nor did it invent a new method of nucleotide sequencing; it "applied known sequencing techniques to identify the nucleotide order of the BRCA genes."[359] He

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[348] *Id.* at 1338 (Moore, J., concurring).
[349] *Id.*
[350] *Id.*
[351] *Id.* at 1339.
[352] *Id.* at 1339–40.
[353] *Id.* at 1340.
[354] *Id.* at 1340–41.
[355] *Id.* at 1341–42.
[356] *Id.* at 1342–43.
[357] *Id.* at 1343–47.
[358] *Id.* at 1349 (concurring-in-part and dissenting-in-part).
[359] *Id.* at 1349–50.

believed that isolated DNA "fall[s] clearly on the 'unpatentable' side of the line the [Supreme] Court drew in *Chakrabarty*," because DNA exists in the body, and the only material change made to it from its natural state is the extraction from its environment.[360] He analogized isolating DNA to extracting a mineral from the earth or finding and propagating a newly discovered plant, which although difficult, does not transform the mineral or plant into patent eligible subject matter.[361] Further, to hold that the breaking of a chemical bond transforms material into a new product would allow, for example, patents on isolated lithium (which exists only as a part of a compound and would be isolated by breaking chemical bonds).[362]

Isolated DNA is separated from the chromosomal protein at boundaries predefined by nature that "preserve the ability of the gene to express the protein for which it is coded."[363] The "extraction of a product in a manner that retains the character and function of the product as found in nature does not result in the creation of a human invention."[364] Although stating that *Prometheus* did not control the inquiry, Judge Bryson opined that "a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product"—it should involve an "inventive" contribution to the product of nature and involve more than "'well-understood, routine, conventional' elements[.]"[365] Specifically, isolated DNA is not patentable if the isolation of DNA is a known process, making it "the product not of innovation but of ordinary skill and common sense."[366]

The Supreme Court granted certiorari on November 30, 2012 on the question of whether human genes are patentable.[367] It affirmed in part and reversed in part the Federal Circuit's decision, holding that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that certain types of cDNA are patent eligible because they are not naturally occurring.[368] While the basis for the Supreme Court's holding was that DNA is naturally occurring, it also seemed to rely on the premise that isolating DNA is routine:

> DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well known laboratory methods. These methods allow scientists to isolate specific segments

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[360] *Id.* at 1350.

[361] *Id.*

[362] *Id.* at 1351.

[363] *Id.* at 1352.

[364] *Id.* at 1353 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980)).

[365] *Id.* at 1355 (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294–97 (2012)).

[366] *Id.* (citing Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1302 (Fed. Cir. 2007)).

[367] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694, 695 (2012).

[368] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2120 (2013).

> of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used.[369]

The Court also noted that cDNA is synthetic DNA created in the laboratory from mRNA (messenger RNA).[370] The Supreme Court believed that "Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 gene[] [sequences,]" mutations in which can dramatically increase the individual's risks of developing breast and ovarian cancer.[371]

The Supreme Court, in holding that the DNA at issue was naturally occurring, noted that Myriad "[did not] create or alter any of the genetic information" in the genes at issue and that the "location and order of the nucleotides existed in nature before Myriad found them."[372] Further, Myriad did "not create or alter the genetic structure of DNA."[373] Its "principal contribution was uncovering the precise location and genetic sequence" of the genes at issue.[374] Rather than creating a new composition of matter, Myriad simply found an important and useful gene, "but separating that gene from its surrounding genetic material is not an act of invention."[375] Myriad's discovery did not render the genes a "new . . . composition[] of matter" under § 101.[376] That isolating DNA from the human genome severs chemical bonds and "creates a nonnaturally occurring molecule" did not render Myriad's claims patent-eligible, because the claims were not expressed "in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA."[377] Its claims were directed to the information contained in the genetic sequence, not the chemical composition of a particular molecule.[378]

By contrast, the Supreme Court found that creating a cDNA sequence results in a molecule that is not naturally occurring.[379] Even though "the nucleotide sequence of cDNA is dictated by" the original DNA sequence, a new composition of matter is created when cDNA is made.[380] cDNA is therefore "not a 'product of nature' and is patent eligible under § 101."[381]

The Supreme Court's holding was limited to the patent-eligibility of DNA and certain types of cDNA. The Court held that "genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material," but did not address the patent-eligibility of methods

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[369] *Id.* at 2112.
[370] *Id.*
[371] *Id.* at 2113.
[372] *Id.* at 2116.
[373] *Id.*
[374] *Id.*
[375] *Id.* at 2117.
[376] *Id.* (alteration in original).
[377] *Id.* at 2118.
[378] *Id.*
[379] *Id.* at 2119.
[380] *Id.*
[381] *Id.*

of manipulating genes or applications of knowledge about the claimed genes.[382] Limited as it was, the Supreme Court's decision does not provide substantive guidance on the "product of nature" exception to subject matter eligibility, nor does it address wider issues of interest to the biochemistry or nanotechnology industries.

Arguably, *Myriad* did not require, at least for patent-eligibility purposes, materials based on products found in nature to be "a new thing commercially or therapeutically,"[383] or in other words, commercially and therapeutically useful where the natural substance was not.[384] It simply required that the claimed composition (cDNA) be different from the naturally occurring substance (DNA).[385] In that sense, it may broaden patent protection for products based on, or inspired by, natural materials. The Court's holding that isolating natural materials is insufficient to confer patent eligibility may cast doubt on the patentability of many biotechnology and nanotechnology inventions if broadly applied to areas other than the human genome.

V. THE POTENTIAL EFFECT OF *PROMETHEUS* AND *MYRIAD* ON BIOTECHNOLOGY AND NANOTECHNOLOGY

Questions remain as to what effect *Prometheus* and *Myriad* will have on the biotechnology industry. The latter decision, though narrow, calls into question whether isolated products of nature are patentable, although it seems to permit patenting synthetic versions of natural products (assuming all other conditions for patentability are met).[386] The effect of these cases on the biotechnology industry may be illustrative of their effect on the nascent nanotechnology industry. Biotechnology "involves the use of a broad range of techniques and procedures for modifying living organisms to suit human purposes."[387] From 1981 to 2006, approximately forty percent of all FDA-approved pharmaceuticals were either "a biologic, natural product, or derived from a natural product."[388] Some in the industry believe that *Prometheus* will have a significant impact on biomedical research and personalized medicine[389] as expressed in the Petitioners' brief in *Myriad,* others believe and note that certain patents, particularly on genes, stifle basic research and have negative

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[382] *Id.* at 2120.

[383] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911).

[384] Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 161 (4th Cir. 1958).

[385] *See Myriad,* 133 S. Ct. at 2119.

[386] *Id.* at 2111.

[387] JOHN R. THOMAS, CONG. RESEARCH SERV., R42815, MAYO V. PROMETHEUS: IMPLICATIONS FOR PATENTS, BIOTECHNOLOGY AND PERSONALIZED MEDICINE 1 (2012).

[388] Susan McBee & Bryan Jones, *The Supreme Court Should Be Mindful of Naturally Derived Products Other Than Nucleic Acids When Deciding* Myriad, SCOTUSBLOG (Feb. 7, 2013, 10:16 AM), http://www.scotusblog.com/2013/02/the-supreme-court-should-be-mindful-of-naturally-derived-products-other-than-nucleic-acids-when-deciding-myriad/.

[389] THOMAS, *supra* note 387, at 1. According to Thomas, "Personalized medicine involves tailoring medical treatment to the individual characteristics of each patient, as well as classifying individuals based on their susceptibility to a particular disease or their response to a specific treatment." *Id.* at 2.

effects on patient treatment options by placing certain genes off limits.[390] The biotechnology industry, however, depends on patent rights to a great extent, because they are the most important asset for obtaining funding.[391] For example, McBee and Jones asserted, "[F]or start-up biotechnology companies, patents covering such products are incredibly important, 'as they are often the most crucial asset they own in a sector that is extremely research-intensive and with low imitation costs.'"[392] Venture capital funding, one of the most important sources for biotechnology funding, may be reduced if patent protections for biotechnology inventions are weakened.[393] Further, studies have shown that intellectual property rights have not inhibited basic research,[394] and in fact, one study reported that "the productivity gains conferred by the licensed research tools were thought to be worth the price" by researchers.[395]

Further, given that biotechnology inventions almost always start with "natural" materials, a rule that makes it difficult to establish that something extra that distinguishes a patentable invention from a product of nature may make patenting such inventions much more difficult. An example from a SCOTUSblog post highlights this difficulty:

> [c]onsider, for example, *Taq* polymerase. The inclusion of *Taq* into a process called polymerase chain reaction (PCR) has often been credited as being the single most important technological advance to the modern biotechnology industry. PCR uses repeated cycles of increasing and decreasing temperatures in the presence of a polymerase to amplify a target nucleic acid. In the original iteration of PCR, new polymerase enzyme had to be added to the reaction mixture after each heat cycle, because the high temperature permanently deactivated the enzyme. *Taq*, however, is heat stable and thus does not lose activity when subjected to high temperatures. Because of this stability, *Taq* only needs to be added to a PCR reaction mixture once, thus greatly reducing the costs and the time of performing the process, and permitting easy automation. Clearly, then, the identification and characterization of this enzyme is a

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[390] THOMAS, *supra* note 387, at 10, 13; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998) (explaining patents on upstream technology can stifle downstream innovation by imposing significant transaction (licensing) costs).

[391] THOMAS, *supra* note 387, at 3.

[392] McBee & Jones, *supra* note 388.

[393] THOMAS, *supra* note 387, at 3.

[394] *See, e.g.,* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1060–61 (2008); John P. Walsh et al., *Working Through the Patent Problem*, 299 SCI. 1021, 1021 (2003); AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, INTERNATIONAL INTELLECTUAL PROPERTY EXPERIENCES: A REPORT OF FOUR COUNTRIES, 12, 14–15 (2007), *available at* http://sippi.aaas.org/Pubs/SIPPI_Four_Country_Report.pdf (last visited Jan. 1, 2014).

[395] *See* John P. Walsh, et al., *Effect of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 301 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

> significant technological advance, from which the public obtains a significant benefit. Yet the properties of *Taq* that make it so attractive for PCR are a consequence of its structure and function in the natural world. *Taq* is naturally produced by *Thermus aquaticus*, a bacterium that is naturally found in hot springs. Therefore, in nature, just like in PCR, *Taq* functions as a thermostable enzyme that catalyzes the amplification of a nucleic acid. Why should this render *Taq* unpatentable?[396]

Some commentators have opined that *Prometheus* renders almost every biotechnology patent suspect because most are based on products of nature or use natural processes.[397] Others are more concerned about the lack of guidance, given that the criteria for what constitutes a natural process was not clearly articulated in *Prometheus*,[398] and such uncertainty may discourage costly research programs, particularly in the area of diagnostics.[399] Indeed, the courts have already invalidated other patents to diagnostic methods, including those for "screening methods to estimate the risk of fetal Down's syndrome,"[400] and a noninvasive prenatal test using cell-free DNA circulating in the blood of a pregnant woman.[401] Of course, some viewed the decision as within the norms of other countries, which generally prohibit the patenting of diagnostic methods, and as beneficial to patients and basic medical research.[402]

Others believe that the underpinnings of the decision are shaky in that the concepts at issue are not natural laws. As one commentator states:

> [T]he Prometheus claims involve a correlation between a non-naturally occurring drug metabolite and the optimal dosage of a drug. The drug metabolite does not occur naturally, but is created as a byproduct when the human body breaks down the precursor drug. Hence the correlation between metabolite level and optimal dosage does not occur naturally, but only as the result of human intervention.[403]

Because the correlation "at the heart of the [*Prometheus*] claims" is not a natural phenomenon, determining that the claim is "patent ineligible for claiming a natural phenomenon" is incorrect.[404] Under the Supreme Court's definition of "natural

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[396] McBee & Jones, *supra* note 388.

[397] THOMAS, *supra* note 387, at 9.

[398] Chris Holman, *Mayo v. Prometheus: Analysis and Implications of an Important Supreme Court Decision,* HOLMAN'S BIOTECH IP BLOG (Mar. 21, 2012, 5:20 p.m.), http://holmansbiotechipblog.blogspot.com/2012/03/prometheus-v-mayo-analysis-and-html.

[399] *Id.*

[400] PerkinElmer, Inc. v. Intema Ltd., 496 Fed. App'x 65, 65, 73 (Fed. Cir. 2012).

[401] Aria Diagnostics, Inc. v. Sequenom, Inc., No. C 11-06391 SI, 2012 WL 2599340, at *11–12 (N.D. Cal. July 5, 2012).

[402] THOMAS, *supra* note 387, at 10.

[403] Holman, *supra* note 398.

[404] *Id.*

phenomena," most life science or biotechnology patents would be based on the discovery of such a phenomenon.[405]

A broad reading of the requirement that any steps beyond a concept deemed to be a natural law must be "novel" (or not "routine" or "conventional") could drastically reduce the ability to obtain a patent.[406] Previous application of a similar rule (that elucidated in *Funk Brothers*)[407] resulted in a wave of unpatentable process improvements, including those for (1) producing silica gel,[408] (2) electrostatic welding,[409] (3) making a lead/lead oxide suspension,[410] and (4) enterically coated trypsin.[411] These four process improvements were held unpatentable because they were based on "newly discovered scientific fact[s]" coupled with other steps that did not demonstrate invention.[412] *Myriad*, while limiting its holding to DNA and certain types of cDNA,

> also creates significant uncertainty for other classes of naturally occurring isolated biomolecules often critical to the biotechnology industry, such as additional nucleotide forms (e.g., antisense, interfering RNA), carbohydrates, lipids, and proteins (e.g., antibodies, and specifically human antibodies). In this regard, patent claims are often directed to *isolated* forms of these types of biomolecules and the court's decision in *Myriad* suggests that such claims may now need to be viewed under a more stringent 35 U.S.C. § 101 standard.[413]

Because little more than a year has passed since the *Prometheus* decision, and the *Myriad* decision is only a few months old, the effects on the industry are difficult to measure. The reports for activity in the industry for 2012 are not yet finalized. R&D increased in 2010 and 2011 to approximately $17.2 billion after a drop off in 2009.[414] Capital raised in the industry in 2011 was $33.4 billion, an

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[405] *Id.*

[406] *See* Jeffrey Lefstin, *Playing with Fire: What's Really at Stake in Myriad*, PATENTLY-O (Mar. 3, 2013, 4:51 PM), http://www.patentlyo.com/patent/2013/03/guest-post-by-dr-jeffrey-lefstin-on-whats-really-at-stake-in-myriad.html.

[407] *See id.*

[408] Davison Chem. Corp. v. Joliet Chems., Inc., 179 F.2d 793, 794 (7th Cir. 1950) (holding a process that maintained the temperature of a wash as unpatentable).

[409] *In re* Arnold, 185 F.2d 686, 774 (C.C.P.A. 1950) (finding that a welding method that used a particular frequency was unpatentable).

[410] Nat'l Lead Co. v. Western Lead Prods. Co., 324 F.2d 539, 544–45 (9th Cir. 1963) (concluding that a process in which the temperature of a reaction was controlled to yield a uniform product was unpatentable).

[411] Armour Pharm. Co. v. Richardson-Merrell, Inc., 396 F.2d 70, 72–73 (3d Cir. 1968) (deciding that coated trypsin was obvious, and hence unpatentable, once discovery was made that trypsin could be absorbed by the small intestine).

[412] *See* Lefstin, *supra* note 406.

[413] Atulya R. Agarwal et al., *Implications of the U.S. Supreme Court's Myriad Decision on Human Gene Patents and Other Biotechnology Inventions*, MONDAQ (July 19, 2013), http://www.mondaq.com/unitedstates/x/252074/Life+Sciences+Biotechnology/Implications+Of+The+US+Supreme+Courts+Myriad+Decision+On+Human+Gene+Patents+And+Other+Biotechnology+Inventions (emphasis in original).

[414] BEYOND BORDERS 2012, *supra* note 160, at 27.

increase from the $25.8 billion raised in 2010.[415] Those in the industry are predicting a decrease in investment, however. For example, at a roundtable hosted at George Washington School of Law, Phil Johnson, Chief Intellectual Property Counsel at Johnson & Johnson, pointed out that "capital is hard to come by these days and people are reluctant" and that safer avenues, such as R&D for consumer products, exist for investment.[416] Further, it is unclear whether the Supreme Court's decision sufficiently weighed the practical effects of restricting the ability to patent biotechnology inventions against the risks of stifling innovation.[417]

The *Prometheus* and *Myriad* decisions will have serious implications for nanotechnology as well, because "nanotechnology has been borrowing concepts and materials from nature."[418] Nanomaterials "may be found in nature, albeit in a different form from a commercially useful form."[419] Some nanomaterials "are[] . . . in space or in the earth," prompting the question: "Is one merely purifying something found in nature?"[420]

Nanotechnology has risen similarly to biotechnology, with a somewhat slower path to commercialization. In 1959, physicist Richard Feynman gave a lecture at the American Physical Society at Caltech on December 29, 1959 entitled "There's Plenty of Room at the Bottom," which contemplated the ability to manipulate matter on an atomic scale.[421] Commercialization has only recently started, however, and the industry is considered in its "infancy."[422]

The nanotechnology industry might not be as heavily dependent on venture capital funding as biotechnology because it is heavily funded by government sources, particularly the National Nanotechnology Initiative.[423] As such, the industry might not be as sensitive to the ability to obtain patents as the biotechnology industry. Private funding is beginning to increase, however. Industry estimates of private investment in nanotechnology R&D, which comes primarily from corporations and venture capital, are that approximately $3.5 billion was raised in the U.S., and $9.6 billion raised worldwide, in 2010.[424] Nanotechnology patent applications have increased from about 285 U.S. Patent applications per year in 2000 to 3,729 in

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[415] *Id.* at 39.

[416] Roy Zwahlen, Mayo v. Prometheus*: Thought Leaders Express Concern and Evaluate the Impact*, BIOTECHNOW (May 21, 2012), http://www.biotech-now.org/public-policy/patently-biotech/2012/05/mayo-v-prometheus-thought-leaders-express-concern-evaluate-business-impact-and-discuss-the-future.

[417] *Id.*

[418] J. Stephen Rutt, *The Controversial Myriad Case and Nanotech: Some Thoughts*, CLEANTECH & NANO (July 31, 2011), http://www.nanocleantechblog.com/2011/07/31/the-controversial-myriad-case-and-nanotech-some-thoughts.

[419] *Id.*

[420] *Id.*

[421] Richard P. Feynman, *There's Plenty of Room at the Bottom*, 23:5 CAL. INST. TECH. ENG'G & SCI 22, 22–26 (Feb. 1960)

[422] JOHN F. SARGENT JR., CONG. RESEARCH SERV., RL34511, NANOTECHNOLOGY: A POLICY PRIMER 8 (2013).

[423] *Id.* at 1. Congress appropriated approximately $1.8 billion for nanotechnology R&D for FY2012 and President Obama has request approximately $1.7 billion for FY2014. *Id.* at 6.

[424] *Id.* at 9.

2008.[425] As of 2004, approximately 91 U.S.-based public companies and 317 U.S.-based private companies were active in some aspect of nanotechnology, with 352 start-ups arising in the U.S. between 1989 and 2004.[426]

The same arguments regarding patentability of biotechnology products apply to nanotechnology products. Many nanotechnology inventions rely upon the inherent properties of the material at the nanoscale, and the question will be either: (1) whether a sufficient "inventive concept"[427] exists to show that the invention is not claiming a law of nature; or (2) whether the material is no more than an "isolated" naturally-occurring product.[428]

For example, nanotube technology would be impacted by changes to the "product of nature" doctrine. According to one definition, "Nanotubes are cylinders made up of a layer of carbon atoms, either a single tube (single-wall carbon nanotubes) or multiple tubes within each other (multiwall carbon nanotubes)."[429] The discovery of nanotubes dates to approximately 1991.[430] Two years after the discovery of a carbon nanotube, IBM applied for a patent including a claim for "[a] hollow carbon fiber having a wall consisting essentially of a single layer of carbon atoms."[431] Although the language was broad enough to encompass a single-wall carbon nanotube,[432] such nanotubes are readily found in nature.[433]

As one author explains:

> [M]ethods of producing . . . nanocompounds might mimic natural[] . . . processes . . . . There are numerous patents for methods of producing [Buckminsterfullerenes ("]buckyballs["")], for example. Yet, as with nanotubes, buckyballs are found in [nature, specifically] in exhaust from vehicles, soot, and even after lightning strikes sand. The heating of a substance to increase the presence of [buckyballs] is a fundamental principle of chemistry and a process that occurs . . . in nature.[434]

If patents are granted on nanotechnology inventions that are simply laws or products of nature, arguably they are overbroad and may stifle innovation.[435] As

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[425] Yan Dang et al., *Trends in Worldwide Nanotechnology Patent Applications*: *1991 to 2008*, 12 J. NANOPARTICLE. RES. 687, 690 (2010).

[426] CENTER FOR ECONOMIC GROWTH AND THE LALLY SCHOOL OF MANAGEMENT AND TECHNOLOGY, NANOTECHNOLOGY SECTOR REPORT 6 (2004).

[427] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012).

[428] Ass'n for Molecular Pathology v. U.S. Pat. & Trademark Office, 689 F.3d 1303, 1354 (Fed. Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), *aff'd in part and rev'd in part*, 133 S. Ct. 2107 (2013).

[429] Burger et al., *supra* note 18, at 245.

[430] *Id.* (citing Sumio Iijima, *Helical Microtubules of Graphitic Carbon*, 354 NATURE 56, 56–58 (Nov. 7, 1991)).

[431] *Id.* (citing U.S. Patent No. 5,424,054 cl. 3 (filed May 31, 1993)).

[432] *Id.* (citing C.J. MILLER ET AL., THE HANDBOOK OF NANOTECHNOLOGY 70 (John Wiley & Sons, Inc., 2004)).

[433] *Id.* (citing Iijima, *supra* note 430).

[434] *Id.* (citing L.E. Murr, et al., *Carbon Nanotubes, Nanocrystal Forms*, and *Complex Nanoparticle Aggregates in Common Fuel-Gas Combustion Sources in Ambient Air*, 6 J. OF NANOPARTICLE RES. 241, 241–51 (2004)).

[435] *Id.* at 245–46.

with biotechnology, however, these concerns may be more theoretical than actual, and there is no doubt that the development of nanotechnology and its applications are beneficial.

Graphene, a two-dimensional material, has recently become a focus of scientific research and development.[436] The 2010 Nobel Prize in Physics was awarded to two University of Manchester Scientists, Andre Geim and Konstantin Novoselov, for ground-breaking experiments regarding graphene.[437] Pham and Fayerberg defined grapheme as a "flat monolayer of carbon atoms tightly packed into a two-dimensional (2D) honeycomb lattice, and . . . a basic building block for graphitic materials of all other dimensionalities."[438] Although graphene has been known for many years,[439] Geim and Novoselov were the first to isolate it by "micromechanical cleavage," also known colloquially as the "Scotch Tape technique."[440] Graphene patent applications numbered 110 in 2009, 224 in 2010, and approximately 336 for 2011, "a 50% increase over 2010 and a[] . . . 200% increase over 2009."[441] The excitement surrounding graphene, however, has much to do with its "natural" properties such as thermal conductivity and strength.[442] If graphene's amazing properties are seen to be solely due to its natural properties, or if graphene is seen as existing in nature, with only the need to be isolated, how will the ability to obtain patents on its various applications and other two-dimensional materials be affected?

VI. CONCLUSION

The Supreme Court's decisions in *Prometheus*, which addresses the patentability of so-called "natural laws," and *Myriad*, which addresses the "product of nature" exception to patent-eligible subject matter under § 101, may have a significant effect on the biotechnology and nanotechnology industries. Given that both industries depend on building blocks of nature and/or the "natural" properties of materials, broadly construing the product of nature exception to subject matter eligibility may curtail the ability to obtain patents in those fields. While patent protection should not be so broad as to stifle innovation, if it is difficult to obtain or enforce patents, funding for further applications in those industries may become limited, slowing future advances. The federal courts should carefully consider those risks in applying *Prometheus* and *Myriad*.

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[436] Chin H. Pham & Roman Fayerberg, *Current Trends in Patenting Graphene and Graphene-based Inventions*, 8 NANOTECHNOLOGY L. & BUS. 10, 10 (2011).

[437] *The Nobel Prize in Physics 2010*, NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/physics/laureates/2010/ (last visited Jan. 1, 2014).

[438] Pham & Fayerberg, *supra* note 436, at 10 (citing A.K. Geim & K.S. Novoselov, *The Rise of Graphene*, 6 NATURE MATERIALS 183, 183 (2007)).

[439] *Id.* (citing Geim & Novoselov, *supra* note 438, at 183).

[440] *Id.* at 10–11 (citing Geim & Novoselov, *supra* note 438, at 185).

[441] Pham & Fayerberg, *supra* note 436, at 13.

[442] *See Graphene: World-leading Research and Development*, MANCHESTER GRAPHENE (UNIVERSITY OF MANCHESTER), http://www.graphene.manchester.ac.uk/story/properties/ (last visited Jan. 1, 2014).