PATENTABLE SUBJECT MATTER MATTERS: NEW USES FOR AN OLD DOCTRINE

By Jeffrey M. Kuhn

Controversy has swirled around the expansion of patentable subject matter throughout the history of patent law. In recent years, biotechnology and computer software have provided the most fuel for the fire, and through these areas, applicants have pushed the boundaries of patentable subject matter nearly to the point of non-existence.[1] Advances in biotechnology and computer software correspond almost, but not quite, with two traditionally unpatentable categories of subject matter: physical substances unchanged from their natural states and processes that do not alter physical substances. Both of these prohibitions seem to suggest a traditional, fundamental intuition of patent law: to merit a patent the inventor must *physically change* something in a new,[2] useful,[3] and non-obvious[4] way.

Of course, this traditional conception is no longer considered the *sine qua non* of patent law, and it may not reflect the subtle economics necessary to align incentive structures with rapidly changing technologies. Indeed, the industries that seek protection under an expanded subject matter doctrine, such as computer software, business, and biotechnology seem to be thriving, though widespread protection also creates significant costs. Decades of subject matter expansion by the United States Patent and Trademark Office (USPTO) and Federal Circuit with no restrictions imposed by Congress or the Supreme Court created the impression that subject matter was effectively a dead doctrine.

The subject matter discussion has been somewhat revitalized in the wake of renewed Supreme Court interest in patent law and, in particular,

---

1. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952) for the proposition that patentable subject matter "include[s] anything under the sun that is made by man"); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 (1998) (showing that .07% of invalid patents surveyed were invalidated on subject matter grounds); Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 4 (2001) (describing the question of software patentability as "a matter for the history books"); ROBERT P. MERGES, SOFTWARE AND PATENT SCOPE: A REPORT FROM THE MIDDLE INNINGS, http://www.utexas.edu/law/conferences/ip/MergesPaper.pdf (last visited Apr. 2, 2007).

2. *See* 35 U.S.C. § 102 (2000).

3. *See* 35 U.S.C. § 101 (2000).

4. *See* 35 U.S.C. § 103 (2000).

the Supreme Court's dismissal of certiorari as improvidently granted in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*[5] *Lab. Corp.* concerned the validity of a claim for measuring a B vitamin deficiency in the body.[6] The claimed invention required measuring the level of homocysteine in the body and "correlating" that level with the B vitamin level.[7] Thus, a practitioner could indirectly measure the level of B vitamins, which are traditionally difficult to detect, by directly measuring homocysteine, tests for which exist in the prior art.[8] The majority of the Court held for dismissing certiorari, ostensibly because the parties did not refer to § 101 in the lower courts.[9] Justice Breyer, however, would have heard the case and invalidated the patent claim as covering a law of nature.[10]

This Note will use *Lab. Corp.* as a starting point to examine the development of subject matter and its role in a modern patent system. The debate about *Lab. Corp.*, and indeed the very question presented to the Supreme Court,[11] regarded whether claim 13 covered a law of nature. *Lab. Corp.* illustrates that the erosion of the principle of physical change in patent law makes it difficult, if not impossible, to police *any* line with respect to subject matter without running counter to established case law and risking the loss of significant incentives through restrictions on software or gene patents. However, traditionally unpatentable areas of subject matter were off limits for good reasons that cannot be ignored without incurring considerable costs. Patents that cross traditional subject matter lines compose some of the most important innovations in industries vital to the economy, but they can potentially block research and create high transaction costs if they are over-broad, somewhat obvious, or have little specific utility at the time of filing. This Note contends that subject matter has a role to play in the modern patent system, though not through traditional

---

5. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926-29 (2006) (Breyer, J., dissenting). Justice Stevens and Justice Souter joined in dissent. Chief Justice Roberts took no part in the decision.

6. *Id.* at 2923-24.

7. *Id.*

8. *Id.* The patent also covered improved tests for homocysteine, but these were not at issue since the prior art included inferior tests, and competitors had since developed superior tests. *Id.* at 2923.

9. *Id.* at 2922, 2925.

10. *Id.* at 2927.

11. Justice Breyer explained, "We granted certiorari in this case to determine whether the patent claim is invalid on the ground that it improperly seeks to 'claim a monopoly over a basic scientific relationship,' namely, the relationship between homocysteine and vitamin deficiency." *Id.* at 2922 (quoting Pet. for Cert. i).

bright line restrictions. Rather, courts should consider subject matter as a relevant factor in analyzing other requirements of patentability and should take care to apply those doctrines strictly for patents that cover traditionally unpatentable subject matter.

Part I of this Note illustrates the history of patentable subject matter as one of consistent backpedaling, with each Federal Circuit case redrawing the ostensibly bright line to encompass a bit more subject matter. Part II shows how the inability of patent law to settle on a definition for subject matter may derive from the fundamental difference between classical technology on which technology was based and the fast-paced, cutting-edge technology of the modern era. In effect, drawing a meaningful line with subject matter is likely impossible. Part III suggests ways in which patent law can adapt and remain current amidst rapidly changing technology.

I. HISTORY OF PATENTABLE SUBJECT MATTER DOCTRINE

Subject matter was a substantive requirement of patentability early in the development of U.S. patent law. Courts began to relax this restriction in the early 1980s when faced with developments in biotechnology and computer science that steadily pushed the boundaries of patentability. This process occurred without significant intervention by Congress or the Supreme Court. It seems reasonable to suggest that given the relative success of the biotechnology and computer industries, both institutions simply may have felt no need to correct the course and risk upsetting the delicate balance of patent law despite the costs and theoretical difficulties inherent in subject matter expansion.

A. Laws of Nature, Abstract Ideas, and Natural Phenomenon

Section 101 of the Patent Act outlines the basic requirements of patentability: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[12] Courts and scholars interpret the Patent Act as setting forth several major elements of patentability.[13] Specifically,

12. 35 U.S.C. § 101 (2000).

13. *See* ROBERT P. MERGES & JOHN F. DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 65 (3d ed. 2002).

an invention must be novel, useful, non-obvious, and adequately disclosed in the patent.[14]

An invention must also meet the patentable subject matter requirement.[15] Though its statutory grounding stems from § 101, subject matter jurisprudence is primarily based on case law.[16] Rather than affirmatively defining categories of inventions patentable, courts have generally chosen to set forth categories of unpatentable subject matter, though clarity and precision have never been hallmarks of the doctrine.[17]

> Sometimes the Court has referred to the prohibited category as "[p]henomena of nature, . . . mental processes, and abstract intellectual concepts." Gottschalk v. Benson, 409 U.S. 63, 67 (1972). In other cases, the Court has stressed that a "principle" or "fundamental truth" is unpatentable. Parker v. Flook, 437 U.S. 584, 589 (1978) (quoting Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1853)). Elsewhere, the Court has asserted simply and boldly that "[a]n idea of itself is not patentable." Rubber-Tip Pencil Co. v. Howard, 87 U.S. (20 Wall.) 498, 507 (1874).[18]

Patent law exists to "promote the Progress of Science and the useful Arts," an economic motivation extending to patentability requirements such as subject matter.[19] The prohibition against patenting laws of nature reflects "both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in [those basic principles] and . . . the enormous transaction costs that would be imposed on would-be users."[20]

Sections I.B and I.C will show that with the concurrent development of the computer and biotechnology industries in the early 1980's, patentable subject matter began to wane as a substantive bar to patentability. Courts seemingly bent doctrine to account for perceived pragmatic necessity in both fields, creating two parallel strands of case law.

---

14. *Id.*
15. *Id.*
16. *Id.* at 66.
17. *Id.* at 77.
18. *Id.*
19. *See* U.S. CONST. art. I, § 8, cl. 8.
20. Lab. Corp. of Am. Holdings v. Metabolite, Inc. 126 S. Ct. 2921, 2923 (Breyer, J., dissenting) (citing W. LANDES & R. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 305-06 (2003)).

B. Pharmaceuticals and Biotechnology

1. Patenting Natural Substances Was Originally Not Allowed

Pharmaceutical and biotechnological inventions typically yield patents for compositions of matter or the processes used to produce those compositions. Patent law historically disallowed patenting of compositions of matter that were unchanged from their natural form.[21] Of course, most of the products that industries and consumers use must be changed or refined from their natural form to be useful. The Supreme Court originally invalidated patents that claimed a "purified" form of a substance existing in nature in *American Wood-Paper Co. v. Fibre Disintegrating Co.*[22] According to Justice Strong, a purification process may be patentable, but "the thing itself when obtained cannot be called a new manufacture."[23] Although the Court invalidated the patent in *American Wood-Paper* on novelty grounds, later holdings by both lower courts and the USPTO reaffirmed the principle Justice Strong articulated.[24]

2. Development and Acceptance of the "Purification Test"

Divergent rulings in lower courts precipitated the erosion of the principle that purification could merit a process claim but not a claim for the purified substance. A circuit split developed from a line of cases in the Seventh Circuit beginning with *Kuehmsted v. Farbernfabrikin of Elberfeld, Co.*, where the court upheld the plaintiff's patent on purified acetyl salicylic acid, a drug sold under the brand name Aspirin, despite the defendant's prior art production of an impure version of the compound.[25] At the time, the standard infringement test for composition of matter claims hinged on whether the two compounds were structurally similar.[26] The court declined to apply this test because the plaintiff's patented invention was structurally similar to the defendant's prior invention, only purified.[27] Instead, the

---

21. *See* Am. Wood-Paper Co. v. Fibre Disintegrating Co., 90 U.S. (23 Wall.) 566, 593-94 (1874).

22. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 332 (2002) (citing *Am. Wood-Paper*, 90 U.S. (23 Wall.) 566).

23. *Am. Wood-Paper*, 90 U.S. 23 (Wall.) at 593-94.

24. Demaine & Fellmeth, *supra* note 22, at 332-33 (citing Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884); *Ex parte* Latimer, 1889 Dec. Comm'r Pat. 123, 123, 125-27 (1889)).

25. *Id.* at 334-35 (citing Kuehmsted v. Farbenfabrikin of Elberfeld Co., 179 F. 701 (7th Cir. 1910)).

26. *Id.*

27. *Id.*

court held that purification made the plaintiff's product "therapeutically different" from the prior art.[28] Judge Learned Hand in the Southern District of New York reached a similar conclusion in *Parke-Davis v. H.K. Mulford Co.* when he held that the prohibition on patenting natural phenomena did not preclude patenting natural substances, including an extract from animal supernal glands, in a purified form.[29]

Throughout this period, the Third Circuit, the Court of Customs and Patent Appeals (CCPA), and the Board of Patent Appeals and Interferences (BPAI) each invalidated patents on similar facts.[30] After the passage of the 1952 Patent Act, however, the Fourth Circuit joined with the Seventh Circuit in *Merck & Co v. Olin Mathieson Chemical Corp.* and broadened the "therapeutic value" test, which allowed patenting a substance produced in nature if it was modified to have therapeutic value, to include anything with "commercial value."[31] The CCPA, and later the Federal Circuit, also changed course and slowly adopted the purification reasoning.[32] This move resolved the circuit split by recognizing purified natural products as subject matter eligible for patenting, which paved the way for DNA patents.

Even at this point, however, the Supreme Court took care to distinguish between patentable inventions and unpatentable discovered properties of pre-existing natural objects. In a precursor to modern biotechnology cases, the Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.* invalidated claims for a combination of six "mutually non-inhibitive" bacteria that together functioned as "[a]n inoculant for leguminous plants."[33] Although the inventors chose the specific claimed combination of different bacterial strains, they did not change the bacteria from their natural state.[34] According to the Court, the properties of the bacteria were "manifestations

28. *Id.*

29. *See* Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911). *But see* Demaine & Fellmeth, *supra* note 22, at 337 (suggesting that the defendant in the infringement suit did not argue for invalidity on subject matter grounds, possibly because it wished to obtain its own patent).

30. Demaine & Fellmeth, *supra* note 22, at 339-42 (citing General Electric Co. v. De Forest Radio Co., 28 F.2d 641 (3d. Cir. 1928) (invalidating a patent on purified tungsten) and *In re* Merz, 97 F.2d 599 (C.C.P.A. 1938) (affirming a decision by the BPAI refusing to grant a patent for purified ultramarine dye)).

31. *Id.* at 349-51 (citing Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958)).

32. *Id.* at 356-59 (citing *In re* Bergstrom, 427 F.2d 1394 (C.C.P.A. 1970), Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir.), *cert. denied sub nom*, Genetics Inst. v. Amgen, Inc., 502 U.S. 856 (1991)).

33. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 127-28 (1948).

34. *Id.* at 129-30.

of laws of nature, free to all men and reserved exclusively to none."[35] Patentability could only derive from application of natural laws to a "new and useful end."[36]

3. Biotechnology

With the advent of modern biotechnology came new challenges for the application of the patentable subject matter doctrine. In *Diamond v. Chakrabarty*, the Supreme Court confronted a patent for a genetically-modified bacterium designed to break down components of crude oil via two hydrocarbon-degrading pathways.[37] The patentee modified a pre-existing bacterium by adding genetic components to achieve a new result.[38] In contrast, neither the patent in *Parke-Davis*, which covered a purified form of a pre-existing chemical, nor the patent in *Funk Brothers Seed Co.*, which covered a mixture of pre-existing bacteria, involved structural alteration of the underlying natural phenomenon.[39]

The Court's decision that a live, human-made microorganism was a patentable "manufacture or composition of matter" opened the door for patenting the products from new field of biotechnology.[40] According to the Court, "[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[41] Following the decision, the USPTO granted patents for inventions such as genetically modified oysters[42] and a genetically modified, cancer-prone "oncomouse,"[43] expanding the scope of patents on living organisms beyond the single-celled level.

The purification doctrine has generated significant controversy throughout its history and has faltered at times, specifically with the problems caused by patenting expressed sequence tags (ESTs).[44] ESTs are random base pair sequences used as probes to locate genes on DNA se-

35. *Id.* at 130.

36. *Id.*

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

38. *Id.*

39. *See* Parke-Davis & Co. v. H. K. Mulford, 189 F. 95, 102 (S.D.N.Y. 1911); *Funk Bros.*, 333 U.S. at 130.

40. *See Diamond*, 447 U.S. at 309-10.

41. *Id.* at 309 (citing S. REP. NO. 1979, 82d Cong., 2d Sess., at 5 (1952) and H.R. REP. NO. 1923, 82d Cong., 2d Sess., at 6 (1952)).

42. *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (B.P.A.I. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

43. U.S. Patent No. 4,736,866 (filed June 22, 1984).

44. Demaine & Fellmeth, *supra* note 22, at 323-26.

quences.[45] In the early 1990's, the National Institute of Health [NIH], which was working on the Human Genome Project under Congressional funding, began submitting up to 4,000 patent applications per year for ESTs.[46] The USPTO responded to this flood by rejecting EST applications on utility grounds, a tactic which the Federal Circuit upheld.[47]

The purification doctrine seemed a pragmatic, unplanned response to unpredictable, developing technology. The line of cases from which it arose seems contrary to both Supreme Court holdings[48] and Congressional intent.[49] Neither Congress nor the Supreme Court ever overturned this line of cases, however, and over time, the patent community accepted purified substances as patentable subject matter. The acquiescence of Congress and the Supreme Court to the flow of law in the lower courts and USPTO likely stemmed from the fact that, despite the cost and controversy regarding patent protection, the industry generally seems to have enjoyed rapid growth.[50] Thus, granting patents on certain products of nature presented few practical problems—only theoretical ones.

C. Computer Technology and Business Methods

Tensions regarding patenting of natural laws first arose in electronic communication technology, but early courts had little difficulty in drawing the line between inventions and laws of nature. The line began to blur with patents that covered not the electronic equipment itself, but rather the abstract instructions, or software, that drove the equipment. The advent of business method patents pushed upon the prohibition on patents covering

---

45. *Id.* at 323.

46. *Id.*

47. *See In re* Fisher, 421 F.3d 1365, 1367, 1379 (Fed. Cir. 2005).

48. Demaine & Fellmeth, *supra* note 22, at 357 (noting that the Supreme Court held products of nature were not patentable in Parker v. Flook, 437 U.S. 584 (1978) and Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

49. *Id.* at 359-60 (citing H.R. REP. NO. 99-807, at 21-22 (1986) for the proposition that "removing impurities does not "materially change" a chemical produced by a patented process" and S. REP. NO. 100-83, at 49-50 (1987)).

50. *See, e.g.*, News Release, Ernst & Young, Double-Digit Growth Pushes Biotechnology Industry Revenues Over $60 Billion, According to Ernst & Young's 2006 Global Biotechnology Report, (Apr. 4, 2006), *available at* http://www.ey.com/global/content.nsf/US/Media_-_Release_-_04-04-06DC (describing strong performance and rapid growth in the biotechnology industry worldwide as well as in the United States). A survey by the U.S. Department of Commerce found strong growth in the biotechnology industry. However, 35 percent of respondents identified third-party patent rights as a barrier to advancement, and 35 percent of respondents identified patent fees and the approval process as a barrier to advancement. *Survey: U.S. biotech industry poised for growth*, ITWORLD.COM, Nov. 13, 2003, http://www.itworld.com/Tech/4535/031113usbiotech.

abstract ideas, a trend that recently culminated in the BPAI's decision to eliminate the technological arts requirement.[51]

1. Patenting Laws of Nature Was Originally Not Allowed

One may find the legal roots of the prohibition on patenting laws of nature in the Supreme Court's response to patents covering early electronic communication equipment. In *O'Reilly v. Morse*, the Court invalidated a claim by the inventor of the telegraph covering any use of electromagnetism to communicate at a distance.[52] The Court reasoned that such a claim was directed to "an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it."[53] The *Morse* Court distinguished the earlier English case of *Neilson v. Harford*, where the English court upheld a patent on a heating system that improved efficiency by injecting hot air rather than cold air into the furnace, on the ground that the Neilson patent "'does not merely claim a principle, but a machine, embodying a principle . . . .'"[54] The Court developed the doctrine further in *The Telephone Cases* when it distinguished *O'Reilly v. Morse* and allowed a broad claim on Alexander Graham Bell's telephone because the claims were directed to an actual invention rather than the utilization of the principle of telephony.[55]

In *Gottschalk v. Benson*, the Supreme Court applied the law of nature doctrine to invalidate claims for mathematical algorithms.[56] The patents claimed a general "method for converting binary-coded decimal (BCD) numerals into pure binary numerals" that "were not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use."[57] The Court reasoned that to allow such a claim would be to allow patenting of an idea, which was forbidden under the law of nature doctrine.[58] Although patenting of computer programs was imper-

51. *Ex parte* Lundgren, Appeal No. 2003-2088 (B.P.A.I. 2004).
52. O'Reilly v. Morse, 56 U.S. 62, 120 (1854).
53. *Id.*
54. *Id.* at 114-16 (citing Neilson v. Harford, Web. Pat. Cases 295, 371 (1844)).
55. The Telephone Cases, 126 U.S. 1, 535-36 (1888).
56. Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972).
57. *Id.* at 64.
58. It is conceded that one may not patent an idea. But in practical effect, that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.

Id. at 71-72.

missible under statutory authority, the Court stated that Congress could allow the patenting of computer programs if it so chose.[59] However, the Court noted that the President's Commission on the Patent System expressly rejected patenting programs and stated that evading the existing prohibition by clever drafting should not be permitted.[60]

The Court reiterated the invalidity of algorithm claims in *Parker v. Flook*.[61] The patent at issue covered a new mathematical algorithm for updating alarm limits.[62] Alarm limits were dynamically-determined numerical values that represented the safety margins of a manufacturing process.[63] An alarm might indicate unsafe conditions if a certain variable in the process, such as temperature or pressure, exceeds its alarm limit.[64] The Court held that even this useful post-solution activity was insufficient to allow patentability and that patentability may be denied on subject matter grounds even "if a process application implements a principle in some specific fashion."[65] The danger in allowing such abstract patent claims, the Court noted, was that it would "make the determination of patentable subject matter depend simply on the draftsman's art."[66] This latitude would allow patentees to skirt the prohibition against patenting ideas and phenomena of nature by claiming the application rather than the idea directly.[67]

2. *Relaxing The Restrictions for Software Patents*

The Supreme Court reversed course in its restrictions on software patents with its 5-4 decision in *Diamond v. Diehr*.[68] There a machine used an

---

59. *Id.* at 72-73.

60. Direct attempts to patent programs have been rejected on the ground of nonstatutory subject matter. Indirect attempts to obtain patents and avoid the rejection, by drafting claims as a process, or a machine or components thereof programmed in a given manner, rather than as a program itself, have confused the issue further and should not be permitted.

Id. at 72 (quoting "To Promote the Progress of . . . Useful Arts," from Report of the President's Commission on the Patent System (1966)).

61. Parker v. Flook, 437 U.S. 584, 585-86 (1978).

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.* at 589-93.

66. *Id.* at 593.

67. *Id.* ("The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect.").

68. Diamond v. Diehr, 450 U.S. 175, 185-88 (1981) (comparing past software patent cases to *Diamond*).

algorithm as part of a rubber curing process.[69] Although the separate steps of the process may not have been individually patentable, this did not preclude the patentability of the machine as a whole.[70] According to the Court, post-solution activity provided a sufficient condition for patenting computer software.[71] *Diamond v. Diehr* seemed to represent the narrow principle that an invention meeting all the other requirements of patentability was not unpatentable simply because it contained software.[72]

The USPTO interpreted the decision broadly, however, and began "issuing patents for algorithms and a wide range of other software-related innovations."[73] The Federal Circuit did likewise. In *In re* Alappat, the court ruled that software is patentable under § 101 when the claim is actually directed to a machine that uses the software.[74] Since every piece of software must run on a machine to function, this holding effectively allowed patenting all computer software algorithms. Unlike the Supreme Court in *Diamond v. Diehr*, the Federal Circuit did not demand post-solution activity or some tie to the physical world beyond it being used on a computer.[75]

The Federal Circuit then expanded the scope of abstract patents even further to cover technology that is only non-obvious from a business perspective in *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*[76] The "hub and spoke" data processing system at issue in *State Street Bank* allowed mutual funds (the spokes) to pool their assets into a common investment portfolio (the hub) to gain economies of scale in administration and tax advantages through partnership.[77] The court reasoned that an invention is patentable if it involves a practical application and "it pro-

69. *Id.* at 175, 181.

70. *Id.* at 187.

71. *Id.*

72. *See id.* at 192-93 ("[W]e do not view respondents' claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products.").

73. Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1094 (1990).

74. *In re* Alappat, 33 F.3d 1526, 1542 (Fed. Cir. 1994); *see also In re* Beauregard, 53 F.3d 1583, 1584 (Fed. Cir. 1995) (remanding because the Commissioner of Patents and Trademarks stated "'that computer programs embodied in a tangible medium, such as floppy diskettes, are patentable subject matter under 35 U.S.C. § 101 . . .'").

75. *See Diamond*, 450 U.S. at 191-92.

76. State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998).

77. *Id.* at 1370.

duces a useful, concrete and tangible result."[78] According to the court, the data processing system met this test, so the patent was valid.[79] Congress entrenched the Federal Circuit's decision by passing 35 U.S.C. § 273, which mandated prior user rights for patented methods.[80] A year later, the Federal Circuit ruled that computer algorithms standing alone were patentable.[81]

Even after *State Street Bank*, USPTO rules confined business method patents to subjects within the "technological arts," namely those tied to a computer or electronic device.[82] The USPTO used that rule to reject patent applications that treated innovations outside the technological arts on section 101 grounds.[83] The BPAI eliminated this test in *Ex parte* Lundgren, a precedential opinion issued in 2005, on the ground that such a test has never been judicially recognized.[84] This decision both expanded the scope of business method patents and "widens the gap between the U.S. and many other countries who are still debating patentability of software."[85] While the Federal Circuit could overrule the *Lundgren* decision, this would mark a significant change of course in a long trend of liberalizing restrictions on subject matter.

Like the purification test, patentability for software seemed a pragmatic response to developing technology that initially generated significant debate.[86] As with purification patents, it seems likely that neither Congress

78. *Id.* at 1373.

79. *Id.*

80. *See* 35 U.S.C. § 273 (2000).

81. AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1356-57 (Fed. Cir. 1999).

82. *Ex parte* Bowman, 61 U.S.P.Q.2d 1669, 1669-71 (B.P.A.I. 2001).

83. Travis Thomas, *Responding To "Unpatentable Subject Matter" Rejections Of Algorithm Patent Claims Citing* Ex parte Bowman, INTELLECTUAL PROPERTY REPORT, http://www.bakerbotts.com/file_upload/TravisThomasArticle.htm (last visited Dec. 10, 2006).

84. *Ex parte* Lundgren, Appeal No. 2003-2088 (B.P.A.I. 2004).

85. Patent Board Eliminates "Technological Arts" Requirement For Business Method Patents, http://www.patentlyo.com/patent/2005/10/patent_board_el.html (Oct 17, 2005).

86. *See, e.g.*, Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959 (1986); Lee A. Hollaar, *Justice Douglas Was Right: The Need for Congressional Action on Software Patents*, 24 AIPLA Q.J. 283 (1996); Allen Newell, *Response: The Models are Broken, The Models are Broken!*, 47 U. PITT. L. REV. 1023 (1986); Pamela Samuelson, Benson *Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025, 1093 (1990); Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994); Merges, *supra* note 1, at 3-4 (quoting MIT Communications Forum, "Software Patents: A Horrible Mistake," Mar. 23, 1989, Semi-

nor the Supreme Court overturned these developments because the software industry has thrived rather than faltered. Now most commentators believe that the decision, for better or worse, has already been made.[87] While this may be true for software, patent applicants are still pushing the boundaries of patentable subject matter in other areas.[88]

D. *Lab. Corp.* and Other Recent Developments

Metabolite owns U.S. Patent No. 4,940,658 ("the '658 patent"), which claims methods for detecting deficiencies in the body of B vitamins cobalamin or folate, biochemicals known respectively as B[12] and folic acid.[89] Levels of cobalamin and folate are difficult to measure directly.[90] However, they are inversely correlated with the total level of another chemical, homocysteine, because in normal metabolic function they break down homocysteine into smaller constituent parts.[91] Thus, a higher than normal level of homocysteine implies a lower level of B vitamins.[92] Claim 13 of the '658 patent teaches a method that utilizes this discovery to derive the level of B vitamin deficiency:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[93]

Although it originally granted certiorari to decide whether the subject matter of claim 13 was patentable, the Court later dismissed certiorari as improvidently granted.[94] According to Justice Breyer, dismissal was likely predicated on the fact that the parties did not raise patentable subject mat-

---

nar Notes (citing statement of Daniel Bricklin, President of Software Garden, Inc.)); Gordon Irlam and Ross Williams, League for Programming Freedom, Software Patents: An Industry at Risk, 1994, http://lpf.ai.mit. edu/Patents/industry-at-risk.html.

87. *See, e.g.*, Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CALIF. L. REV. 1, 3 (2001); Merges, *supra* note 1.

88. *See, e.g.*, Patent Board Eliminates "Technological Arts" Requirement For Business Method Patents (Oct 17, 2005), http://www.patentlyo.com/patent/2005/10/patent_board_el.html; *Ex parte* Lundgren, Appeal No. 2003-2088 (B.P.A.I. 2004).

89. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2923-24 (2006) (Breyer, J., dissenting); U.S. Patent No. 4,940,658 (filed Nov. 20, 1986).

90. *Lab. Corp*, 126 S. Ct. at 2923-24.

91. *Id.*

92. *Id.*

93. The '658 patent, col. 41, ll. 58-65.

94. *Lab. Corp*, 126 S. Ct. at 2922.

ter as a validity issue in the lower courts.[95] However, he opined that this was not a serious concern because the parties had argued the issue through other doctrines.[96] Moreover, industry and lower courts evinced a pressing need for clarification in this area.[97] The lack of appropriate pleading may have been dispositive, however, in an area where any ruling would likely present a drastic alteration of the patent landscape. Such potentially sweeping effects would militate against resolving a case where the issue was not properly framed.

Writing for Justices Stevens, Souter, and himself in dissent, Justice Breyer said that he would decide the case and would invalidate the patent because it claimed a law of nature.[98] Distinguishing between patentable and unpatentable subject matter is a difficult endeavor.[99] After all, many a patentable invention rests upon its inventor's knowledge of natural phenomena; many "process" patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process.[100] According to Justice Breyer, however, claim 13 was invalid "no matter how narrowly one reasonably interprets that doctrine."[101] Metabolite argued that the claim recited a valid process because it physically transformed matter and produced a "useful, concrete, and tangible result."[102] Justice Breyer responded that the fact that the homocysteine test involved an unpatented transformation of blood was irrelevant to the claim as a whole.[103] Furthermore, he stated that the "useful, concrete, and tangible result" test from *State Street Bank*, if interpreted to validate the claim at issue, "would cover instances where the Court has held the contrary."[104] Claim 13 failed because it "simply described the natural law at issue in the abstract patent language of a 'process.'"[105] Justice Breyer reasoned that because the correlation itself was unpatentable as a law of nature, a process claim whose first step was to obtain data and whose second step

95. *Id.* at 2925.
96. *Id.* at 2925-26.
97. *Id.*
98. *Id.* at 2925-27. Chief Justice Roberts took no part in the consideration or decision of the case.
99. *Id.* at 2926.
100. *Id.*
101. *Id.* at 2927.
102. *Id.*
103. *Id.*
104. *Id.* at 2928 (citing State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998); O'Reilly v. Morse, 15 How. 62, 14 L.Ed. 601 (1854); Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972)).
105. *Id.*

was to apply the correlation effectively covered a law of nature and was thus unpatentable.[106]

II. HIGH STAKES, BUT AN IMPOSSIBLE LINE TO DRAW

The hasty retreat from subject matter enforcement discussed in Part I may reveal more than adaptation to new technology. Theoretically consistent and judicially administrable subject matter rules may be impossible to draw in a way that would not be over-inclusive or nearly non-existent. The difficulty in restricting subject matter "just a bit" without treading on too many useful patents might be the true reason for the Supreme Court's dismissal of certiorari as improvidently granted in *Lab. Corp.* Indeed, *Lab. Corp.* presents a useful vehicle for examining subject matter because it illustrates the problem of capturing laws of nature, particularly in biotechnology, as well as the difficulties inherent to abstract claims. Section II.A discusses subject matter as it relates to the biotechnological industry, while Section II.B deals with problems created by abstract patent claims, particularly in software and business methods.

A. Compositions of Matter

Biotechnological and pharmaceutical patents typically concern compounds rather than processes because it is more difficult to produce a different biochemical or drug with the same effect as a patented biochemical or drug than it is to discover an alternative to a patented production method. *Lab. Corp.* is interesting because it does not concern a patent on a physical substance, but rather a method of diagnosis. However, an analysis of patents for physical substances serves to ground the analysis of the policy concerns underlying process patents. Section II.A.1 discusses a way of determining the theoretical gray area for patents on physical substances. Section II.A.2 discusses the costs and benefits associated with patenting pre-existing substances.

1. Natural Substances—The Substantial Transformation Test

Professors Demaine and Fellmeth suggest that a careful analysis of the theory and history of § 101 reveals the existence of a subject matter re-

106. *Id.* While describing claim 13 as abstract seems contrary to the trend of case law established in Sections II.B and II.C, it demonstrates the absence of a firm theoretical grounding for that trend. After all, claim 13 is analogous to claiming a process for measuring the radius of a circle and "correlating" the square of that value with pi to determine the circle's area. Surely the act of measuring is insufficient physical instantiation of the abstract concept to merit a patent.

quirement that parallels novelty, utility, and nonobviousness.[107] Under their analysis, only subject matter that is sufficiently "inventive" and "new" is patentable.[108] Inventiveness stands apart from obviousness because inventiveness hinges upon the degree of inventor contribution, not the difficulty of the discovery.[109] Thus, a newly discovered law of nature would not be patentable subject matter because the inventor neither created it nor contributed to its formation in any way.[110] Newness stands apart from novelty because newness hinges upon whether the invention previously existed, not whether one can find it in the prior art.[111] Thus, a newly discovered gene would not be new in the patentable subject matter context, despite its apparent novelty, because it previously existed in nature.

Focusing in the inventive step, according to Demaine and Fellmeth, would allow a patent on a composition of matter if it has undergone a "substantial transformation," a test used to distinguish two products in customs and trade laws.[112] The primary factors in determining a substantial transformation are the new character and use of the resulting product—factors that courts must determine on a case-by-case basis.[113] Relevant characteristics of a substance that indicate a new character and use include such factors as whether it is a consumer good or industrial input, whether it has an "independent identity" or has been incorporated into a larger product, and whether it has a different use or function.[114]

The substantial transformation test would disallow several types of patents currently issued by the USPTO and upheld by the courts.[115] It would require that applicants do more than simply create a complimentary DNA ("cDNA") replica of a DNA strand, since creating cDNA is part of the standard sequencing process and does not change the character and use of the substance.[116] Instead, applying the test would require that the se-

---

107. *See* Demaine & Fellmeth, *supra* note 22, at 360-88.

108. *Id.* at 461-65.

109. *See id.* at 365-84.

110. *See id.* at 370 ("It is important to draw the distinction, when speaking of patentable subject matter, between discoveries of things not previously known and discoveries of things not previously existing.").

111. *See id.* at 384-88.

112. *Id.* at 393-94.

113. *Id.* at 394.

114. *Id.* at 397-99.

115. *Id.* at 406-07.

116. *Id.* at 408. cDNA is "DNA that is synthesized to be complementary to a mRNA molecule. By definition a cDNA represents a portion of the DNA that specifies a protein (is translated). If the sequence of the cDNA is known, by complementarity, the sequence

quenced DNA be transformed "into a vaccine, pharmaceutical, diagnostic, or therapy."[117] This seems like a substantially higher bar than the specific utility principle set forth in *In re* Fisher, but it is actually different in kind.[118] A substantial transformation test would not focus on whether use of the transformed substance was sufficient to meet a utility bar, only on the degree to which it differed from the natural substance.

Professors Demaine and Fellmeth provide the example of an avocado tree genetically altered to produce avocados in a different climate.[119] Under the substantial transformation test, an applicant could obtain a patent on the genes used to transform the tree if she substantially altered those genes, but she could not obtain a patent on the tree as a whole because its character and use was not substantially altered.[120] It still produces avocados.[121] If, on the other hand, the molecular biologist spliced the tree's genome with a hormone-producing gene so that the tree produced avocados that had a therapeutic effect once eaten, she would have substantially altered the function of a tree as a whole, which would merit a patent of equivalent scope.[122] Rather than producing normal avocados, the tree would produce a therapeutic product.[123]

2. *Cost-Benefit Analysis*

Patenting substances that exist in nature may represent a net decrease in incentives by moving the point of patenting too early in the research process.[124] Early in the history of biotechnology, sequencing genes and DNA was difficult and time consuming, and rewarding basic research seems to have yielded incentive benefits with relatively acceptable

---

of the DNA is known." Glossary, http://ucbiotech.org/glossary (last visited Feb. 10, 2007).

117. *Id.* at 407.

118. *See In re* Fisher, 421 F.3d 1365, 1370-72 (Fed. Cir. 2005) (explaining the specific utility requirement).

119. Demaine & Fellmeth, *supra* note 22, at 410.

120. *Id.*

121. *Id.*

122. *Id.*

123. *Id.*

124. *See* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1078 (1989) (discussing the optimal scope of the experimental use exemption); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 136-50 (1999) (discussing how to reconcile the norms of basic research with the needs of industry).

costs.[125] After all, some of the first purified chemicals, such as insulin, had immediate therapeutic use. However, recent developments in sequencing technology have made sequencing genes and DNA relatively easy, and patents on basic research make later, more directed research quite costly.[126] First, researchers incur significant, sometimes prohibitive, costs to conduct research involving patented, naturally occurring molecules or organic tissue.[127] Second, researchers face the prospect of conflicting or blocking patents that arise later in the research process.[128] Blocking patents may be stifling truly innovative patents through licensing and transaction costs.[129] Further, high pendency at the USPTO increases examination time and may decrease quality for more significant patents.[130] Third, patents are costly to acquire. Companies generally cannot choose to avoid the costs because patents may profit companies relative to each other without a net gain by the industry or society as a whole.[131] These costs may even cause researchers to avoid work in certain areas of biotechnology.[132] Allowing patents on natural genes may situate patenting too early in the research process. It may be more profitable to patent early research and strategically wait for others to use it than to continue more directed research, suggesting that patents create an inefficiently high level of incentives.

However, one may reasonably argue that eliminating patents on sequenced genes or purified substances may result in the loss of significant incentives for basic research. Once a gene is identified and its use is discovered, the argument goes, others could free ride on this work and reap the rewards without paying the costs. Thus, scientists would have fewer incentives to research the function of genes because others could freely exploit any discovery of knowledge related to gene function. The decrease of incentives for innovation would result in a decrease in innovation in

---

125. *See, e.g.*, Demaine & Fellmeth, *supra* note 22, at 392 (arguing that "the PTO remains mystified by recombinant DNA technology" despite significant advances in the field that made DNA sequencing mechanical where it was once quite difficult.").

126. *Id.* at 391-92. "Dr. James Watson—co-discoverer of the double helical structure of DNA—observed in 1991 that 'virtually any monkey' can run an automated sequencing machine." *Id.* at 391-92 (citing Leslie Roberts, *Genome Patent Fight Erupts*, 254 SCI. 184, 184 (1991) (quoting Dr. James Watson)).

127. *Id.* at 415.

128. *Id.*

129. *Id.*

130. *Id.* at 414.

131. *See id.* at 416 (citing "high costs associated with the issuance of patents on discovered phenomena").

132. *See id.*

biotechnology. In biotechnology, determining a use for a gene is quite difficult and paves the way for invention and commercialization.

The tension in biotechnology patents lies in the fact that allowing patents on "a gene and a use" both protects the groundbreaking new discoveries with potential to move the field forward and gives the potential for widespread abuse. Thus, employing the substantial transformation test may be somewhat costly and inefficient, since basic research would be insufficiently rewarded, but allowing patents on such innovation opens the industry to considerable costs. Though *Lab. Corp.* did not concern a patent on a physical substance, the controversy regarding the patent at issue may be best illuminated by the motivation behind the substantial transformation test—identifying the theoretical and practical "gray area" of subject matter.

B. The Problem with Abstraction

The controversy in *Lab. Corp.* regarded whether the patent effectively claimed a law of nature.[133] As Justice Breyer noted, many patents rely on the inventor's knowledge of natural substances and natural laws.[134] However, determining whether a particular patent came too close to capturing a natural law is a particularly difficulty inquiry, and not one that seems to lend itself to bright-line rules.[135] One could think of patent claims for physical objects as falling on a spectrum from objects already existing in nature to objects thoroughly different from any that had previously existed. Similarly, patent claims for processes can be thought of on a spectrum from concrete processes that effect a significant physical transformation to processes that are entirely abstract. *Lab. Corp.* may have spurred particular discomfort in the patent community not only because it dealt with a patent that covered a law of nature, but because the claim at issue was unusually abstract for an art area typified by composition of matter claims.

1. Abstract Patent Claims

An abstract process may be defined as one in which both the input and the output of the process is information, and any physical steps are essen-

133. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926-27 (2006) (Breyer, J., dissenting).

134. *Id.*

135. *See id.* at 2926 ("[T]he category of non-patentable 'phenomena of nature,' like the categories of 'mental processes,' and 'abstract intellectual concepts,' is not easy to define.").

tially generic.[136] For example, if a patent claims an algorithm implemented on a machine, such as a computer, there nothing unique about the computer. Further, the computer is not physically doing anything not present in the prior art other than executing the series of steps defined by the algorithm. The innovation lies in the informational realm, not the physical realm. Of course, there is no bright line between the two. Thus, concrete-abstract is not a binary bifurcation, but rather a spectrum on which inventions may lie.

Analogizing from the substantial transformation test for substances, an abstract process could be thought of as one that does not substantially transform physical materials. In *Lab. Corp.*, claim 13 did not specify any particular method of determining homocysteine levels.[137] Indeed, many such tests exist in the prior art.[138] Step 2 could conceivably be entirely mental. In effect, claim 13 covers the correlation itself, or at least its use in one direction.[139] *Lab. Corp.* is interesting, and perhaps controversial, because it involves an abstract claim that falls under neither the software nor the business method category. Instead, it is a method of medical diagnosis. However, the problems and issues associated with the *Lab. Corp.* patent mirror those associated with abstract patents more closely than those associated with other patents in pharmaceuticals or biotechnology. Abstract claims are more common in software and business methods. Technically, computer software is implemented in a way that physically changes bits in hardware, yet the actual computer employed is irrelevant and, moreover, unchanged after completion of the process.

Natural laws are inherently abstract because they describe principles that govern the natural world. Natural laws are not things, or even, strictly speaking, processes. Instead, they are ideas, correlations, and causative relationships. Thus, applicants must draft abstract claims in order to approach patenting natural laws. As with "gene and a use" patents in biotechnology, abstract patents may represent the best and worst of the patent system.

---

136. *See, e.g.*, David S. Olson, *Patentable Subject Matter: The Problem of the Absent Gatekeeper* 27-29 (Sept. 27, 2006), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=933167 (describing the Supreme Court's approach to abstraction in Cochrane v. Deener, 94 U.S. 780 (1876)).

137. *Lab. Corp.*, 126 S. Ct. at 2921, 2924 (Breyer, J., dissenting).

138. *See id.* at 2923-24.

139. *See id.* at 2924.

2. *Problems with Abstraction*

Patents with fundamentally abstract claims include the latest developments in computer science and business, yet as *Lab. Corp.* demonstrates, the patent community is not yet fully comfortable with them. This discomfort may stem from the fact that allowing abstract patent claims is like opening Pandora's box—once patents are allowed for some abstract claims, such as software, courts may find it difficult (i.e. theoretically inconsistent and practically impossible) to limit the scope to a single art area.[140] Further, as with gene patents in biotechnology, patents on software and business methods often seem both an aid to businesses and a significant source of industry problems.

As in *Lab. Corp.*, applicants may craft abstract claims to cover laws of nature. Patents on laws of nature yield significant enforcement problems. For example, suppose in *Lab. Corp.* that homocysteine was also correlated with the presence of a deficiency in a different vitamin, such as C. Then a doctor who ordered a noninfringing homocysteine test to check for a C vitamin deficiency and thereupon discovered and diagnosed a B vitamin deficiency would automatically infringe claim 13.[141] This hypothetical illustrates how the physical transformation test to highlight abstraction overlaps with another judicial method of determining unpatentable subject matter, the mental steps doctrine.[142]

Further, it is difficult to identify prior art for abstract claims because the claims rely on ideas rather than physical objects. In business and software, practitioners create tools to accommodate the practical exigencies of particular goals and often do not record them in a way that would make them searchable by applicants or the patent office. Business and software are broad and fast-paced, contrary to the more stolid, cumulative progress of traditional industry. The dearth of prior art makes determining novelty and nonobvious difficult. The difficulty inherent in the nonobviousness inquiry is compounded by the fact that business and software developments proceed primarily by common sense and general understanding ra-

---

140. *See generally* Nari Lee, *Patent Eligible Subject Matter Reconfiguration and The Emergence of Proprietarian Norms—The Patent Eligibility of Business Methods* (Oct. 14, 2002), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=400100 (discussing the worldwide reconfiguration of subject matter restrictions that has resulted from allowing patents on abstract methods).

141. While 35 U.S.C. § 271(c) significantly limits the remedies available for infringement of claims covering medical procedures and thus would likely protect doctors who infringed claim 13, such protection is unavailable for most abstract process claims. *See, e.g.*, MERGES & DUFFY, *supra* note 13, at 183-84.

142. *See id.* at 30-31 (citing *In re* Heritage, 150 F.2d 554, 556-58 (Pat. 1945)).

ther than specific combination of previous elements in a technically nonobvious way. In effect, the traditional tests and definitions for nonobviousness may be less applicable to abstract innovations. Particularly in software, the question is not whether the precise series of claimed steps was obvious, but rather whether the abstract principle on which they were based was obvious. Business methods also present a particular difficulty because they do not hinge on technological innovation. Thus, it becomes difficult to define a person of ordinary skill in the art or determine the appropriate amount of innovation necessary to meet the nonobviousness bar.

Software has several properties which make it ill-suited to the traditional patent system. In particular, it is easy to claim software that captures laws of mathematics in the same way that the patent in *Lab. Corp.* captures the correlation between homocysteine and B-vitamins. However, this can be difficult for a person unskilled in the art to see for several reasons. Innovation in software often involves mathematical, rather than experimental, research. Computer software is expressed in a language where symbols represent abstract mathematical ideas rather than chemicals that exist in nature. This makes software concepts more difficult to analogize to things persons unskilled in the art can understand. Put simply, a chemist could explain the properties of chemicals and what she does with them in a basic way, but a mathematician may be hard-pressed to offer a similar explanation. Chemistry is limited by the physical constraints of matter, while mathematics has no such boundaries, thus allowing software that is arbitrarily complex.

Indeed, applicants for many software inventions *must* seek to patent a mathematical principle or a would-be infringer might easily achieve the same result using the principle revealed by the patent in a different way. The claiming system for U.S. patents is peripheral and thus ill-suited to claiming a central principle. Computer science, like mathematics, is best explained in pseudo-code and formulae, not in English, and the correctness of a description hinges not on whether it encapsulates every application of an idea, but rather on whether it fully convinces the reader of the validity of the principle. Fully extrapolating from the idea is neither necessary nor possible. Thus, a nonobviousness inquiry that centers on peripheral claims does not reflect the nature of the underlying technology. The nonobviousness mismatch often results in claims whose scope extends far beyond the inventive step or claims that those skilled in the art can easily invent around.

III. TOWARD A MORE SOPHISTICATED PATENT SYSTEM

Part I showed how the history of patentable subject matter has been one of consistent backpedaling, with each new case moving an ostensibly bright line one bit further to respond to the needs of industry. Yet the final answer, in which nearly anything that meets the utility, nonobviousness, and novelty bars is patentable, is hardly satisfying. Biotechnology, computer science, and their progeny, such as nanotechnology and bioinformatics, promise to revolutionize the human experience in unforeseen ways. Part II discussed how these new industries may be different in kind from the classical technology for which patent law was designed. Like the industries it seeks to assist, patent law must evolve and adapt. The tensions illustrated by changes in patentable subject matter cannot be resolved by tweaking the bright-line rules by which patent law usually operates. Rather, Congress, the courts, and scholars should mold these rules in new ways to account for new innovation.

A. Policy Levers & Equity

Judicial understanding and recognition of the different features of industries will allow courts to apply patent law with the necessary flexibility. Already the Supreme Court has returned patent injunctions to their equitable roots.[143] While splitting patent law according to art area may be inadvisable and practically impossible, the specific doctrines of patent law may be molded to accommodate the needs of different industries.[144] It is too late to return to a time when the subject matter in the gray areas discussed in Part II was entirely unpatentable, and given the importance of these areas of innovation to the economy, it would likely be detrimental as well. However, judges could use these traditional tests not to invalidate

143. *See* eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-40 (2006). For a discussion of post-*eBay* patent injunction cases, see Jeremy Mulder, Note, *The Aftermath of* eBay*: Predicting When District Courts Will Grant Permanent Injunctions in Patent Cases*, 22 BERKELEY TECH. L.J. 67 (2007).

144. Commentators are currently debating the types of contours an industry-specific patent law would exhibit. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002); R. Polk Wagner, *Of Patents and Path Dependency: A Comment on Burk and Lemley*, 18 BERKELEY TECH. L.J. 1341 (2003); R. Polk Wagner, *Comment: Exactly Backwards: Exceptionalism and the Federal Circuit*, 54 CASE W. RES. L. REV. 749 (2004); *see also* Cohen & Lemley, *supra* note 1, at 53-56 (discussing ways courts might apply doctrine of equivalents analysis specifically to the software industry); Dan L. Burk & Mark A. Lemley, *Designing Optimal Software Patents* 81-82, 91-100 (Stanford Law School Pub. Law & Theory Working Paper Series, Working Paper No. 108, 2005; University of Minnesota Law School Legal Studies Research Paper Series, Research Paper No. 05-11, March 2005) (suggesting ways that software patents could be changed to suit the software industry).

patents, but rather to distinguish patents that may merit extra scrutiny and particularly strict application of other patent law bars. A curious feature of the U.S. patent system is that each requirement of patentability stands mostly alone.[145] The final goal is to uphold patents in a way that creates meaningful incentives while minimizing costs, and this could be best achieved by understanding and embracing subject matter as an important issue, even if not as one that serves as a bar to patentability.

B. Innovative New Systems

Commentators have suggested offering different grades of patents based on examination intensity and money invested.[146] The resulting patents might carry different burdens of proof and presumptions of validity. Adding subject matter guidelines to such patents seems like a reasonable way to better align patent law with the needs of industry. Forcing patents with abstract claims into a lower grade of patent might deter many of the current costs associated with abstract patent claims.

One possibility for handling patents in the gray areas would be to grant them shorter terms, perhaps five or ten years instead of twenty. This would alleviate the negative affects of blocking patents on research and business development, but would keep the incentives for innovation. In particular, a shortened time limit may be sufficient for a scientist to research a bio-chemical innovation based on substantial transformation that would meet the full-fledged patent requirements. Software and business, on the other hand, develop quickly enough that the traditional twenty-year term may not be necessary. Development of new technology in software and business methods does not entail the kind of painstaking research traditionally present in invention, thus lowering the capital and operational expenditures relative to physical inventions. The incentive structure of the patent system was set up with the costs of physical innovation in mind. It is easy to see that if the costs of innovation are substantially lower for abstract

145. In Japan, for instance, the requirements of patentability are not as distinct as in the United States. Statutory subject matter is a substantive bar under which an invention must involve a technical idea that utilizes a law of nature and must have industrial applicability. *See* Patent Law, No. 121 (1959) ch. 1, § 2(1), *available at* http://www.wipo.int/clea/docs_new/pdf/en/jp/jp006en.pdf ("'Invention' in this Law means the highly advanced creation of technical ideas by which a law of nature is utilized.").

146. Mark Lemley, Doug Lichtman & Bhaven Sampat, *What to Do about Bad Patents?*, 28 REG. 10 (Winter 2005-06), *available at* http://www.cato.org/pubs/regulation/regv28n4/v28n4-noted.pdf; *see also* What is a Patent?, http://www.ipaustralia.gov.au/patents/what_index.shtml (last visited Feb. 16, 2007) (discussing the two-tier Australian patent system).

patents, then the concomitant rewards from the patent system should be lower.[147]

Another possibility is creating a different form of patent protection for business methods. Professors Duffy and Abramawitz suggest that protection should be granted for business methods that are commercially, rather than technically, non-obvious.[148] This would better align incentives with the beneficial effects to society.[149] Although their particular solution may not be optimal, it illustrates the kind of significant alterations that may be necessary to ensure that patent law performs its proper function. Indeed, such innovations may be as novel and non-obvious as the inventions they protect.

IV. CONCLUSION

Abstract methods and natural substances were traditionally unpatentable, but those barriers have eroded to the point of nonexistence. Patents that cover traditionally unpatentable subject matter include some of the most technologically advanced and important scientific advancements, such as cutting-edge work in biotechnology and computer software. However, other patents in this category, including patents on technologically obvious business methods and sequenced genes of questionable utility, also exhibit great potential for inefficiently high awards and significant costs to industry.

Subject matter may no longer be a substantive bar to patentability, but it can potentially play two important functions in modern patent law. First, it can highlight patents that should be subject to heightened scrutiny, both judicially and academically, due to the higher costs and benefits associated with such patents. Second, it can highlight subsets of patent law that are ripe for innovation. The patent system should certainly adapt the application of existing rule according to subject matter and should leave open the possibility of large-scale changes or *sui generis* protection to deal with subject matter traditionally outside the scope of patent protection.

While none of these suggestions provide a definite method of reaching a satisfying result in *Lab. Corp.*, they do suggest an alternate approach. Deciding validity under an eroded and perhaps unworkable subject matter

147. *See, e.g.*, Peter S. Menell, *Tailoring Legal Protection for Computer Software*, 39 STAN. L. REV. 1329 (arguing for *sui generis* intellectual property protection for computer software).

148. John F. Duffy & Michael Abramawitz, *Intellectual Property for Market Innovation* 45-51 (Univ. of California Berkeley Law & Econ. Workshop, Paper No. 10, 2006).

149. *Id.*

doctrine risks the creation of confusing and theoretically unsound precedent. Instead, courts should have analyzed validity aggressively under other patent doctrines because the patent covering traditionally unpatentable subject matter.