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Everything is Patentable

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EVERYTHING IS PATENTABLE

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INTRODUCTION

The currently confused and inconsistent jurisprudence of patentable subject matter¹ can be clarified by implementing a single rule: any invention that satisfies the Patent Act's requirements of category, utility, novelty, nonobviousness, and specification is patentable.² In other words, if a discovery otherwise meets the requirements of patentability, then the discovery will be properly patentable without need to consider non-statutory subject matter restrictions such as the bars against mathematical algorithms, products of nature, or natural phenomena.³

This Article's proposal is based on both positive and normative analysis. Positively, a historic review of United States Supreme Court opinions provides evidence that general patentability criteria—and not subject matter—were key to the Court's primary subject matter precedents. In each case reviewed, the Court's analysis concerned the underlying patentability of the particular claim at issue—

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^{1.} See generally 35 U.S.C. §§ 101, 102, 103, 112 (2000). Section 101 lists the subject matter for which patents may be obtained. Patentable subject matter is "any new and useful process, machine, manufacture, or composition of matter..." *Id.* § 101. Sections 102 and 103 require an invention's novelty and nonobviousness. Novelty means that an invention is new, that it has not been patented in the United States or a foreign country, or that no one has applied for a patent for that invention. *Id.* § 102. An invention is obvious if the subject matter is "such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *Id.* § 103. Section 112 requires specificity in a patent application. A patent application must contain "a written description of the invention, and of the manner and process of making and using it…as to enable any person skilled in the art…to make and use the same…" *Id.*

^{2.} See id. §§ 101–103, 112.

^{3.} One case suggested such an approach nearly fifty years ago. Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 162 (4th Cir. 1958) ("[W]here the requirements of the Act are met, patents upon products of nature are granted and their validity sustained."). The approach suggested by the *Merck* court has not been widely accepted doctrinally. *See, e.g.*, Parker v. Flook, 437 U.S. 584, 593 (1978) ("First, respondent incorrectly assumes that if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101 and the substantive patentability of the particular process can then be determined by the conditions of §§ 102 and 103.").

problems such as obviousness or insufficient disclosure—even if its opinions nominally recited broad subject matter limitations. Further, other patentability criteria could easily meet the underlying policy concerns of the Court. As a result, current patentable subject matter jurisprudence is based not on actual issues the Court historically decided, but instead on sweeping dicta that outlined unsubstantiated concerns about broad patent claims.⁴

Normatively, if courts always reach the right result for the wrong reasons, then little need be done to change the status quo. However, due to the lack of clear and rigorous precedential support for limiting patentable subject matter, current patentable subject matter jurisprudence is inconsistent and, if extended to logical conclusions, would bar patentability of almost any invention or discovery, which certainly would present a suboptimal outcome.⁵ For example, in *Parker v. Flook*, the Supreme Court stated, "[W]e must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress."⁶ However, the subject matter areas of some of the most important breakthroughs in history could not have been foreseen by Congress when patent laws were originally drafted. Many patents throughout history, from the telegraph to the airplane to the transistor, would be invalid under the *Flook* approach to unforeseeable technology areas.⁷

Only two years after *Flook*, in *Diamond v. Chakrabarty* the Court considered whether live bacteria used to clean oil spills could be patented.⁸ The

^{4.} See, e.g., In re Bilski, No. 2007-1130, 2008 WL 4757110, at *58 (Fed. Cir. Oct. 30, 2008) (Rader, J., dissenting) ("Much of the court's difficulty lies in its reliance on dicta taken out of context from numerous Supreme Court opinions dealing with the technology of the past. In other words, as innovators seek the path to the next tech[no]-revolution, this court ties our patent system to dicta from an industrial age decades removed from the bleeding edge.").

^{5.} See Kristin Osenga, Ants, Elephants Guns, and Statutory Subject Matter, 39 ARIZ. ST. L.J. 1087, 1093–1103 (2007) (describing inconsistent subject matter decisions).

^{6.} *Flook*, 437 U.S. at 596. Interestingly, the Court cites *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972), to support its position. Congress enacted 35 U.S.C. § 271(f) in direct response to the narrow view of the patent law taken by the Court in *Deepsouth Packing Co. See* Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746, 1751–52 (2007); Pub. L. No. 98-622, Title I, § 101(a), 98 Stat. 3383 (Nov. 8, 1984). This "correction" implies that Congress intended the act to be construed broadly, and that the Court in *Deepsouth* and *Flook* need not have interpreted the statute so narrowly.

^{7.} See Thomas D. Kiley, *Common Sense and the Uncommon Bacterium – is "Life" Patentable?*, 60 J. PAT. OFF. SOC'Y 468, 474 (1978) (arguing that the Court's approach in *Flook* would mean that new technologies could not be patented until Congress decided otherwise after the fact); Expanded Metal Co. v. Bradford, 214 U.S. 366, 384–86 (1909) (determining that the definition of "process" should be construed broadly, not narrowly).

^{8.} Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980). Prior attempts to clean oil used a combination of bacteria, whereas Chakrabarty genetically engineered a single bacterium that could "eat" multiple chemicals. *Id.* at 305 n.2. The *Chakrabarty* Court expressly compared the new bacteria with the combination in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), discussed in Part III.A. *Id.* at 310.

Court ruled that a living organism could very well be patentable if it was novel.⁹ Importantly, the Court made clear that simply because a technology was unforeseen at the time a statute was enacted was no reason to exclude that technology from patentability.¹⁰ This approach makes intuitive sense, given that the primary justification for patent law is to encourage new technologies.¹¹ However, *Chakrabarty*'s ruling is directly contrary to the policy set forth in *Flook*, which has never been expressly overruled.¹²

Nearly thirty years after *Flook*, court rulings have not borne any further clarity. In a 2006 dissent from dismissal in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, three justices admitted that "the category of non-patentable 'phenomena of nature,' like the categories of 'mental processes,' and 'abstract intellectual concepts,' is not easy to define."¹³ Similarly, the Federal Circuit's recent en banc opinion in *In re Bilski* admitted the difficulty.¹⁴

Despite the difficulty of providing clear definitions, these cases are trending toward more subject matter rejections. Further, scholars continue to advocate the "gatekeeping" role of courts in barring patents of a particular subject matter.¹⁵

12. *Id.* at 316 ("This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."); *see also* U.S. CONST. art I, § 8, cl. 8 ("To promote the Progress of . . . useful Arts").

13. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2926 (2006) ("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.") (Breyer, J., dissenting). Courts invalidating claims based on subject matter have recognized this much as well. Parker v. Flook, 437 U.S. 584, 589 (1978) ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear.").

14. In re Bilski, No. 2007-1130, 2008 WL 4757110, at *5 (Fed. Cir. Oct. 30, 2008) ("Unfortunately, this inquiry is hardly straightforward. How does one determine whether a given claim would pre-empt all uses of a fundamental principle? Analogizing to the facts of *Diehr* or *Benson* is of limited usefulness because the more challenging process claims of the twenty-first century are seldom so clearly limited in scope as the highly specific, plainly corporeal industrial manufacturing process of *Diehr*; nor are they typically as broadly claimed or purely abstract and mathematical as the algorithm of *Benson.*").

15. See, e.g., Eileen M. Kane, Splitting the Gene: DNA Patents and the Genetic Code, 71 TENN. L. REV. 707, 725 (2004); David Olson, Patentable Subject Matter: The Problem of the Absent Gatekeeper 3–4 (Stanford Law School Center for Internet and Society 2006), available at

^{9.} *See id.* at 309–10 ("His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use." (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887))).

^{10.} Chakrabarty, 447 U.S. at 315.

^{11.} *See id.* at 308 (stating that the Patent Act "embodied [Thomas] Jefferson's philosophy that 'ingenuity should receive a liberal encouragement'" (quoting Letter from Thomas Jefferson to Oliver Evans (May 2, 1807), *in* V THE WRITINGS OF THOMAS JEFFERSON 76 (H.A. Washington, ed., 1859).

As a result, historical reliance on unexamined dicta may now lead to the wrong results, one of this Article's principal normative concerns.

The virtue of the proposed rule is that it provides a doctrinal standard for determining patentability that is more consistent and more rigorous than supposed "bright line" subject matter rules¹⁶—or at least as rigorous as the remainder of the statute will allow. The goals of this proposal are utilitarian: to increase the benefits of the patent system and to decrease the costs.

The proposal is agnostic about whether too many patents will result, in part because it is simply too hard to identify, let alone measure the effect of subject matter rules on innovation. Instead, the Article focuses on where historical court decisions focused: rejecting patents that do not pass muster.

Thus, this Article assumes that maximum social value is obtained by the issuance of only those patents that are justified under the statute.¹⁷ As part of the analysis the Article examines constitutional limitation and statutory interpretation arguments, finding that the proposal is at best mandated and at worst not foreclosed by precedent.

Under this normative statutory metric, rigorous application of the Patent Act's patentability criteria ensures optimal patent issuance and scope.¹⁸ On the one hand, extra-statutory, unprincipled subject matter bars do not reduce the number of bad patents, but might cause harm in other ways. In fact, even if without rigorous application of other patentability criteria, unclear subject matter rules create costs without adding much benefit. Some of the costs associated with the status quo are unsettled expectations, over and under-allowance of bad or

http://ssrn.com/abstract=933167. *But see* Rick Nydegger, *B2B, B2C and Other "Business Methods": To Be or Not To Be Patent Eligible?*, 9 U. BALT. INTELL. PROP. L.J. 199, 216 (2001) ("A statutory section that is as deeply founded on policy considerations as § 101 is ill suited to serve as a 'gatekeeper' to the grant of patent protection. That role is best left to considerations of the merits (e.g., novelty and nonobviousness under §§ 102 and 103) of a particular invention in the given technological field.").

^{16.} Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of "Lock-Out" Programs*, 68 S. CAL. L. REV. 1091, 1168–69 (1995) ("In particular, the requirements . . . that a claimed invention be novel and nonobvious . . . may be used to accomplish what the statutory subject matter inquiry cannot achieve: a rule that permits analytic dissection of claims into statutory and non-statutory elements for purposes of identifying which computer program-related inventions are patentable."); Osenga, *supra* note 5, at 1091–92 ("The PTO and some commentators are using § 101 rejections as a means to avoid tackling other policy or practical issues that should be handled through other means. The rejections thus serve as proxies for inquiries that should be made more appropriately under other requirements of patentability, such as utility, novelty, nonobviousness, adequate written description, and enablement.").

^{17.} See, e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1669 (2003) [hereinafter Burke & Lemley, *Policy Levers*] ("[W]e think the solution is for the courts to get their decisions right, rather than for them to wash their hands of involvement in the calibration of policy."). This Article argues that courts cannot "get their decisions right" if those decisions are based on generalized subject matter rules.

^{18.} See 35 U.S.C. §§ 100–103, 112.

good patents respectively, reduction in innovation caused by uncertainty, unnecessary examination costs, and increased litigation costs.

On the other hand, those who favor non-expansion and even contraction in patent protection might fear that the proposed rule will expand the types of discoveries considered patentable, leading to patents covering inventions that should be in the public domain.¹⁹ Reliance on judicially created subject matter rules to answer this concern is misplaced for several reasons. First, judges lack the empirical information to make subject matter policy. Second, opinions must focus on a single case rather than entire industries (or multiple industries), which leads to unintended effects of any given rule. Third, the judiciary should not be responsible for legislating patent eligibility beyond the categories defined by Congress, especially where such pronouncements are admittedly divorced from the statute. For those who argue that application of the statute rather than fidelity to it is warranted.

However, statutory overhaul may not be necessary to achieve the goal of reducing patenting in controversial areas. While this Article asserts no position on the number and types of patents that should issue, it does demonstrate that abandoning subject matter restrictions in favor of rigorous application of patentability requirements will not necessarily lead to more patents in controversial areas.²⁰ In fact, the proposal may reduce the number of discoveries that are currently considered patentable in a manner consistent with the goals of the Patent Act.²¹

Furthermore, the proposed rule does not foreclose congressional restriction in a narrowly tailored and consistently applicable manner—of patentable subject matter based on actual evidence of harm caused by particular types of patents.²² Of course, broad congressional action that suffers from the same problems as judicial opinions may not be desirable, but the judiciary should not limit the subject matter of *all* patents based on *any single case* at bar, and it certainly should not do so without concrete evidence of the supposed harm that an entire class of patents might allegedly cause.

Part I briefly describes the five prerequisites for obtaining a patent, including the requirements of patentable subject matter. Part II is descriptive; it examines

2008]

¹⁹ For example, by allowing tax methods patents, though even more subtle expansion is possible.

²⁰ *Bilski*, 2008 WL 4757110, at *62 (Rader, J. dissenting) ("[R]eading section 101 as it is written will not permit a flurry of frivolous and useless inventions. Even beyond the exclusion for abstractness, the final clause of section 101-'subject to the conditions and requirements of this title' ensures that a claimed invention must still satisfy the 'conditions and requirements' set forth in the remainder title 35. Id. These statutory conditions and requirements better serve the function of screening out unpatentable inventions").

^{21 &}quot;Rigorous" here means strict fidelity to the Patent Act and its requirements of category, utility, novelty, nonobviousness, and description. 35 U.S.C. §§ 101, 102, 103, and 112. This is more fully described in Part II.D.

²² See, e.g., 42 U.S.C. § 2181(a) (2000) (banning patents on certain nuclear technologies).

several patentable subject matter judicial decisions and reconciles each "subject matter" outcome with the five prerequisites of patentability. In each case, a patentability decision could have been—and often was—reached without determinative consideration of the patent's subject matter.

Parts III and IV are normative. Part III discusses how the proposed rule should apply to current or controversial technologies such as DNA and business method patents. Part IV discusses and responds to potential criticism of the proposed rule.

I. Obtaining a Patent

In order to obtain a patent, the inventor(s) must file an application that meets several criteria.²³ First, the invention must be described in sufficient detail so that one with ordinary skill in the subject matter of the patent (the "art") can both make and use the invention.²⁴ The invention described must meet the requirements for patentability: it must be useful,²⁵ it must be novel,²⁶ and it must not be obvious to one with ordinary skill in the subject matter of the patent.²⁷

Additionally, inventions are patentable only if they are of an approved subject matter.²⁸ Subject matter standards emanate from two sources: legislation and case law.²⁹ The Patent Act describes broad subject categories, allowing patents for any "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."³⁰

Case law, however, is more restrictive than the Patent Act. Since the early 1800s, courts have stated that patents incorporating products of nature,³¹ natural phenomena,³² mental steps,³³ and mathematical algorithms³⁴ should not issue.³⁵

29. *See id.* § 101; Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (identifying subject matter that courts treat as unpatentable).

30. 35 U.S.C. § 101. There is often an important distinction between processes and the other possible subjects of inventions. Processes are a series of steps used to accomplish some end result or product, while machines and compositions are specific physical objects. Corning v. Burden, 56 U.S. 252, 267 (1854) ("A new process is usually the result of discovery; a machine, of invention."). As a result, processes may often be more abstract with less specific elements. On the other hand, sometimes a process for creating a composition may be novel, even though the composition is not. The product/process difference becomes a pivot on which many cases relating to patentable subject matter turn.

31. See Funk Bros., 333 U.S. at 130.

32. *See generally* O'Reilly v. Morse, 56 U.S. 62, 116 (1854) (stating that "the discovery of a principle in natural philosophy or physical science" is not patentable).

^{23.} See 35 U.S.C. § 111.

^{24.} Id. § 112. The specific invention must be "claimed" so that others know when they might be infringing. Id.

^{25.} Id. §§ 101, 112.

^{26.} *Id.* § 102(a). Novelty generally means that no one has "anticipated" the invention by previously inventing, describing, or using it.

^{27.} *Id.* § 103(a).

^{28.} Id. § 101.

However, during the last thirty years courts have removed many subject matter limitations; for example, the United States Patent and Trademark Office (PTO) has issued and courts have affirmed patents covering segments of DNA,³⁶ business methods,³⁷ and computer programs incorporating mathematical algorithms.³⁸ As a result, courts invalidate few patents on subject matter grounds, though the historical bars have never been overruled.³⁹

This recent expansion of patentable subject matter, for example into tax strategies,⁴⁰ has caused consternation among scholars.⁴¹ A primary concern is the notion that inventors might remove from the public domain not just particular inventions, but the broad types or categories of inventions that would create greater social value in the public domain.⁴² This concern over patentable subject matter is somewhat misplaced. As discussed in Part II, patentable subject matter uncertainties in Supreme Court jurisprudence stem from a failure of the particular invention to qualify for a patent on other grounds. Further, as discussed in Parts

37. *See generally* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F. 3d 1368 (1998).

38. See generally Diamond v. Diehr, 450 U.S. 175 (1981). The algorithm in the abstract is still barred.

39. Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371, 406–07 (2005) [hereinafter Burk & Lemley, *Inherency*]; Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 519 (2006) ("[Subject matter rejections'] relative dormancy should not be mistaken for obsolescence.").

40. See, e.g., U.S. Patent No. 6,567,790 (filed Dec. 1, 1999).

^{33.} *See In re* Musgrave, 431 F.2d 882, 893 (C.C.P.A. 1970). *See generally In re* Comiskey, 499 F.3d 1365 (Fed. Cir. 2007) (stating that mental processes by themselves are not patentable).

^{34.} *See* Gottschalk v. Benson, 409 U.S. 63, 67 (1972). *See generally Flook*, 437 U.S. at 591 (stating that a mathematical algorithm, without more, is not patentable).

^{35.} Many of these cases predate the 1952 Patent Act, though judicial exclusions have never been tied to particular statutory language.

^{36.} *See, e.g.*, Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566–69, 1571–74 (Fed. Cir. 1997) (invalidating one of the plaintiff's patents covering cDNA on written description grounds, not on patentable subject matter grounds, and finding a patent on "DNA Transfer vector and transformed microorganism" valid, but not infringed. U.S. Patent No. 4,431,740 (filed June 8, 1982)); U.S. Patent No. 5,589,579 (filed July 19, 1994) (presenting the identification, cloning, and characterization of tumor-associated carbonic anhydrase and its cDNA sequence).

^{41.} See, e.g., John M. Conley & Roberte Makowski, Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part II), 85 J. PAT. & TRADEMARK OFF. SOC'Y 371, 388 (2003) ("The PTO's current view of the product of nature doctrine can be stated succinctly: it is a dead letter."); Burton T. Ong, Patenting the Biological Bounty of Nature: Re-examining the Status of Organic Inventions as Patentable Subject Matter, 8 MARQ. INTELL. PROP. L. REV. 1, 23–24 (2004) (criticizing the court in Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958), for ignoring patentable subject matter rules).

^{42.} Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 868–69 (1990) (discussing the effect of patent scope on incentives).

III and IV, strict application of the patentability criteria should not have a significant deleterious effect on the patent system.

II. Patentable Subject Matter Through a Different Lens

Virtually all of the important⁴³ historical patentable subject matter cases may be explained by applying each of the other requirements for patentability. When viewed through this lens, subject matter concerns are at bottom patentability concerns.⁴⁴ The cases can be grouped into three broad categories: obviousness, specification/inventorship, and novelty/utility.

A. Obviousness

Several cases that otherwise appear to be subject matter cases instead apply rigorous obviousness thresholds, barring patentability of combinations that do not create synergies—a whole greater than the sum of the combined parts.⁴⁵ Some might argue that strict application of nonobviousness standards fell by the wayside after passage of the 1952 Patent Act; however the cases discussed herein continue to be cited well after passage of the 1952 Patent Act.⁴⁶ Furthermore, the Supreme Court's recent opinion in *KSR International Co. v. Teleflex Inc.* revived a stricter requirement of nonobviousness.⁴⁷

^{43.} Because appellate cases often cite to statements made in Supreme Court cases in applying or extending the law, "important" here refers to Supreme Court cases only. There are several important lower court cases, such as *Parke–Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (C.C.S.D.N.Y. 1911) (L. Hand, J). Many of these cases will be discussed in Part III below.

^{44.} *Cf.* United States Patent and Trademark Office, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility* (Nov. 22, 2005) (conflating subject matter question with other patentability criteria), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf. *But see* Kane, *supra* note 39, at 546:

It could be argued that there are shadow doctrines behind each exclusion from patentable subject matter which amplify why they cannot be patented. The patenting of natural phenomena and laws of nature most directly implicates issues of novelty, while the patenting of abstract ideas would be most immediately objected to on disclosure grounds. This is not to suggest that these exclusions are redundant to existing doctrines—the Supreme Court certainly adheres to the categorical exclusions from patentable subject matter as the meaningful components of a public domain.

^{45.} *See*, *e.g.*, KSR Int'1Co. v. Teleflex Inc., 127 S. Ct. 1727, 1727 (2007); Funk Bros. Seed Co. v. Kato Inoculant Co., 333 U.S. 127, 127 (1948); Am. Fruit Growers, Inc. v. Brodex Co., 283 U.S. 1, 1 (1931).

^{46.} *See, e.g.,* Giles S. Rich, *The Principles of Patentability*, 14 FED. CIR. B.J. 135, 145 (2004), *reprinted from* 42 J. PAT. OFF. SOC'Y 75 (1960) (arguing that 1952 Patent Act dispensed with the requirement of "invention" in favor of a less restrictive standard of obviousness to one with skill in the art).

^{47.} See, e.g., KSR Int'l Co., 127 S. Ct. at 1742 ("The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing

For example, in *American Fruit Growers, Inc. v. Brogdex Co.*, the Court addressed a claim for fruit that had been soaked in a borax solution, creating mold-resistant fruit.⁴⁸ The Court ruled that a fruit combined with borax was simply the combination of two known raw materials, not something new, and therefore was not a "manufacture" under the statute.⁴⁹

The Court followed similar reasoning in Funk Brothers Seed Co. v. Kato Inoculant Co., in which the applicant sought to patent a combination of different bacteria.⁵⁰ The Court did not consider the claimed method of selecting bacteria to combine; it only determined whether the final combination could be patented.³¹ The Court essentially held that an end-product combination of preexisting products is obvious if the individual functions of the combined parts do not change.⁵² In so holding, the Court emphasized that the qualities of bacteria were properties of nature and thus could not be patented.⁵³ This pronouncement was hardly required to reach the holding-the Court could have simply ruled that a combination of parts is obvious if no new product features are created. Some might argue that this view of Funk Brothers pushes obviousness too far. The case cites Cuno Engineering Corp. v. Automatic Devices Corp.,⁵⁴ a case whose "flash of genius" holding was expressly overruled by statute in the 1952 Patent Act.⁵⁵ Despite Funk Brothers's dubious reliance on Cuno, the Court's obviousness jurisprudence soon reached this very rule, which is still valid today: a combination of known pieces that adds nothing new is obvious.⁵⁶

Justice Frankfurter's concurring opinion in *Funk Brothers* pointed out the problems with the majority's focus on the naturalness of the components:

48. Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 6 (1931).

55. 35 U.S.C. § 103(a) (2000) ("Patentability shall not be negatived by the manner in which the invention was made.").

56. Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152–53 (1950) ("A patent for a combination which only unites old elements with no change in their respective functions, such as is presented here, obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men."), *cited with approval in* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007), *and in* Graham v. John Deere Co., 383 U.S. 1, 11–12 (1966). *Cf. Graham*, 383 U.S. 1, 15–17 (1966) (1952 Patent Act did not change pre-1953 patentability standards other than "flash of genius" requirement of *Cuno*).

that the combination of elements was 'obvious to try."").

^{49.} Id. at 11-12, 14.

^{50.} Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

^{51.} *Id.* at 130–31.

^{52.} See id. at 131 ("The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee."); Conley & Makowski, *supra* note 41, at 379 ("So, in the biological context, it is clearly insufficient to bring about, without more, an unprecedented combination of existing species.").

^{53.} Funk Bros., 333 U.S. at 130.

^{54. 314} U.S. 84, 91 (1941).

It only confuses the issue, however, to introduce such terms as "the work of nature" and the "laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature."⁵⁷

Consider what would have happened if the results of the bacterial combination had resulted in previously unknown but naturally occurring effects, such as the generation of electricity. The Court's focus on "natural phenomena" subject matter would have required the PTO to reject such a hypothetical patent covering a method for generating bacterial electricity no matter how novel and nonobvious it may have been.⁵⁸

B. Specification/Inventorship

A second case grouping in which the Court cited subject matter issues as the rationale for its decisions, but which really turned on other factors, relates to specification and inventorship. In this group, the Court was concerned with whether the claimed "natural" invention was described or enabled in the patent⁵⁹ and thus whether the inventor actually invented the claimed invention in the first place.⁶⁰

In *O'Reilly v. Morse*, the Supreme Court considered a claim that encompassed any process for transmitting printed information by an electromagnetic signal by any means.⁶¹ While the Court had no problem affirming a particular form of such transmission—the telegraph—it invalidated the broader claim based on a failure to describe or enable the particular invention:⁶²

If this claim can be maintained, *it matters not by what process or machinery the result is accomplished*. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, *without using any part of the process or combination set forth in the plaintiff's specification*....

^{57.} Funk Bros., 333 U.S. at 134–35 (Frankfurter, J., concurring).

^{58.} *Cf.* Diamond v. Chakrabarty, 447 U.S. 306, 310 (1979) ("the patentee has produced a new bacterium with markedly different characteristics from any found in nature . . . ").

^{59.} In fact, the Court in *Funk Brothers* could have ruled on specification grounds. Justice Frankfurter pointed out in a concurrence that the patent did not actually describe which strains of bacteria could be combined and thus was unpatentable for lack of disclosure. *Funk Bros.*, 333 U.S. at 133–34.

^{60.} See, e.g., Corning v. Burden, 56 U.S. 252, 256 (1854).

^{61.} O'Reilly v. Morse, 56 U.S. 62, 77-78 (1853).

^{62.} Robert A. Kreiss, *Patent Protection for Computer Programs and Mathematical Algorithms: The Constitutional Limitations on Patentable Subject Matter*, 29 N.M.L.REV. 31, 69 (1999) (agreeing that the Court believed "that Morse's claim was too broad" but attributing the ruling to "constitutional theories" rather than to statutory claiming requirements); Kane, *supra* note 15, at 748.

... In fine he claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent.⁶³

Despite the relatively narrow language that implicates both the specification and novelty requirements, it did not take long for *Morse* to be reinterpreted as a subject matter ruling that simply invalidated a claim for the natural phenomenon of electromagnetic communications.⁶⁴

Similarly, in *Corning v. Burden*, the Supreme Court considered a method for making iron malleable.⁶⁵ The trial court instructed the jury that the patent covered *any* method of creating malleable iron, so long as that method performed the same steps as the patentee's machine.⁶⁶ The Court, however, made clear that the proper subject matter of the patent at bar was the *specific* machine described, and not the known process employed by the machine.⁶⁷ *Corning* is the analogue of *Morse*: if a particular means for achieving an end is invented, then the means may be patented, but the general end may not be patented if it is not new.⁶⁸ Here too, however, the Court focused on a specification and novelty issue; the inventor was limited only to the particular machine invented and described⁶⁹ and was not allowed a patent for a general process that he did not discover or describe.⁷⁰

In *Powder Co. v. Powder Works* the patentee initially claimed methods for "exploding nitro-glycerin[]" but later attempted to modify the claims to include new explosive products (such as nitroglycerin combined with gunpowder) in reissue proceedings.⁷¹ The case has been cited as relevant to the patentability of

^{63.} *Morse*, 56 U.S. at 113 (emphasis added); *see also id*. at 118–19 (describing the importance of description of the patented invention). *Morse* may be the first famous use of re-issue to broaden a claim to cover later invented technology. *Id*. at 114. *See also* Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 98 (1939) (stating that the patentee cannot claim an invention that was not disclosed in the patent simply by broadening claims to cover competition).

^{64.} The Telephone Cases, 126 U.S. 1, 534 (1888) ("The effect of [*Morse*] was, therefore, 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. In the present case the claim is not for the use of a current of electricity in its natural state").

^{65.} Corning v. Burden, 56 U.S. 252, 252 (1854).

^{66.} *Id.* at 253.

^{67.} *Id.* at 268 ("[I]t is well settled that a man cannot have a patent for the function or abstract effect of a machine, but only for the machine which produces it.").

^{68.} *Id.* at 269.

^{69.} *Id.*("In fine, his specification sets forth the 'particulars' of his invention, in exact accordance with its title in the patent, and in clear, distinct, unequivocal, and proper phraseology.").

^{70.} *Id.* at 268 ("It is clear that Burden does not pretend to have discovered any new process by which cast iron is converted into malleable iron.").

^{71.} Powder Co. v. Powder Works, 98 U.S. 126, 133 (1878). Reissue is a process by which a patentee may amend the claims of an issued patent after it issues. 35 U.S.C. § 251 (2000); 37 C.F.R. §§ 1.171, 1.173 (2007); *see also*, 3 JOHN GLADSTONE MILLS, III, DONALD CRESS REILEY, III, & ROBERT CLARE HIGHLEY, PATENT LAW FUNDAMENTALS § 15.109 (2d ed. 2008) (explaining requirements and procedure for reissue).

certain processes.⁷² However, a simpler reading of *Powder Co.* shows that the Court ruled that a process claim (covering steps to a process) cannot reissue as a composition of matter claim (covering physical objects) if the initial patent specification did not disclose the newly claimed physical matter.⁷³

C. Novelty/Utility

Novelty issues help illustrate the Court's construction of the "new and useful" requirement of 35 U.S.C. § 101.⁷⁴ These issues can be divided into two sub-categories that emanate from the claiming of natural phenomena—preexisting materials⁷⁵ and non-useful claims.⁷⁶

1. Preexisting Materials and Methods

In *Cochrane v. Badische Anilin & Soda Fabrik*, the Court considered a composition of matter made by a new process.⁷⁷ It held that even though the composition was "artificial" when made by the new process, the composition had the same chemical make-up as a naturally occurring product and thus could not be novel.⁷⁸ One of the Court's key concerns was specification because the patent application described only the process and not the composition.⁷⁹

75. 35 U.S.C. § 102(a) bars a patent where the invention is "known or used by others in this country." The language of § 102 becomes important in inherency analysis as well as analysis relating to natural products not known or found in the U.S., as discussed in Part IV.C, *infra*.

76. 35 U.S.C. § 101. Creations must be "useful."

77. Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311–12 (1884). The patent related to an improved process of preparing alizarine. *Id.* at 294.

78. Id.

^{72.} William T. Goglia, Annotation, Supreme Court's Views as to What is Patentable Subject Matter Under Federal Law as "Process," "Machine," "Manufacture," or "Composition of Matter," 65 L. Ed. 2d 1197, 1205 (1981).

^{73.} *Powder Co.*, 98 U.S. at 135 ("[I]n all this specification there is not a hint of any new mixture or new composition of matter having been invented by the patentee.").

^{74. 35} U.S.C. § 101 (2000). The general consensus is that "new" is now subsumed by "novelty" under 35 U.S.C. § 102. *In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979) ("Notwithstanding the words "new and useful" in § 101, the invention is not examined under that statute for novelty because that is not the statutory scheme of things or the long-established administrative practice."). However, some argue that inventions and discoveries should be "new" independent of § 102 requirements. *In re* Nuijten, 500 F.3d 1346, 1363–64 (Fed. Cir. 2007) (Linn, J., dissenting) (arguing that "new" has meaning in addition to novelty provisions of § 102); Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 361, 364 (2002) (arguing that "new" in § 101 and "novel" in § 102 are distinct, even though "courts and commentators have been assuming that novelty and newness were the same since the 1952 Patent Act was passed"); *cf.* Glue Co. v. Upton, 97 U.S. 3, 6–7 (1877) (no "new" composition is created by breaking a known composition into pieces).

^{79.} Id. at 310 ("Every patent for a product or composition of matter must identify it so that it

In The Wood-Paper Patent, the Court considered extracts from wood to create paper and explicitly ruled that extracts from a known product cannot be novel because they already exist.⁸⁰ The Court stated, "What the law looks to ... is the inventor and discoverer who finds out and introduces a manufacture which supplies the market for useful and economical purposes with an article which was previously little more than the ornament of a museum.' But this is no such case."⁸¹ Likewise, in *Glue Co. v. Upton*, the Court considered an "instant" glue created by crushing large, previously known glue flakes that were then grated into small, uniform grains of glue.⁸² The inventor claimed the glue product but did not attempt to patent the method used to create the glue.⁸³ Unfortunately for the inventor, the Court ruled that breaking up a known substance into smaller parts was insufficiently novel to patent those parts as a separate product: "There is nothing new in the fact that the solution of a soluble substance is accelerated by increasing its fragmentary division."⁸⁴ The Court ruled that a new compound "must be more or less efficacious, or possess new properties by a combination with other ingredients; not from a mere change of form produced by a mechanical division."85

Finally, in *Parker v. Flook*, the Supreme Court considered a claim related to automobile catalytic converters.⁸⁶ The claimed method was for determining the level of temperature, pressure, or flow rate necessary to trigger an alarm and included a mathematical algorithm to determine the proper "alarm limit."⁸⁷ The Court ruled that the only allegedly "new" part of the three-step method was the mathematical algorithm.⁸⁸ The Court then held that discovery of a mathematical

81. Id. at 596 (citation omitted).

87. Id.

2008]

can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.").

^{80.} The Wood-Paper Patent, 90 U.S. 566, 593 (1874). ("[I]t is equally clear, in cases of chemical inventions, that when, as in the present case, the manufacture claimed as novel is not a new composition of matter, but an extract obtained by the decomposition or disintegration of material substances, it cannot be of importance from what it has been extracted."). The Court also took issue with (but did not decide) the notion that "purification" of a product creates a new product. *Id.* at 594.

^{82.} Glue Co. v. Upton, 97 U.S. 3, 4-5 (1878). At the time of the invention, glue was sold in solid form, and soaked in water to create a malleable substance. *Id.* at 4. The invention apparently shortened the time it took for the glue to become viscous. *Id.* at 4-5.

^{83.} Id. at 5.

^{84.} *Id.* at 6.

^{85.} *Id.* at 6–7 ("Where certain properties are known to belong generally to classes of articles, there can be no invention in putting a new species of the class in a condition for the development of its properties similar to that in which other species of the same class have been placed for similar development; nor can the changed form of the article from its condition in bulk to small particles, by breaking or bruising or slicing or rasping or filing or grinding or sifting, or other similar mechanical means, make it a new article, in the sense of the patent law.").

^{86.} Parker v. Flook, 437 U.S. 584, 584 (1978).

^{88.} Id. at 585-86. This is a "point of novelty" analysis that is generally disfavored. See id. at

algorithm cannot be novel even if the algorithm was previously unknown: "Whether the algorithm was in fact known or unknown at the time of the claimed invention, as one of the 'basic tools of scientific and technological work' it is treated as though it were a familiar part of the prior art."⁸⁹ In other words, the Court ruled that a scientific principle could not be novel because it must have existed in nature.⁹⁰ On the other hand, the decision could have been decided as a matter of disclosure, such that the patent claim was not enabled or properly described because the inventor omitted details about selection of the alarm limit.⁹¹

2. Non-useful Claims

While utility is generally considered a separate requirement for patentability, novelty and utility tend to merge with respect to claims for mathematical algorithms and similar methods that involve no "action."⁹²

The utility/novelty nexus appeared in the early Supreme Court case, *Le Roy v. Tatham.*⁹³ Though the patent at issue related to mundane machines used to

91. Richard S. Gruner, *In Search of the Undiscovered Country: The Challenge of Describing Patentable Subject Matter*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 395, 406 (2007) ("The Court held that this invention did not constitute patentable subject matter because it involved only a formula for computing an alarm limit without associated details on how to 'select the appropriate margin of safety, the weighing factor, or any of the other variables' and did not 'contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system.''') (citations omitted); Osenga, *supra* note 5, at 1120 ("To satisfy enablement under § 112, the application must disclose the claimed invention sufficiently to allow a person having ordinary skill in the art to practice the invention without undue experimentation—the very essence of repeatability or predictability.").

92. 35 U.S.C. § 101 (2000) (inventions or discoveries must be "new and useful"); *In re* Bergy, 596 F.2d 952, 960 (C.C.P.A. 1979).

93. Le Roy v. Tatham 55 U.S. 156, 171 (1852).

^{599–600 (}stating that "a claimed process [should] lose[] its status at subject matter patentability simply because *one step* in the process would not be patentable subject matter if considered in isolation") (Stewart, J., dissenting). It may, however, be relevant in obviousness analysis. Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (discussing the step of comparing the claim to the prior art).

^{89.} *Id.* at 591–92 (citation omitted); *see* Cohen, *supra* note 16, at 1169 (noting that most objections to computer software patents are lack of novelty and obviousness). Of course, another way to view the case is that *Flook* was a subject matter case disguised as a novelty case. This is not an unreasonable view; the difficulty of reconciling *Flook* with other precedents is discussed further below.

^{90.} See Flook, 437 U.S. at 584 (citing Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)) (explaining that a phenomena of nature is not novel by itself). Because *Flook* undertook a "point of novelty" analysis, another way to look at the issue is that the entire claim was obvious because the use of the algorithm added nothing to the remainder of the elements, which were previously known. *See Flook*, 437 U.S. at 594 n.16 (applying § 103 type analysis to § 101); Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1056–57 (Fed. Cir. 1992) ("In accordance with *Flook*, the claims were analyzed [as a whole] to determine whether the process itself was new and useful, assuming the mathematical algorithm was 'well known.'").

manufacture metal pipes, *Le Roy* was one of the first cases to assert in dicta that laws of nature cannot be patented:

[A] principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.... The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.⁹⁴

Despite this sweeping statement, the Court was concerned with the utility requirement as it related to nature: "In all such cases, the processes used to extract, modify, and concentrate natural agencies, constitute the invention. The elements of the power exist; the invention is not in discovering them, but in applying them to useful objects."⁹⁵ As in *Morse*, the Court also linked enablement and novelty to consider whether the applicant actually invented the claimed invention.⁹⁶ Despite the Court's dicta, the holding relied on obviousness and had little to do with natural phenomena; previewing *Funk Brothers* and other cases, the Court held that a combination of parts must be new.⁹⁷

More recently, in *Gottschalk v. Benson*, the Supreme Court considered a patent relating to the mathematical conversion of binary coded decimals into pure binary format, a conversion that was known and could be done by pencil and paper.⁹⁸ *Gottschalk* is often cited for the notion that pure mathematical algorithms are unpatentable subject matter,⁹⁹ but the opinion implies that the Court was more concerned with the inventor's failure to describe the process in such a way that it was clear that the applicant actually invented the claimed invention.¹⁰⁰ The real concern appeared to be that the claim fell short of the

^{94.} *Id.* at 174–75; *see also* Eames v. Andrews, 122 U.S. 40, 54 (1887) ("The novelty of the process under consideration does not lie in a mechanical device It consists in the new application of a power of nature").

^{95.} Le Roy, 55 U.S. at 175.

^{96.} *Id.* ("A new property discovered in matter, when practically applied, in the construction of a useful article of commerce or manufacture, is patentable; but the process through which the new property is developed and applied, must be stated, with such precision as to enable an ordinary mechanic to construct and apply the necessary process.").

^{97.} Id. at 177.

^{98.} Gottschalk v. Benson, 409 U.S. 63, 65 (1972); see id. at 67.

^{99.} See id. at 71–72. While Benson does say this, the dicta is, by its own terms, a "nutshell" of the actual holding, which is that one may not patent a non-useful algorithm where the particular method for carrying out the process is neither described nor novel. This is an example of unchallenged dicta later interpreted as a bright-line rule. See also Parker v. Flook, 437 U.S. 584, 585 (1978).

^{100.} Benson, 409 U.S. at 68 ("Here the 'process' claim is so abstract and sweeping as to cover both known and *unknown* uses of the BCD to pure binary conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus.") (emphasis added); see also id. at 69–70 (discussing other cases in terms

specification and novelty requirements.¹⁰¹ Furthermore, a pure algorithm with no practical purpose was not "useful" as required by § 101.¹⁰²

In *Diamond v. Diehr*, the Court again considered whether a patent should issue if a claim included a mathematical algorithm, this time in a method for processing and curing rubber.¹⁰³ The process included a well-known algorithm, which calculated the time required to cure rubber.¹⁰⁴ The patent applicant argued, and the Court agreed, that the process could be novel and useful because the claimed invention described a process for accurately measuring the temperature that was later used in the mathematical algorithm.¹⁰⁵ Thus, the Court ruled that the patent could not be rejected on subject matter grounds.¹⁰⁶ The decision did not turn on the mathematical nature of one of the steps; indeed, the process could have contained a *non-mathematical* step that was well known, so long as it was only one step in the process.¹⁰⁷

D. Rigorous Patentability

An alternate lens focused on patentable subject matter leads to a different view of patentability, which this Article calls "rigorous patentability." Under rigorous patentability, concerns about patentable subject matter are addressed primarily by the application of the patent requirements on a case-by-case basis. These requirements must be (a) systematic, logical, and as consistent as possible; (b) based on adherence to the statutory language; and (c) applied with a goal that only patents deserving of protection are issued.¹⁰⁸ Attention to rigorous

101. Benson, 409 U.S. at 71.

104. *Id*.

of definiteness). The Court does go on to define a process as one that changes matter from one state to another, but such language is not necessarily about subject matter. Rather, the language concerns definiteness where a particular step of the process was not defined. *Id.* at 70. In making this ruling, the Court cites to *Morse*, which invalidated Morse's broad claim based on specification issues as well. *Benson*, 409 U.S. at 68; O'Reilly v. Morse, 56 U.S. 62, 112–13 (1853). In another example, the Court forgave the failure to claim a particular method for grinding an ingredient to a powder because that step is just one in a chain that transforms a material. Cochrane v. Deener, 94 U.S. 780, 787–88 (1876). The claim was not simply for a process whereby an ingredient is ground to a powder; such processes have been around since the dawn of humankind. *Id.* at 788.

^{102.} *Id.*; *see also* Kreiss, *supra* note 62, at 68. Note that all statutes are citing to 35 U.S.C. unless otherwise specified.

^{103.} Diamond v. Diehr, 450 U.S. 175, 177 (1981).

^{105.} *Id.* at 178–79, 187 ("Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the use of that equation.").

^{106.} Id. at 191.

^{107.} See, e.g., *id.* at 181 ("The respondents' claims were not directed to a mathematical algorithm or an improved method of calculation but rather recited an improved process for molding rubber articles *by solving a practical problem* which had arisen in the molding of rubber products.") (emphasis added). The Court did not reach the question of whether the patent claim satisfied the statutory requirements of novelty or nonobviousness. *Id.* at 191.

^{108.} Rigorous patentability may also resolve patent policy concerns unrelated to subject

application of the patentability standards would replace unclear and undefined subject matter rules based on unsupportable statutory interpretations of the Patent Act.¹⁰⁹

What does rigorous patentability require? For the most part, the requirements are already set forth in the statute as interpreted by the courts.¹¹⁰ The following is a short discussion of what rigorous patentability means with respect to the elements of patentability discussed in Part I.

•*Statutory Category*: A claimed invention must fit into one of the statutory categories: "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."¹¹¹ While rare, inventions do exist that may fall outside these categories.¹¹² The issue should not be whether a claim is, for example, a law of nature, but instead whether the claim falls into a statutory category.

•*Utility*: A claimed invention must meet practical utility standards.¹¹³ Process and product claims must lead to a result that can be used to some substantial and specific practical end. Patents should not issue on inventions that are simply useful for further study.¹¹⁴

•*Novelty*: A claimed invention must be new.¹¹⁵ No patent should issue for compositions that exist either artificially¹¹⁶ or naturally,¹¹⁷ unless they are purified

110. Burk & Lemley, *Policy Levers, supra* note 17, at 1590–93. Burk and Lemley point out that many of these criteria are more strictly enforced in some industries rather than others. *Id.* Rigorous patentability standards would dictate that such standards be applied equally in all industries, though there may be some costs to such uniformity.

111. 35 U.S.C. § 101 (2000).

112. See In re Nuijten, 500 F.3d 1346, 1357 (Fed. Cir. 2007) ("signal" does not fall into statutory category); Kreiss, *supra* note 62, at 58 ("[F]or the most part, laws of nature, natural phenomena, and abstract ideas do not fall within any of the four classes of patentable subject matter listed in § 101."); Rich, *supra* note 46, at 135 ("Russian is not a patentable invention because it is outside of the enumerated categories . . . "). Note that Judge Rich believed that certain business models were also outside the statute. *Id.* at 135 ("Also outside [the statute] is one of the greatest inventions of our times, the diaper service.").

113. Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (requiring specific and substantial utility); 35 U.S.C. §§ 101, 112 (requiring that an invention be "new and useful" and that "[t]he specification shall contain . . . the manner and process of making and using it").

114. *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005) ("It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research."). Part IV of this Article discusses why this requirement satisfies rigorous patentability requirements, but subject matter restrictions do not.

115. 35 U.S.C. § 102(a) ("A person shall be entitled to a patent unless (a) the invention was known or used by others in this country"); *Id.* § 102(f) (no patent awarded if inventor "did not himself invent the subject matter sought to be patented"); Evans v. Eaton, 16 U.S. 454, 513–14

2008]

matter; however, such policy concerns are outside the scope of this Article.

^{109.} See In re Bergy, 596 F.2d 952, 960–61 (C.C.P.A. 1979) ("Section 101 states three requirements: novelty, utility, and statutory subject matter. The understanding that these three requirements are separate and distinct is long-standing and has been universally accepted.... Thus, the questions of whether a particular invention is novel or useful are questions wholly apart from whether the invention falls into a category of statutory subject matter. ..." (emphasis omitted)).

to a point that the invention is different in kind from what exists in nature.¹¹⁸ As discussed in Part III, this standard may be difficult to apply,¹¹⁹ but the focus of patentability decisions should be on novelty and not subject matter.

•*Obviousness*: A claimed invention must be nonobvious, and the determination of obviousness should not be limited to any particular test.¹²⁰ Instead, the court must have broad latitude to find an invention obvious.

116. See The Wood-Paper Patent, 90 U.S. 566, 593 (1874) ("When . . . the manufacture claimed as novel is not a new composition of matter, but an extract obtained by the decomposition or disintegration of material substances, it cannot be of importance from what it has been extracted."); see also Glue Co. v. Upton, 97 U.S. 3, 6 (1878) ("[T]o render the article new in the sense of patent law, it must be more or less efficacious, or possess new properties by a combination with other ingredients; not from a mere change of form produced by a mechanical division.").

117. *In re* Ridgway, 76 F.2d 602, 603 (C.C.P.A. 1935) ("[W]hile appellants might be entitled to a patent on a method of purifying alpha alumina, they would not be entitled to a patent on the article alpha alumina, a natural product, merely because of the degree of purity of the article.").

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

119. *Id.* ("The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.").

^{(1818) (&}quot;[T]he 6th section of the general patent act... declares, that if the thing was not originally discovered by the patentee, but had been in use, or had been described in some public work, anterior to the supposed discovery of the patentee, judgment shall be rendered for the defendant, and the patent declared void." (emphasis omitted)); WILLARD PHILLIPS, THE LAW OF PATENTS FOR INVENTIONS; INCLUDING THE REMEDIES AND LEGAL PROCEEDINGS IN RELATION TO PATENT RIGHTS 150 (American Stationers Co. 1837) ("It is an essential requisite that the invention shall be *new.*"). Note that under the 1952 Patent Act, only § 102 governs novelty and not the requirement of a "new" invention, as stated in § 101. *In re* Bergy, 596 F.2d 952, 961 (C.C.P.A. 1979) ("new" in § 101 defined solely under § 102), *cited with approval in* Diamond v. Diehr, 450 U.S. 175, 190 (1981).

^{120.} KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1738 (2007). The Supreme Court's recent opinion in KSR makes implementation of this standard much more likely. For example, "brute force" inventions that are the result of computer processing time or repetitive combinatorial experimentation rather than invention would usually be obvious. See Funk Bros., 333 U.S. at 131 (noting that the combination of species may have led to a discovery, but "[i]t is no more than the discovery of some of the handiwork of nature and hence is not patentable"); John M. Golden, Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System, 50 EMORY L.J. 101, 115 (2001) ("However, advances in technology and in laboratory techniques have eased and automated much of this process, substantially routinizing a variety of tasks that had previously required considerable effort and ingenuity.... [T]he sequencing of [species' genomes] has become only a matter of attention and time."). Compositions created through the application of known processes to known materials would also be obvious. See also Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152-53 (1950); Sakraida v. Ag Pro, Inc., 425 U.S. 273, 282 (1976), both cited with approval, KSR Int'l Co., 127 S. Ct. at 1739-40. Inventions that were "obvious to try" would be obvious. Id. Inventions that are combinations of known elements that do not provide for functionality beyond the known elements would be obvious. Id. Of course, not all inventions meeting the above criteria would be obvious those determinations would have to be made on a case-by-case basis.

Discretion is counterintuitive to a rigorous requirement; however, the ability to reject patents as obvious requires flexibility.¹²¹

•*Specification*: A claimed invention must be supported not only by a detailed disclosure enabling one skilled in the art to make and use the invention, but also by a full description of the invention¹²² such that the PTO, courts, and other interested parties can determine whether the inventor actually invented the fullest scope of the claimed subject matter¹²³ and whether the inventor "possesses" all the elements of the claimed invention.

III. Applying Rigorous Patentability

One test of this Article's proposal is whether application of rigorous patentability standards satisfactorily answers new or controversial questions of patentability without regard to non-statutory subject matter bars. This section applies the standards to a few areas of concern.

A. Business Methods

The United States Court of Appeals for the Federal Circuit's express sanction allowing business method patents in 1998¹²⁵ led to an increase in patent applications for processes divorced from physical transformations.¹²⁶ Critics

125. State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1375 (Fed. Cir. 1998) ("Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method."). Though the Federal Circuit has since disapproved of the "tangible, concrete and useful" test of *State Street*, it reaffirmed that business methods may be patented. *In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *10 ("We rejected just such an exclusion in *State Street*, noting that the so-called 'business method exception' was unlawful....").

126. Anne H. Chasser, *Developments at the United States Patent and Trademark Office*, 19 TEMP. ENVTL. L. & TECH. J. 27, 28, 31 (2000) (discussing growth of patent applications and numbers of examiners in business methods and software); Mark A. Lemley & Bhaven M. Sampat, *Is the Patent Office a Rubber Stamp?*, Stanford Public Law and Legal Theory Workshop Paper Series Research Paper No. 999098, at 41 (July 2007), *available at* http://ssrn.com/abstract=999098 (Class 705 for business methods receives the most patent

2008]

^{121.} See KSR Int'l Co., 127 S. Ct. at 1739 (finding that obviousness is a difficult standard to apply consistently and categorically stating, "[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it").

^{122.} Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1566–67 (Fed. Cir. 1997); O'Reilly v. Morse, 56 U.S. 62, 118 (1853).

^{123.} But see Christopher M. Holman, Is Lilly Written Description a Paper Tiger?: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO, 17 ALB. L.J. SCI. & TECH. 1, 80–82 (2007) (reviewing written description cases and finding that a strict rule is not broadly or consistently applied by the PTO or courts).

^{124.} See Eli Lilly & Co., 119 F.3d at 1567 ("Whether or not [the specification] provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5.").

assert that business methods have no place among patentable subject matter.¹²⁷ However, business methods have been approved as patentable subject matter for at least 150 years.¹²⁸ Samuel Morse claimed, and the Court upheld, "the system of signs, consisting of dots and spaces . . . in combination with machinery for recording them, as signals for telegraphic purposes."¹²⁹ This claim is nothing more than a particular business method for communicating by telegraph. Modern internet-based business methods are different from the telegraph only in medium, and are usually much narrower than Morse's claim.

In short, business methods should be patentable if they otherwise meet rigorous patentability standards. They are processes under § 100, which defines a process to include a new use of existing machines, compositions of matter, manufactures—even existing processes—and they are not otherwise barred by the statute.¹³⁰ Thus, if a business method is novel, nonobvious, and adequately described, no bar to patentability should exist, whether or not the process is tied to a machine or transforms something physical.¹³¹

One criticism of business method patents is that the PTO grants patents to otherwise obvious methods.¹³² Yet, this is not a problem of subject matter, but of

127. Robert P. Merges, As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform, 14 BERKELEY TECH. L.J. 577, 581 (1999) (discussing "bad business concept patents"); Kreiss, *supra* note 62, at 52 ("[T]he State Street panel treats § 101 as if it could be read literally.... A little common sense shows that this cannot possibly be true.").

128. O'Reilly v. Morse, 56 U.S. 62, 101 (1853) ("The art is distinct from the means employed in its exercise; both may be, and under this patent are patented."). *See also Bilski*, 2008 WL 4757110, at *37 (Newman, J., dissenting) (listing business methods patents from 18th century England).

129. Morse, 56 U.S. at 86.

130. 35 U.S.C. § 100(b) (2000) (process includes any method, including a new use for a machine). In fact, they were expressly recognized by Congress after the *State Street* decision. *Id.* § 273 (prior users of business methods not liable for infringement).

131. *Bilski*, 2008 WL 4757110, at *10–14 (rejecting categorical exclusions for non-technological arts and business methods, but creating a new "machine or transformation" test for patentability of processes).

132. Nuno Pires de Carvalho, *The Primary Function of Patents*, 2001 U. ILL. J.L. TECH. & POL'Y 25, 59 (2001) ("The problems with some business ideas that have been granted patents are not peculiar to business ideas but respect all inventions: the problems of obviousness and utility."). The case that gave rise to the "business method exception" was a novelty case. *See* Hotel Security Checking Co. v. Lorraine Co., 160 F. 467, 472 (2d Cir. 1908) (holding that a method of hotel bookkeeping was non-novel, and stating in dicta that such processes cannot be patented in any event).

applications); *see also, e.g.*, eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388, 390 (2006); U.S. Patent No. 6,085,176 (filed Mar. 8, 1999) (claiming "[a] computer-implemented method of searching for an item in a plurality of independently operated electronic auctions interconnected by a computer network, each electronic auction having an associated data repository, the method comprising: receiving input identifying an item; and instructing a software search agent to search for the item on the computer network in the respective data repositories of one or more of the electronic auctions").

examination. Over time, the PTO has applied patentability criteria more strictly, granting fewer business methods patents.¹³³

Another concern with business method patents is that they protect methods that are widely, even publicly, practiced, but that the PTO cannot discover such prior art in order to reject patents.¹³⁴ This too is not an issue of subject matter; patent law has never barred patents because others have used methods secretly.¹³⁵ Indeed, one of the rationales for patent law is to encourage disclosure of trade secrets.¹³⁶ Inventors who fail to patent a secret invention risk having their later use of that invention be found to infringe another's patent, even when the inventor secretly practiced it first.¹³⁷ In any event, in 1999, Congress considered the question and decided that business methods patents may still issue, but departed from earlier law by protecting prior, secret users of a business method from infringement suits.¹³⁸

B. Tax Methods

Tax minimization claims are particular types of business methods that recently caused considerable concern. Policymakers and scholars question whether methods for tax minimization should be patentable.¹³⁹ As with other

134. Merges, *supra* note 127, at 589 ("There is every reason to believe that there is a vast volume of non-patent prior art in the software-implemented business concept field, as is widely believed to be the case with software patents in general.").

135. W.L. Gore & Assocs., Inc., v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

136. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 487–88 (1974); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 151 (1989); WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 328–29 (2003).

137. See Macbeth-Evans Glass Co. v. Gen. Elec. Co., 246 F. 695, 707 (6th Cir. 1917); 5 DONALD CHISUM, CHISUM ON PATENTS § 16.03[4] (Supp. 2005) ("One of the purposes of the patent system is to encourage prompt disclosure of new innovations. Innovators who decline to seek patents on innovations and, instead, utilize them as trade secrets can be said to act contrary to that purpose.").

138. Pub. L. 106-113, div. B, § 1000(a)(9) (codified at 35 U.S.C. § 273(b)(1) (2000)) (effective date Nov. 29, 1999). Admittedly, the protection of § 273 reduces the penalties for failing to patent a method.

139. Hearing on Issues Relating to the Patenting of Tax Advice Before the Subcomm. on Select Revenue Measures of the H. Comm. on Ways & Means, 109th Cong. 109–77 (2006) ("We at the USPTO recognize that the patenting of tax planning strategies has raised a number of concerns in Congress, the IRS, and the financial services community.") (statement of James A. Toupin, General Counsel, United States Patent and Trademark Office); William A. Drennan, *The Patented Loophole: How Should Congress Respond to this Judicial Invention?*, 59 FLA. L. REV.

2008]

^{133.} Dennis Crouch, Evidence Based Prosecution IV: Business Method PAIR Entries (Oct. 19, 2006), http://www.patentlyo.com/patent/2006/10/evidence_based__1.html (business methods patents being examined more closely in the PTO); Dennis Crouch, Evidence Based Prosecution V: Business Method Rejections (Oct. 22, 2006), http://www.patentlyo.com/patent/2006/10/evidence_based__2.html (business method patents subject to more resistance in PTO than "general population").

business methods, tax methods fit into the process subject matter category under § 101.¹⁴⁰

Under a rigorous patentability test, however, most tax minimization methods would be considered obvious.¹⁴¹ While creative, pure tax methods are merely an obvious combination of transactions that are considered nontaxable under the Internal Revenue Code.¹⁴² Tax methods may even be automated, but automation alone is not patentable unless the means for automation are novel and nonobvious.¹⁴³

C. DNA and Other "Natural Products"

The patentability of naturally occurring biotechnological products, such as DNA,¹⁴⁴ is one area where abandoning subject matter restrictions¹⁴⁵ and applying rigorous patentability standards would likely disallow many patents that are currently allowed.¹⁴⁶ The Supreme Court has not recently considered the patentability of products derived from nature.¹⁴⁷ The Court had the opportunity to consider one such patent in *In re Bergy*,¹⁴⁸ a companion case to *Chakrabarty*.¹⁴⁹

142. *See, e.g.*, U.S. Patent No. 6,567,790, col.2 1.43-67, col.3 1.1-16 (filed Dec. 1, 1999) (describing invention in terms of transactions that satisfy Tax Code and IRS regulations).

143. Dann v. Johnston, 425 U.S. 219, 230 (1976) (holding that automation of bookkeeping system is obvious).

144. *See In re* O'Farrell, 853 F.2d 894 (Fed. Cir. 1988) (providing a relatively simple description of DNA technology); Michael Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L.J. 293, 309 (1995) (providing the same).

145. Stephen McKenna, Note, *Patentable Discovery*?, 33 SAN DIEGOL. REV. 1241, 1253–54 (1996) (arguing that legislative history shows Congress knew that natural compositions of matter were "discovered" and that they are thus patentable).

146. But see Dan L. Burk, *Biotechnology in the Federal Circuit: A Clockwork Lemon*, 46 ARIZ. L. REV. 441, 441–42, 449–50 (2004) (arguing that the combination of theories applied by the Federal Circuit are not beneficial to the biotech industry).

147. Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 889 (2006) ("Unlike other issues that arise in patent litigation, the status of gene and protein discoveries as statutory subject matter has managed to escape review at all adjudicatory levels."). *Chakrabarty* related to artificial entities, and *Funk Bros*, related to a combination, rather than a derivation.

148. In re Bergy, 596 F.2d 952 (1979).

^{229 (2007);} Matthew A. Melone, *The Patenting of Tax Strategies: A Patently Unnecessary Development*, 5 DEPAUL BUS. & COM. L.J. 437, 438 (2007).

^{140.} Ironically, tax methods might be patentable under the Federal Circuit's stringent "machine or transformation" test if they were carried out by a machine.

^{141.} Melone, *supra* note 139, at 459 ("Moreover, tax strategy patents invariably involve the combination of well known tax techniques that, when used in isolation, are patently obvious."). *But see* Hearing, *supra* note 139 (statement of Richard Gruner) ("In short, a patent mediated world of tax planning may be one in which greater efforts are devoted to the types of innovative tax planning methods that are nonobvious advances over prior methods and that can qualify for patents."); Drennan, *supra* note 139, at 257–59 (proving lack of novelty of tax patents may be difficult due to non-public prior use).

However, Bergy withdrew his application prior to the ruling, and the Court dismissed the appeal as moot.¹⁵⁰

Products derived from nature fit within the § 101 categories as compositions of matter or manufactures and should not be barred on subject matter grounds.¹⁵¹ Three primary tests exist, however, that might limit claiming natural products under rigorous patentability standards: novelty, obviousness, and disclosure.¹⁵² Each criterion sets important, but different, limits on the patentability of natural derivatives.¹⁵³

1. Novelty/Utility

Since Judge Learned Hand's opinion in *Parke-Davis*, the test for novelty of naturally occurring products has been whether a product has been "isolated and purified" from its state in nature.¹⁵⁴ In general, novelty and utility are intertwined¹⁵⁵ such that determination of patentability depends on just how useful

154. Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911). Judge Hand's decision was not the first making this ruling, but it is the most famous. Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 F. 701, 705 (7th Cir. 1910) (upholding the appellee's patent because the compound, though similar in make-up to appellant's, significantly increased Aspirin's therapeutic benefits); *see also In re* Bergstrom, 427 F.2d 1394, 1402 (C.C.P.A. 1970) ("[P]ure materials necessarily differ from *less* pure . . . materials, and if the latter are the only ones existing and available as a standard of reference . . . perforce the 'pure' materials are 'new' with respect to [the existing materials]."); Conley & Makowski, *supra* note 41, at 387 ("[T]he CCPA made clear that Bergstrom was a section 102 novelty case, not a section 101 patentable subject matter case.").

155. Demaine & Fellmeth, *supra* note 74, at 338 ("A doctrinal problem with the test is that, as one commentator has suggested, it mistakes utility for newness."); *cf*. GEORGE TICKNOR CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS IN THE UNITED STATES OF AMERICA (C.C. Little and J. Brown 1849) (novelty and utility discussed together in a single chapter).

2008]

^{149.} Diamond v. Chakrabarty, 447 U.S. 303, 306 (1980).

^{150.} Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

^{151.} Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 161–62 (4th Cir. 1958) ("There is nothing in the language of the [1952 Patent] Act which precludes the issuance of a patent upon a 'product of nature' when it is a 'new and useful composition of matter' and there is compliance with the specified conditions for patentability. All of the tangible things with which man deals and for which patent protection is granted are products of nature in the sense that nature provides the basic source materials. The 'matter' of which patentable new and useful compositions are composed necessarily includes naturally existing elements and materials. A product of nature which is not a 'new and useful . . . machine, manufacture, or composition of matter' is not patentable, for it is not within the statutory definition of those things which may be patented. Even though it be a new and useful composition of matter it still may be unpatentability are not satisfied. In dealing with such considerations, unpatentable products have been frequently characterized as 'products of nature.' But where the requirements of the Act are met, patents upon products of nature are granted and their validity sustained." (citations omitted)).

^{152.} See 35 U.S.C. §§ 102, 103, 112 (2000).

^{153.} Id.

the isolated and purified natural product may be.¹⁵⁶ This is true for DNA as well.¹⁵⁷ However, over time, the "purification" requirement has become less important in judicial decision-making.¹⁵⁸

Rigorous application of patentability standards implies that "isolation from nature" should be re-examined with respect to novelty.¹⁵⁹ An illustrative example is *General Electric v. DeForest Radio*, in which the Third Circuit determined

158. Conley & Makowski, *supra* note 41, at 390 ("'Pure,' in other words, simply meant 'isolated.'") (quoting Schering Corporation v. Amgen, Inc., 35 F. Supp. 2d 375, 399 (D. Del. 1999)). Even *Parke-Davis* allowed the patentability of adrenalin salts because the particular method of making such salts had been attempted without success in the past and the resulting isolated product had great benefit. *Parke-Davis*, 189 F. at 103.

159. Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 Emory L.J. 721, 723 (1990) ("An intuitively appealing objection to patent protection for DNA sequences in the human genome is that the sequences themselves are not new. The human genome resides in every cell of every human being. DNA sequences within this genome exist quite apart from the inventive efforts of the private parties who might seek to patent them, and thus no one may claim to have invented them."); *see also* Davis, *supra* note 144, at 331 ("Although one can forgive Judge Hand in *Parke-Davis* for his self-admitted ignorance as to scientific matters, particularly in view of the general lack of knowledge in the field of biochemistry at the turn of the century, the perpetuation of this legal fiction [of isolation] within the field of intellectual property is somewhat less understandable."); Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261, 282 (2005) ("[P]urifying and isolating a gene is nothing more than just copying it."); *see, e.g.*, Conley & Makowski, *supra* note 41, at 392 ("Fourth, words such as 'isolated,' 'purified,' and 'synthesized,' should not be accorded talismanic status.").

^{156.} Kuehmsted, 179 F. at 705 (determining that the patent for aspirin is valid: "And it makes no difference, so far as patentability is concerned, that the medicine thus produced is lifted out of a mass that contained, chemically, the compound; for, though the difference between [the patent and the prior art] be one of purification only - strictly marking the line, however, where the one is therapeutically available and the others were therapeutically unavailable - patentability would follow. In the one case the mass is made to yield something to the useful arts; in the other case what is yielded is chiefly interesting as a fact in chemical learning."); Parke-Davis, 189 F. at 103 ("But even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically."); Kane, supra note 15, at 739-40 (arguing that the Merck Court's decision eliminated the objection that products of nature are not new for purposes of patentability). But see In re Bergy, 596 F.2d 952, 960–61 (C.C.P.A. 1979) (novelty, utility, and subject matter should be separately considered); Conley & Makowski, supra note 41, at 374 ("Thus, the subject matter inquiry is whether the claimed invention is or is not a statutory machine, manufacture, or composition of matter, and the answer should not be influenced by the presence or absence of novelty or utility.").

^{157.} Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991) ("It is important to recognize that neither Fritsch nor Lin invented EPO or the EPO gene. The subject matter of claim 2 was the novel *purified and isolated* sequence which codes for EPO, and neither Fritsch nor Lin knew the structure or physical characteristics of it and had a viable method of obtaining that subject matter until it was actually obtained and characterized." (emphasis in original)).

that purification of tungsten did not create a "new" composition of matter.¹⁶⁰ The inventor admittedly did not create the metal, nor did the inventor create the properties of the metal.¹⁶¹ While *General Electric* is generally considered to be an outlier,¹⁶² the court's analysis is an application of the rigorous standard of novelty for "new" compositions¹⁶³ and highlights how novelty may be a clearer way to handle isolated products of nature than subject matter.¹⁶⁴

The difficult novelty question for compositions of matter is whether the purification of a substance is in degree or in kind—that is, determining whether the inventor has transformed the starting (preexisting) natural materials into something new rather than simply removed imperfections from what existed before.¹⁶⁵ Simple extraction cannot suffice.¹⁶⁶ If extraction alone were enough to render matter novel, then a person could patent blood because it was isolated from a body through the use of a needle and syringe.¹⁶⁷

162. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 111–12 (4th ed. 2007); Burk & Lemley, *Inherency, supra* note 39, at 408 n.172.

164. While Conley & Makowski consider biotechnological advances in terms of "product of nature" doctrine rather than "novelty," they do provide a very thorough discussion about how several biotech advances should be viewed under a "strict" comparison with pre-existing materials. Conley & Makowski, *supra* note 41, at 393–98.

165. *Parke-Davis & Co.*, 189 F. at 103; Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958) ("[I]f the process produces an article of such purity that it differs not only in degree but in kind it may be patentable. If it differs in kind, it may have a new utility in which invention may rest."), *quoting In re* Merz, 97 F.2d 599, 601 (C.C.P.A. 1938). *See also* Conley & Makowski, *supra* note 41, at 386 ("Purity, in other words, is a basis for patentability only if it creates a material difference between the claimed product and its natural precursor."); Berman & Dreyfuss, *supra* note 147, at 891 (isolated genes and proteins are not different "in kind" from their natural sources); Michael Greenfield, Note, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1069 (1992) ("In short, the central question is whether the greater degree of purity has resulted in such a significant change that a new and useful composition of matter has been created."). *Compare In re* Ridgway, 76 F.2d 602, 603 (C.C.P.A. 1935) (pure alpha alumina not novel) *and In re* King, 107 F.2d 618, 620 (C.C.P.A. 1939) (purified Vitamin C not novel) *with Kuehmsted*, 179 F. at 705 (aspirin is novel because it provides previously unknown and unavailable therapeutic benefit).

166. See Parke-Davis, 189 F. at 103.

167. See, e.g., Stephanie Arcuri, Note, They Call That Natural? An Analysis of the Term "Naturally Occurring" and the Application of Genes to the Patent Act, 40 VAL. U.L. REV. 743, 745 (2006) (comparing gene extraction to plucking a blade of grass). But see McKenna, supra note 145, at 1270 ("The Dennis court recognized the absurdity of denying patent protection to the discoverer while rewarding the mechanic. There would seem to be no valid reason or sound support

^{160.} Gen. Elec. Co. v. De Forest Radio Co., 28 F.2d 641, 643 (3d Cir. 1928). The process to create a purer but non-novel composition may very well be novel, however, as it was in the *General Electric* case. *Id*.

^{161.} Id.

^{163.} Conley & Makowski, *supra* note 41, at 392 (citing *General Electric* with approval: "[D]espite the absence of bright-line tests, the clear import of more than a hundred years of precedent is that, where a claimed invention has a natural precursor or variant, the differences must be quite robust.").

Those in favor of DNA patents may argue that an extraction analogy is inapt. They would argue that the issue is not in the isolation of the blood, but instead that blood cannot be patented because people have known how to extract blood from humans and animals for an eternity. However, the issue is not one of timing: the first human to extract blood with a spear did not invent blood, even though throwing the spear at an animal may have been novel. Likewise, if the method for isolating DNA is novel and nonobvious then the method used would be patentable whether or not the resultant DNA is patentable. Further, using complementary DNA (cDNA) to create proteins was novel the first time the process was used, but after that the process is part of the prior art.

Patenting the actual DNA sequence is another matter. Though more difficult to achieve than extraction, mere isolation and purification of a nucleotide sequence may not be sufficient to render a strand of DNA novel where such DNA exists in human or animal bodies.¹⁶⁸ Fundamentally, DNA is an encoding of information¹⁶⁹ that allows for the production of certain proteins.¹⁷⁰ Thus, a purified cDNA sequence will produce the same protein that is produced by the gene in the human or animal body in the same way.¹⁷¹ Isolation and purification simply may not create something that is novel even if the product provides a previously nonexistent use or benefit.¹⁷² However, placing the cDNA into a bacterium might create something that is novel, though such a combination may be obvious.¹⁷³ Furthermore, if the cDNA were modified, spliced, or otherwise changed to behave in a way that it did not in a human body, then it might very

for a position which would deny to discoveries . . . the protection of our patent laws when such discovery is that an old, or at least well-known chemical product, will . . . produce new, unknown, and unexpected results, whereas one who puts together at least two old and well-known chemical substances . . . and gets new results helpful to man may receive patent protection.") (citing Dennis v. Pitner, 106 F.2d 142, 144 (7th Cir. 1939)).

^{168.} Berman & Dreyfuss, *supra* note 147, at 891.

^{169.} Rebecca S. Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA Sequences*, 49 EMORY L.J. 783, 797 (2000) (discussing DNA as an information repository and concerns about using the patent system to protect information).

^{170.} Arti K. Rai, Intellectual Property Rights in Biotechnology: Addressing New Technology, 34 WAKE FOREST L. REV. 827, 836 (1999).

^{171.} Berman & Dreyfuss, *supra* note 147, at 891 (stating that "[f]or genes, the information is identical whether the gene is isolated or not; for proteins, the shape in a crystal is no different from the shape in nature"); Conley & Makowski, *supra* note 41, at 394. ("[D]espite its nominal chemical distinctiveness, what is patented is functionally indistinguishable from natural DNA and RNA. It contains exactly the same genetic information as its natural counterpart. It can do precisely the same work as a naturally occurring gene-protein synthesis-and it employs precisely the same processes to do it, whether in the body or in the laboratory."); Eisenberg, *Patenting the Human Genome, supra* note 159, at 724.

^{172.} Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (claim is anticipated even if useful new properties of old composition are discovered). See *infra* Part IV, for a discussion of inherency and public benefit.

^{173.} See infra Part III.C.2.

well be novel even when not combined with a bacterium.¹⁷⁴ Thus, patenting of genetically modified proteins and new ways to create those proteins would not be foreclosed.¹⁷⁵

Here, distinguishing novelty from products of nature is important. Isolated DNA and synthesized cDNA are not available directly in nature.¹⁷⁶ Instead, non-coding segments of DNA,¹⁷⁷ called introns, are removed during the creation of isolated or synthesized DNA.¹⁷⁸ As such, they are not products of nature, and every extraction is to some extent purified despite no change in functionality.¹⁷⁹ Even so, they might not be novel.

A related and intertwined bar to patentability of some biotechnology inventions is lack of utility.¹⁸⁰ For example, an inventor may isolate a gene, but may not know what the gene does or how that gene might be used in the future.¹⁸¹ As a result, the simple discovery of a gene sequence is not practically useful and cannot be patented.¹⁸² The Federal Circuit has previously rejected patents on gene fragments for a lack of utility.¹⁸³ A rigorous application of utility standards would bar patentability of non-useful discoveries without a need to rely on product of nature subject matter requirements.¹⁸⁴

180. Berman & Dreyfuss, *supra* note 147, at 889.

183. *In re* Fisher, 421 F.3d 1365, 1371, 1379 (Fed. Cir. 2005) (denying gene fragment claims for failure to show use other than for further study).

184. Golden, *supra* note 120, at 129 ("*Brenner* [v. *Manson*]'s demand that a patentable invention provide a 'currently available' and 'specific' benefit could be used to block patents for

^{174.} Liivak, *supra* note 159, at 291 ("Amgen takes the naturally occurring human DNA and then changes the codons so that preferred expression codons for *E. coli* bacteria are used instead. Some person has decided that this change to the naturally occurring sequence is worth pursuing. Amgen has created an original DNA sequence.").

^{175.} Davis, *supra* note 144, at 339–40; *cf*. Genentech, Inc. v. Wellcome Foundation, Ltd., 29 F.3d 1555 (Fed. Cir. 1994) (genetically engineered protein is not equivalent of naturally derived protein).

^{176.} Jonathan Kahn, *Race-ing Patents, Patenting Race*, 92 IOWA L. REV. 353, 407–408 (2007) ("The PTO constructs cDNA as isolated . . . in the sense of separating the genetic material itself from nature. This is not a scientific process but a legal one.").

^{177.} That is, segments that do not generate amino acids to be used in a protein.

^{178.} Conley & Makowski, supra note 41, at 393–94; Eisenberg, supra note 159, at 727 n.25.

^{179.} Conley & Makowski, *supra* note 41, at 393 ("[A]n inventor can justifiably say that the invention is not, and cannot be, a product of nature."); Golden, *supra* note 120, at 127–28 (stating that "with respect to biotechnology, the century-old 'purification exception' tends to swallow the rule").

^{181.} *Id.* at 886 ("After all, it is not only important that the compound exhibit the biochemical function sought; the drug must also be efficacious in humans and not harm the patient in unanticipated ways.").

^{182.} Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001); Berman & Dreyfuss, *supra* note 147, at 889 (stating that "[n]onetheless, a strong argument can be made that raw information about biological endowments should not be considered patentable unless the advance has end-product functionality"); Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 16–19 (1995).

2. Obviousness

Strict application of obviousness rules may present another bar to patentability of natural derivations both in the final product and in the method used. For example, once the method of putting cDNA into a plasmid is known, then the combination of the two preexisting items should be considered obvious under *Funk Brothers*.¹⁸⁵ Further, where a known¹⁸⁶ method is used to isolate and purify a composition, "brute force" experimentation¹⁸⁷ will usually not be enough to render a newly isolated segment of DNA patentable.¹⁸⁸

Purified, mutated, or otherwise modified DNA could still be patented if such a modification was not obvious.¹⁸⁹ If one were to create a novel and nonobvious automated technique, the end result might be nonobvious. Such DNA would be no different from the modified bacteria in *Chakrabarty*.¹⁹⁰ However, over time one would expect the number of patentable compositions to decrease as methods for their creation become well known.¹⁹¹

Application of an "obvious to try"¹⁹² standard would most likely require a reversal of a number of cases, including *In re Bell*, ¹⁹³ *In re Deuel*, ¹⁹⁴ and *Amgen*,

186. "Known" here means a method used under license from a third party, in the public domain, or even by the patentee if such method is not novel under § 102.

187. Berman & Dreyfuss, *supra* note 147, at 883 ("In today's world, however, this usually involves a variety of automated and computational techniques for screening compounds that are potentially bioactive.").

188. Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1366 (Fed. Cir. 2007) (stating that the end result is obvious even though verification required testing). *But see* Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 976–77 (2006) (noting that poor quality prior art may impede novelty and obviousness analysis). As a policy matter society might want to incentivize investment in costly "brute force" development using known techniques, but that incentive should not come from the patent system; patents should instead promote the development of new techniques. Part IV discusses this issue in more detail.

189. Kahn, *supra* note 176, at 408 ("purification involves stripping the genetic material of its identity as a part of nature—ridding it of its natural associations").

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

191. Demaine & Fellmeth, *supra* note 74, at 306–07 (stating "a few decades ago it might have taken ten years to find a particular gene, but, with modern gene maps, a gene can now often be found with a fifteen second computer search"); Eisenberg, *Patenting the Human Genome, supra* note 159, at 730 ("The fact that the Patent and Trademark Office has issued patents on some DNA sequences thus does not necessarily portend that such patents will continue to issue in the future.").

192. See KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007) ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was

DNA sequences for which 'practical utilities' are more posited than proven – a description that might apply to most existing DNA patent claims." (citations omitted)).

^{185.} *Cf. In re* Mayne, 104 F.3d 1339, 1341, 1343 (Fed. Cir. 1997) (recombination of two proteins obvious); Eisenberg, *supra* note 159, at 726–27 (discussing application of combined DNA and plasmids with respect to *Funk Bros.*).

*Inc. v. Chugai Pharmaceutical Co.*¹⁹⁵ In these cases, the patentee began with some information and starting materials and applied known processes for isolating genetic material or for creating new chemical compositions.¹⁹⁶ The Federal Circuit held in each that so long as the inventor did not know what the result would be, the new compound would not be rendered obvious.¹⁹⁷

Denying patents that are obvious to try is a realistic option in light of the stricter nonobviousness standard announced in *KSR*.¹⁹⁸ *KSR* even cites *Deuel* unfavorably, noting that failure to consider whether a patent was "obvious to try" is error.¹⁹⁹ The ruling has already had some effect on gene patents. In *Ex Parte Kubin*, the Board of Patent Appeals and Interferences ruled that a claim for cDNA was obvious to try in light of known processes.²⁰⁰ Similarly in *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, the Federal Circuit ruled that confirming the suspicions of prior theorists cannot justify a patent: "[T]he inventors merely used routine research methods to prove what was already believed to be the case. Scientific confirmation of what was already believed to be true may be a valuable contribution, but it does not give rise to a patentable invention."²⁰¹

obvious to try might show that it was obvious under § 103.").

195. Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209 (Fed. Cir. 1991) ("obvious to try" known methods in different combinations does not render DNA claim obvious).

196. Deuel, 51 F.3d at 1555–56; Bell, 991 F.2d at 782–83; Amgen, 927 F.2d at 1209.

197. *Deuel*, 51 F.3d at 1559 (stating that "a conceived method of preparing some undefined DNA does not define it with the precision necessary to render it obvious over the protein it encodes"); *Bell*, 991 F.2d at 784; *Amgen*, 927 F.2d at 1209.

198. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007). ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.").

199. KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 (2007). The Federal Circuit relied on *Deuel* in the opinion reversed by the Supreme Court. Teleflex, Inc. v. KSR Int'l Co., 119 Fed. App'x 282, 289 (Fed. Cir. 2005), *rev'd* KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007).

200. *Ex Parte* Kubin, 83 U.S.P.Q.2d (BNA) 1410, 1414 (B.P.A.I. 2007). "The 'problem' facing those in the art was to isolate NAIL cDNA, and there were a limited number of methodologies available to do so. The skilled artisan would have had reason to try these methodologies with the reasonable expectation that at least one would be successful." *Id.* (quoting KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742 (2007)). *In re Kubin* is currently pending before the Federal Circuit. *Id.*, appeal docketed No. 08-1184 (Fed. Cir. Jan 31, 2008).

201. PharmaStem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 1363–64 (Fed. Cir. 2007). *But see* Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356–57 (Fed. Cir. 2007) (citing *Deuel* with approval and ruling that use of routine methods need not render a

^{193.} In re Bell, 991 F.2d 781, 785 (Fed. Cir. 1993).

^{194.} *In re* Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995) (stating that cDNA may be patented even though it was obvious to try a known procedure for isolating DNA). For a thorough discussion of obviousness relating to DNA technology prior to *Deuel, see* Eisenberg, *Patenting the Human Genome, supra* note 159, at 729–35.

One difficulty with a stricter nonobviousness standard in biotechnology is potential conflict with legislative pronouncements on the obviousness of biotechnological inventions. For example, § 103(b) declares that minor biotechnological process improvements are nonobvious by fiat where the result of the process is a patentable composition.²⁰² If, however, a minor process improvement²⁰³ was obvious to try and thus resulted in a novel but obvious composition, then under *KSR*, both the process and the composition would be obvious.²⁰⁴ Section 103(b) could be read to mean that the modified process is nonobvious because it led to a new composition, and the new composition is nonobvious because it was created by a nonobvious process. This circular reading would lead to patentability of the composition without evidence of nonobviousness. The purpose of § 103(b) was to protect potentially obvious processes that yield novel and nonobvious compositions, not to protect obvious compositions created by obvious processes.²⁰⁵

The solution to the § 103(b) conundrum is to focus first on the end composition, whose novelty and nonobviousness is a condition precedent in the statute.²⁰⁶ If the composition is unpatentable under a rigorous novelty test, then the process may not be patented under § 103(b).²⁰⁷ If the composition is novel, the composition should be considered independently to determine whether it is obvious, including the range of production processes available, the starting materials, the techniques used, and how much was already known about the composition's chemical family. If the result is that the composition is nonobvious, then it is patentable, as is its creation process under § 103(b). If not, then the process must withstand the nonobviousness test on its own.

compound "obvious to try" where selection of the starting materials is not obvious).

^{202. 35} U.S.C. § 103(b) (2000). "[A] biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if . . . claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date *Id*. This statute was enacted in response to *In re Durden*, which held that a process for creating a composition was obvious given disclosures of the starting materials and a patent on the final composition. *In re* Durden, 763 F.2d 1406, 1411 (Fed. Cir. 1985); *see also* 2 DONALD S. CHISUM, CHISUM ON PATENTS § 5.04(8)(b)(ii)(B) (2004). The statute is largely irrelevant today because the Federal Circuit considers most process improvements to be nonobvious. *In re* Ochiai, 71 F.3d 1565, 1569 (Fed. Cir. 1995); Chisum, *supra* note 202, at § 5.04(8)(b)(ii)(B). However, the *KSR* decision may rejuvenate the use of § 103(b).

^{203.} Existing processes would arguably be non-novel and also render the composition obvious.

^{204.} KSR, 127 S. Ct. at 1742–43.

^{205.} *See* 141 CONG. REC. S11201-03, S11207 (1995) (statement of Sen. Hatch) ("[T]he current patent law is not adequate to protect our creative American inventors who are on the cutting edge of scientific experimentation ").

^{206.} See 35 U.S.C. § 103.

^{207.} The process may, of course, be nonobvious pursuant to \$ 103(a). 35 U.S.C. \$ 103(a) (2000).

3. Description

In addition to claiming novel and nonobvious compositions, inventors must fully describe claimed compositions in order to obtain a patent.²⁰⁸ As discussed in Part II, the description/specification requirement was critical in early Supreme Court jurisprudence that implicated patentable subject matter.²⁰⁹ The Federal Circuit recently revived a "strict" description requirement in biotechnology and chemistry areas.²¹⁰ For example, in *Regents of the University of California v. Eli Lilly & Co.* the patent disclosed the nucleotide sequence for the gene that produces insulin in rats.²¹¹ However, the claim was broader than the disclosure, claiming technology relating to cDNA in humans and in all vertebrates.²¹² The Federal Circuit affirmed invalidation of the broad claims because the specification did not describe anything other than rat DNA, despite the fact that the patent described how non-rat DNA could be obtained.²¹³ Insisting that the applicant demonstrate "possession" of the invention by fully describing it will tend to reduce the number of broad patents covering basic biological functions.²¹⁴

214. Berman & Dreyfuss, *supra* note 147, at 899–900. "[T]his approach may be appropriate to prevent patentees from gaining control over products that they have not in fact discovered" *Id*. Berman & Dreyfuss argue that strict written description arguments may have the negative consequence of barring patents for those engaged in fundamental research, and creates incentives for creative claiming to avoid restrictions, among other negative consequences. *Id*. *See also* Rai, *supra* note 170, at 839 (strict written description may deny patents that should be granted). *But see* Burk, *supra* note 146, at 442–43 (arguing that a narrow written description requirement can lead to the patenting of obvious advances and suggesting that "[i]f conception requires detailed knowledge and revelation about the structure or detailed physical qualities of the molecule, then in order for a molecule to be 'obvious,' it needs to meet the same criteria – the same degree of detail within the prior art is required for obviousness that is needed in the mind of the inventor for conception"). These criticisms need not be true, however, if each patentability requirement is addressed separately, especially given that compositions might be "obvious to try." *See, e.g.*, Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571–72 (Fed. Cir. 1997) (invention is not disclosed even if it would be obvious from the disclosure).

^{208. 35} U.S.C. § 112 (2000).

^{209.} See, e.g., O'Reilly v. Morse, 56 U.S. 62, 113 (1854).

^{210.} Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

^{211.} Id. at 1562-63.

^{212.} *Id.* at 1567.

^{213.} *Id.* at 1568 ("A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials.") (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). In technical patent law terms, the court ruled that even if the claim is enabled, it must still be described. *Id.* at 1567.

D. Mathematical Algorithms and Computer Software

Like those in other areas, subject matter rejections of software patents should be rare because software falls within the statutory categories.²¹⁵ If combined with a useful process or device, mathematical and other algorithms could be patentable,²¹⁶ as discussed in the well-known cases of *Diamond v. Diehr*,²¹⁷ *In re Alappat*,²¹⁸ and *AT&T Corp. v. Excel Communications*.²¹⁹ The Federal Circuit's most recently announced test, whether the software or algorithm is tied to a machine or transformation, affirms that computer software should not be subject to a categorical exclusion.²²⁰

However, this Article's proposal would abandon the "machine or transformation" test and all attempts to define software as distinct from abstract ideas, mathematical algorithms, or any "post-solution activity."²²¹ Instead, all such claims would be patentable only if they meet rigorous standards for patentability.²²²

For example, a standalone mathematical algorithm would not be patentable because it does not have practical utility, even if the algorithm was a process

216. Chisum, *supra* note 215, at 997 (arguing that it is well settled that mathematical algorithms have been patentable as part of a larger claim) (citing MacKay Radio & Telegraph Co. v. Radio Corp. of Am., 306 U.S. 86 (1939)).

217. Diamond v. Diehr, 450 U.S. 175, 191 (1981).

218. In re Alappat, 33 F.3d 1526, 1540-41 (Fed. Cir. 1994) (en banc).

219. AT&T Corp. v. Excel Commc'ns, 172 F.3d 1352, 1355–56 (Fed. Cir. 1999) (software patentable as a method).

221. See id. at *8.

222. State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F. 3d 1368, 1375 (Fed. Cir. 1998) ("Section 101 specifies that statutory subject matter must also satisfy the other 'conditions and requirements' of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice.") (citations omitted); Vincent Chiappetta, *Patentability of Computer Software Instruction as an "Article of Manufacture:" Software as Such as the Right Stuff*, 17 J. MARSHALL J. COMPUTER & INFO. L. 89, 93 (1998) ("In addition, the resulting failure to clearly and properly define the actual nature of software inventions by applying the patentable subject matter analysis leads to inadequate identification of prior art and insufficiently stringent review for novelty and nonobviousness.").

^{215.} Osenga, *supra* note 5, at 1109 ("A software-related invention will nearly always be a process and will almost never, so long as it has a practical application, fall within one of the three exclusions for law of nature, natural phenomenon, or abstract idea."). Osenga identifies articles that take issue with the statutory categories for software. *Id.* at 1107 n.156. Note that, contrary to Osenga, the proposal in this Article would allow software inventions – on subject matter grounds, at least – even if they included laws of nature, natural phenomenon, or abstract ideas. *See also* Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 972–92 (1986) (discussing and criticizing the *Benson* opinion); Arrhythmia Research Technology, Inc. v. Corazonix, Corp., 958 F.2d 1053, 1056 (Fed. Cir. 1992) (confirming that *Benson* does not require all mathematical algorithms to be unpatentable).

^{220.} *In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *10 n.23 ("[W]e decline to adopt a broad exclusion over software or any other such category of subject matter beyond the exclusion of claims drawn to fundamental principles set forth by the Supreme Court.").

under § 101.²²³ While such an algorithm may allow for new, faster, or more accurate computation of real world effects, it does not act unless coupled with some physical process or device.²²⁴ Practical utility requires some "action" beyond the possibility of calculation.²²⁵ In general, determining whether a process has practical utility should be less difficult than determining whether a process is solely a mathematical algorithm.²²⁶

With respect to software patents, rigorous patentability requires a complete specification: complete written description, enablement, and specific source code or pseudo-code to fulfill the best mode requirement.²²⁷ Rigorous patentability also requires extensive obviousness analysis to ensure that a claimed series of steps was not only unknown but also sufficiently inventive to separate it from the prior art.²²⁸

Professors Burk and Lemley point out that software engineers are considered extremely skilled for purposes of enablement.²²⁹ This level of sophistication has the effect of making obviousness findings more likely because of the small leap it would take for a highly skilled engineer to improve an algorithm.²³⁰ Higher

224. Kreiss, *supra* note 62, at 68 ("Purely mathematical algorithms provide one illustration of the theory that abstract ideas are not patentable.").

225. *In re* Schrader, 22 F.3d 290, 295 (Fed. Cir. 1994) (some sort of transformation is required, even if not physical); *Bilski*, 2008 WL 4757110, at *12 (transformation of data about physical objects required).

226. *In re* Warmerdam, 33 F.3d 1354, 1359 (Fed. Cir. 1994) (difficult to determine whether a process is an algorithm).

227. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1162 (2002) [hereinafter Burk & Lemley, *Technology-Specific?*] ("[A] series of recent Federal Circuit decisions has all but eliminated the enablement and best mode requirements. In recent years, the Federal Circuit has held that software patentees need not disclose source or object code, flow charts, or detailed descriptions of the patented program."); Lawrence D. Graham & Richard O. Zerbe, Jr., *Economically Efficient Treatment of Computer Software: Reverse Engineering, Protection, and Disclosure*, 22 RUTGERS COMPUTER & TECH. L.J. 61, 96–97 (1996) (discussing problems with enforcement of written description, enablement, and best mode).

228. Cohen, *supra* note 16, at 1169 ("Intuitively, the most troubling aspect of many computer program-related patents is that they appear to reward the inventor for recognizing the obvious—that a given function may be performed more efficiently or more accurately if computerized—and using general purpose computer equipment and standard programming techniques to computerize it."); Burk & Lemley, *Technology-Specific?*, *supra* note 227, at 1167–68 (recent Federal Circuit cases "viewed obviousness as a rather substantial hurdle to patenting software").

229. Burk & Lemley, *Technology-Specific?*, *supra* note 227, at 1168, 1170.230. *Id.*

^{223.} Chiappetta, *supra* note 222, at 106 ("Focusing on 'usefulness/utility' of a software invention in a 'useful arts' sense contains the key to resolving the software as patentable subject matter conundrum.") (citing Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7,478 (1996)); *cf. State St. Bank & Trust Co.*, 149 F.3d at 1375 ("The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to – process, machine, manufacture, or composition of matter – but rather on the essential characteristics of the subject matter, in particular, its practical utility.") (footnotes omitted).

rejection rates for software patent claims may not be a social detriment given concerns about patenting software generally.²³¹ Regardless of the optimal level of patenting, when software claims do issue, their disclosures will be opaque because highly skilled engineers require less detail for enablement.²³² Perhaps a way to avoid the conflict between enablement and obviousness is to focus on the description and best mode requirements.²³³ Even if a bare-bones specification enables one skilled in the art to make and use the claimed software, a patentee should still be required to fully describe the software and to disclose the best way of making and using the invention, two requirements that do not allow gap-filling by one skilled in the art.²³⁴ While it is true that courts have assumed that *any* programmer only needs a broad functional description to write a program,²³⁵ rigorous enforcement of description and best mode requirements would require more proof that the patentee actually possessed a particular invention.²³⁶ The resolution of these questions should be based on examination of patentability criteria, not on an absolute subject matter bar.

E. Natural Phenomena

Like products of nature, natural phenomena should not be unpatentable *per se* because most patents are based in part on such phenomena.²³⁷ The most recent case to focus attention on this issue is *Laboratory Corp. of America Holdings v*.

235. Burk & Lemley, *Technology-Specific?*, *supra* note 227, at 1164–65; *see*, *e.g.*, *Robotic Vision Sys.*, 112 F.3d at 1166 ("[I]t is generally sufficient if the functions of the software are disclosed, it usually being the case that creation of the specific source code is within the skill of the art."). *But see* Scott Elengold, Note, *An Inquiry into Computer System Patents: Breaking Down the "Software Engineer,*" 61 N.Y.U. ANN. SURV. AM. L. 349, 372 (2005) (suggesting courts to consider different types of programmers and the skills they have in specialized areas such as graphic design).

236. Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 928 (Fed. Cir. 1990) (stating that best mode is a factual determination).

^{231.} See Cohen, supra note 16, at 1169.

^{232.} Burk & Lemley, Technology-Specific?, supra note 227, at 1168, 1170.

^{233. 35} U.S.C. § 112 (1 (2000) (requiring inventors to describe the best way to practice an invention).

^{234. 35} U.S.C. § 112 (2000); Robotic Vision Sys. v. View Eng'g, 112 F.3d 1163, 1165–66 (Fed Cir. 1997); Lockwood v. Am. Airlines, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997) ("Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed....[A] prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.").

^{237.} *See, e.g.*, MacKay Radio & Telegraph Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) (radio antenna could be patentable subject matter even though its dimensions directly correspond to a natural phenomenon); Wright Co. v. Paulhan, 177 F. 261, 263–64 (C.C.S.D.N.Y 1910) (L. Hand, J.), *rev'd on other grounds*, 180 F. 112 (2d Cir. 1910). The Wright Brothers' invention, for example, was based primarily on the discovery that a rudder could be used for stabilization of airlift caused by wing "warping." *Id*.

Metabolite Laboratories, Inc., in which the Supreme Court first granted certiorari and then dismissed the petition as improvidently granted, which left scholars and practitioners wondering how patent claims relating to medical tests should be treated.²³⁸ In *Metabolite*, the patentee discovered that an elevated homocysteine level was an indicator of a Vitamin B deficiency.²³⁹ The claim at issue involved two steps: first, measure homocysteine levels; second, correlate the results and diagnose a vitamin deficiency if levels are elevated.²⁴⁰ Metabolite alleged that any laboratory performing homocysteine level measurements, whether or not such measurements were patented, contributorily infringed the claim relating to diagnosing vitamin deficiencies.²⁴¹

Three justices dissented from the dismissal, arguing that certiorari was proper, and that the method claim "amounted to" an unpatentable natural phenomenon.²⁴² However, invalidating the claim as a phenomenon of nature, as the dissent might have done, would draw a poorly defined line.²⁴³ Even if *Metabolite* clearly involved a natural phenomenon as the dissent asserted, the proposed ruling would have done nothing to aid the PTO, the courts, or inventors as to proper patentable subject matter in the future.²⁴⁴ Many natural phenomena are simple to apply, both inventively and usefully, once the natural phenomenon is discovered.²⁴⁵

239. Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004), cert. dismissed, 126 S. Ct. 2921 (2006).

240. Id. at 1358-59.

241. *Id.* Metabolite made this argument pursuant to 35 U.S.C. §§ 271(b) and (c). The patent also included a novel claim to a method for performing the homocysteine measurement, but this claim was not at issue. *Metabolite*, 370 F.3d at 1365.

242. Metabolite, 126 S. Ct. at 2922, 2927.

243. *Id.* at 2926 ("I concede that the category of non patentable '[p]henomena of nature,' like the categories of 'mental processes,' and 'abstract intellectual concepts,' is not easy to define.") (Breyer, J., dissenting) (citing Parker v. Flook, 437 U.S. 584, 589 (1978)).

244. See Kevin Emerson Collins, *Propertizing Thought*, 60 SMU L. REV. 317, 353 (2007) ("Phrased in terms of a preemption analysis as suggested in *Benson*, the argument in favor of the patentability of claim 13 has merit"); *cf.* Gruner, *supra* note 91, at 400 ("Much of the current uncertainty in the law of patentable subject matter stems from the failure of the Supreme Court to articulate clear principles for separating patentable applications from unpatentable abstract ideas. The Court has, for the most part, dealt with what are essentially easy cases What the Court's analyses have generally lacked is a clear discussion of what minimum features must be present in order for an implementation of an idea to be considered a practical application rather than just an unpatentable abstract idea.").

245. See Corning v. Burden, 56 U.S. 252, 268 (1854) ("As, for instance, A has discovered that by exposing India rubber to a certain degree of heat, in mixture or connection with certain metallic salts, he can produce a valuable product, or manufacture; he is entitled to a patent for his discovery"); Mackay Radio & Telegraph Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939) (radio antenna could be patentable subject matter even though its dimensions directly correspond to a natural phenomenon); Diamond v. Diehr, 450 U.S. 175, 189 n.12 (1981) ("To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because

2008]

^{238.} Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (per curium).

Instead, with rigorous patentability, the analysis should focus on the patentability criteria rather than on nebulous subject matter definitions. Metabolite, the patent assignee, argued that the inventors not only were the first invent a way to measure homocysteines, but also the first to discover a particular method for finding vitamin deficiency by measuring homocysteine levels; they did so long before anyone else had even discovered how to measure homocysteines in the first place.²⁴⁶ In other words, invention lies not only in the solution, but also in discovery of the specific cause of the problem.²⁴⁷ Here, the purportedly "simple" solution of correlating homocysteine levels was preceded by more complex problems, discovering how to measure homocysteine levels and then discovering how newly measurable homocysteine levels relate to vitamin deficiencies.²⁴⁸

A broad patent claim covering a "simple" solution is not improper, so long as the disclosure describes and enables the broad claim, showing that the inventor truly found the broad but simple solution.²⁴⁹ Thus, the fact that others later

247. *See, e.g.*, Eibel Process Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45, 68 (1923) ("The invention was not the mere use of a high or substantial pitch to remedy a known source of trouble. It was the discovery of the source not before known and the application of the remedy"); Varu Chilakamarri, *Structural Nonobviousness: How Inventiveness is Lost in the Discovery*, 10 VA. J.L. & TECH. 7, 11 (2005) (noting the distinction between "invention" and "discovery").

248. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1358 (Fed. Cir. 2004).

all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious."); Burk & Lemley, *Inherency, supra* note 39, at 406–07 (noting "the problem of characterizing this subject matter category in terms of human intervention); Collins, *supra* note 244, at 353 (noting that "law of nature" analysis does not answer the question posed in *Metabolite*).

²⁴⁶ *Metabolite*, 126 S. Ct. at 2923 (Breyer, J., dissenting); *see* Cochrane v. Deener, 94 U.S. 780, 788 (1877) ("The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result."); *see also* Collins, *supra* note 244, at 333 (difference between claim 1, the homocysteine test, and claim 13, the vitamin deficiency test, was the generality of the method used and not the "natural phenomena").

Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 102 (C.C.S.D.N.Y. 1911) ("There is 249. nothing improper, so far as I can see, in first putting your claims as broadly as in good faith you can, and then, ex abundanti cautela, following them successively with narrower claims designed to protect you against possible anticipations of which you are not yet aware."). But see Michael Meehan, The Handiwork of Nature: Patentable Subject Matter and Laboratory Corporation v. Metabolite Labs, 16 ALB. L.J. SCI. & TECH. 311, 317-22 (2006) (describing several diagnostic tests that could have been patentable under Federal Circuit's decision in Metabolite). Two of the three examples by Dr. Meehan differ from Metabolite in that (a) the diagnoses are easily determined through visual inspection, and (b) do not require analysis by a laboratory. Id. Congress has made clear that doctors cannot be held liable for infringing such patents. 35 U.S.C. § 287(c)(1) (2000). As such, to say categorically that diagnostic measures should not be patented through these examples is unpersuasive. Additionally, the examples Dr. Meehan describes relate to enablement and novelty – did the person who claimed a diagnostic test really invent all such incarnations of that test, or instead just a particular one. See, e.g., Incandescent Lamp Patent, 159 U.S. 465, 475 (1895).

discover different ways to measure homocysteine levels does not necessarily mean that the Metabolite inventors did not inventively solve a different but related problem. Similarly, in *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, the Federal Circuit ruled that a process for analyzing electrocardiograph data was patentable subject matter even though the relationship between the data and health was "natural."²⁵⁰ The Federal Circuit recently expounded on this rule, stating that if a process is tied to a machine or transforms physical objects or data about physical objects then it does not pre-empt a "fundamental principle."²⁵¹

In this sense, the *Metabolite* claim is like any patent claim covering a new use for a known composition or process.²⁵² A new use patent claims the natural phenomenon that a medicine has a certain effect on the body (or, as in *Metabolite*, that certain test process results reflect a certain condition), and the patentee is the first to discover the previously unknown effect.²⁵³ Furthermore, the *Metabolite* test transforms blood to perform a homocysteine test and manipulates data about that physical phenomenon to determine whether there is a vitamin deficiency.

Nonetheless, patentability is not ensured. Strict application of specification requirements under *Morse* might have invalidated the *Metabolite* patent on the basis that the inventors did not "possess"²⁵⁴ *all* homocysteine correlation tests and did not describe or enable such in the specification.²⁵⁵ The Federal Circuit did not consider the broad scope on § 112 enablement grounds; it focused on the "correlating" step rather than the use of *any* test, whether or not invented by the applicants.²⁵⁶ In fact, Laboratory Corp. of America did not even make the

2008]

^{250.} Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1058–60 (Fed. Cir. 1992) ("Arrhythmia Research argues that the claims are directed to a method of detection of a certain heart condition by a novel method of analyzing a portion of the electrocardiographically measured heart cycle.").

^{251.} In re Bilski, No. 2007-1130, 2008 WL 4757110, at *7, 12 (Fed. Cir. Oct. 30, 2008).

^{252. 35} U.S.C. § 100(b) (2000) ("The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."); *see, e.g.*, Rohm & Haas Co. v. Roberts Chems., Inc., 245 F.2d 693, 697 (4th Cir. 1957) (upholding patent for new use of a chemical as a fungicide).

^{253. 35} U.S.C. § 100(b) ("The term 'process' . . . includes a new use of a known process, machine, manufacture, composition of matter, or material.").

^{254.} LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005) (holding that the specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed") (citing O'Reilly v. Morse, 56 U.S. 62, 112–13 (1853))).

^{255.} The Federal Circuit opinion notes that the PTO rejected an initial attempt by the applicants to patent "[a] method for detecting a deficiency" by assaying a body fluid for elevated levels of homocysteines for a failure to describe the method. Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1362 (Fed. Cir. 2004) (quoting from the prosecution history of U.S. Patent No. 4,940,658 (filed Nov. 20, 1986)).

^{256.} Id. at 1366-67.

argument that the claim to the use of *any* test was broader than enabled.²⁵⁷ As discussed below, one harm caused by inordinate focus on subject matter is that such focus detracts from rigorous consideration of patentability criteria.

Regardless of how one would resolve the question of whether the inventors described and enabled such a broad claim,²⁵⁸ a specification question should be answered in place of an unprincipled and potentially unanswerable question of patentable subject matter.

F. Mental Steps and Human Action

More than 35 years ago, the courts stopped barring patent claims simply because they included steps that could be performed by a human,²⁵⁹ but this area remains controversial.²⁶⁰ The Federal Circuit recently reinvigorated the doctrine in *In re Comiskey*, ruling that patent claims based *solely* on human thought processes are not patentable subject matter.²⁶¹ This ruling was extended under *Bilski's* machine or transformation test: mental processes not tied to machines or transformative of matter are barred.²⁶² Even so, there is little principled discussion in the literature or in case law about when and how "mental steps" should be allowed in patents.²⁶³

^{257.} Brief for Petitioner at 38–52, Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2004) (No. 03-1120).

^{258.} *Cf.* Collins, *supra* note 244, at 331–32 ("The recitation of an act of thinking is harmless to the public when that act has been appended onto an otherwise patentable method claim. In this situation, the thinking merely restricts the scope of a patentee's right to exclude. . . . More specifically, a claim is exempted from thought-propertizing status if the steps other than the acts of thinking recite a novel, nonobvious, and useful method.").

^{259.} In re Musgrave, 431 F.2d 882, 893 (C.C.P.A. 1970) ("We cannot agree with the board that these claims (all the steps of which can be carried out by the disclosed apparatus) are directed to non-statutory processes merely because some or all the steps therein can also be carried out in or with the aid of the human mind or because it may be necessary for one performing the processes to think."); see Collins, supra note 244, at 321 ("However, the courts abandoned the mental steps doctrine over a quarter-century ago, and the doctrine was notoriously ill-defined and under-theorized even in its heyday."); id. at 355–57 (summarizing the history of the mental steps doctrine).

^{260.} See, e.g., In re Schrader, 22 F.3d 290, 291 (Fed. Cir. 1994) (holding that auction process is not patentable subject matter); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2923 (2006) (Breyer, J., dissenting) (asserting that mental processes are not patentable subject matter); see also In re Comiskey, 499 F.3d 1365, 1376 n.11 (Fed. Cir. 2007) (arguing that Supreme Court's decision in *Gottschalk v. Benson* undercut *Musgrave*). Even the court in *Musgrave* required that any mental steps be part of "technological arts." *Musgrave*, 431 F.2d at 893.

^{261.} In re Comiskey, 499 F.3d 1365, 1376 (Fed. Cir. 2007).

^{262.} In re Bilski, 2007-1130, 2008 WL 4757110, at *12 (Fed. Cir. Oct. 30, 2008).

^{263.} Collins, *supra* note 244, at 344 ("The mess that resulted from the Supreme Court proceedings in Laboratory Corp. demonstrates that there is no well-established approach for bringing Section 101 and its restriction on the subject matters eligible for patent protection to bear on the propertization of thought.").

Primary concerns with mental steps are that human intervention fails the definiteness,²⁶⁴ usefulness²⁶⁵ or nonobviousness tests.²⁶⁶ Such concerns, however, do not mean that every invention that involves human thought fails to meet these tests—each claim can be tested for definiteness, usefulness, or nonobviousness independently.²⁶⁷ In fact, virtually every method requires human intervention at some point, if only to push a button on a machine that will carry out the method.²⁶⁸

Other theories for barring protection of mental steps might be advanced. For example, some might claim that protecting mental processes would limit free speech and thought, conflicting with the First Amendment.²⁶⁹ However, to the extent that people may think about and discuss—but not practice—the contents of a patent, the First Amendment seems unlikely to be implicated. Further, the Intellectual Property Clause is constitutional as well.²⁷⁰ To the extent that a law is constitutional under the Intellectual Property Clause, First Amendment protection is lessened.²⁷¹ For example, copyright law limits speech by barring the distribution of copyrighted works, but arguments that such a bar is unconstitutional *per se* are unpersuasive.²⁷²

266. Thomas F. Cotter, *A Burkean Perspective on Patent Eligibility*, 22 BERKELEY TECH. LJ. 855, 886 (2007) ("[I]f technological arts and mental steps are to perform a modest but non-negligible function in preventing patents from intruding upon liberty and other important interests, it might be more fruitful to reconsider application of a point of novelty approach.").

267. In re Musgrave, 431 F.2d 882, 893 (C.C.P.A. 1970) ("Of course, to obtain a valid patent the claim must also comply with all the other provisions of the statute, including definiteness under 35 USC § 112. A step requiring the exercise of subjective judgment without restriction might be objectionable as rendering a claim indefinite, but this would provide no statutory basis for a rejection under 35 USC § 101."); McClaskey, *supra* note 264, at 1151–52 (asserting that *O'Reilly v. Morse* stands for the proposition that any useful art— including mental steps—is patentable, so long as it may be described in a definite manner and so long as it leads to predictable results).

268. See, e.g., Wright Co. v. Paulhan, 177 F. 261, 264 (C.C.S.D.N.Y 1910), rev'd on other grounds, 180 F. 112 (2d Cir. 1910). In Wright, the patent claimed a system of ropes and pulleys to automatically adjust the tail rudder in response to wing "warping." *Id.* at 264. Competitors discovered that they could design around the patent if the pilot performed the rudder adjustment manually. *Id.* Judge Learned Hand ruled that the substitution of a person instead of the automatic system was an equivalent and thus infringing. *Id.* at 264.; see also Merges & Duffy, supra note 162, at 821–25. But see Collins, supra note 244, at 329–30 (distinguishing human activity from human thought). Even Collins's test, which asks whether "thought" is a necessary element of a method or merely an additional but non-critical step, would be difficult to administer in practice. *Id.*

^{264.} Norman D. McClaskey, *The Mental Process Doctrine: Its Origin, Legal Basis, and Scope*, 55 IOWA L. REV. 1148, 1165–69, 1195 (1969) (discussing cases relating to indefiniteness of human activity).

^{265.} *In re* Comiskey, 499 F.3d at 1376 ("[W]hen an abstract concept has no claimed practical application, it is not patentable.").

^{269.} See U.S. CONST. amend I.

^{270.} U.S. CONST. art. I, § 8, cl. 8.

^{271.} Roth v. United States, 354 U.S. 476, 492 (1957) (stating that the postal power provides wider latitude relating to First Amendment).

^{272.} Harper & Row, Publishers v. Nation Enters., 471 U.S. 539, 556-57 (1985) ("But

Others might argue that protection of mental steps allows for protection of information that the patent laws intended to dedicate to the public.²⁷³ However, it is difficult to square any definition of "thought" with any statutory intention discernable in the categories in § 101. Additionally, the public dedication theory specifically embraces a "point of novelty" approach, where thought is the point of novelty.²⁷⁴ However, the "point of novelty" argument has been expressly rejected even where the Court has seemed to apply such analysis.²⁷⁵ As such, reliance on point of novelty, however elegant for mental steps theory, is unlikely to yield consistent results in practice, which is a goal of this Article's proposal.

The *Metabolite* case brought newfound attention to the mental steps issue because any doctor could determine the correlation between homocysteine levels and vitamin deficiencies, nearly automatically.²⁷⁶ Applying a mental steps subject matter test, however, draws the wrong lines on patentability. For example, no mental step would be necessary if the method instead claimed an electronic test that flashed a "vitamin deficiency" sign if homocysteines exceeded a particular level (similar to a pregnancy test).²⁷⁷ Further, the *Bilski* machine or transformation test is of little help; drawing and testing blood is a transformation and machines are most certainly used to perform the tests. Thus, determination of the claim's patentability should not hinge on whether the mental step was (or could be) carried out by a device.²⁷⁸ Furthermore, with a binary test the mental process is surely definite and not prone to variation.²⁷⁹

Following *Metabolite*, *In re Comiskey* reasserted the mental steps exclusion in cases where the *entire* claim can be performed by the human mind, but even

274. Collins, *supra* note 244, at 357; Bilski, 2008 WL 4757110, at *8 (quoting Diamond v. Diehr, 450 U.S. 175, 191–92 (1981)) (noting that "insignificant post-solution activity" is to be disregarded in determining whether a claim is tied to a machine).

275. Parker v. Flook, 437 U.S. 584, 594 n.16 (1978).

copyright assures those who write and publish factual narratives... that they may at least enjoy the right to market the original expression contained therein as just compensation for their investment.").

^{273.} *In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *3, 15 (Fed. Cir. Oct. 30, 2008) (noting that mental steps fall under the bar against phenomena of nature and abstract ideas); Collins, *supra* note 244, at 357–60 (arguing that propertizing "thought" allows for removal of too much from the public domain).

^{276.} Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2924 (2006) ("Hence, in reviewing the test results, doctors would look at the [test results] and automatically reach a conclusion about whether or not a person was suffering from a vitamin deficiency."). *But see* Collins, *supra* note 244, at 321 (noting that courts and commentators did not focus on mental steps aspect of *Metabolite* case).

^{277.} In fact, the claim at issue could have been performed by a machine. *See Metabolite*, 126 S. Ct. at 2924 (stating that the inventor's claim required a "correlating" step but that the correlation was nothing more than a binary process; the patient either had or did not have a vitamin deficiency based upon his or her homocysteine levels).

^{278.} *But see* Collins, *supra* note 244, at 330–31 (holding that "thought" steps that can be performed by a machine should still be considered thought steps).

^{279.} The answer would be "yes" or "no."

that definition is problematic.²⁸⁰ The claims at issue in *Comiskey* included enrollment of a person and "unilateral documents" in a mandatory arbitration "system" which incorporated "conducting" arbitration.²⁸¹ The document step is certainly not mental, and conducting an arbitration must include some human interaction.²⁸² While the *Comiskey* court dismissed these objections with little discussion, the case provides little future guidance for determining which claims are *entirely* mentally performed.²⁸³

The Federal Circuit attempts to shore up these failings in *Bilski* by recasting *Comiskey* under the "machine or transformation" standard.²⁸⁴ The recasting adds little certainty, as the "non-mental" aspects of *Comiskey* are now disregarded because they do not recite a machine or transformation.²⁸⁵ This too draws a poor line—Comiskey might simply claim that the agreements are stored on a computer to recite a machine. Determining whether such a claim is "insignificant postsolution activity"²⁸⁶ is no more predictable than determinations under any other test. Instead of having to be re-explained mere months after its issuance, *Comiskey* could have been (and indeed was originally by the PTO) decided on obviousness grounds.²⁸⁷ Because it cannot be consistently applied, the mental steps doctrine should remain unused in lieu of other patentability criteria.²⁸⁸

G. Signals

The recent case of *In re Nuijten* brought further attention to patentable subject matter.²⁸⁹ The applicant sought to patent not only the means for creating and using a signal,²⁹⁰ but also the signal itself divorced from any tangible

290. *Id.* at 1348 ("Nuijten's patent application discloses a technique for reducing distortion induced by the introduction of 'watermarks' into signals. In the context of signal processing,

^{280.} In re Comiskey, 499 F.3d 1365, 1379 (Fed. Cir. 2007).

^{281.} *Id.* at 1368–69.

^{282.} See id. at 1379.

^{283.} *Id.* ("Comiskey's independent claims 1 and 32 seek to patent the use of human intelligence in and of itself.").

^{284.} In re Bilski, 2008 WL 4757110, at *10 ("[W]e actually applied the machine-ortransformation test to determine whether various claims at issue were drawn to patent[-]eligible subject matter.").

^{285.} *Id.* at *10 ("As a result, even a claim that recites 'physical steps' but neither recites a particular machine or apparatus, nor transforms any article into a different state or thing, is not drawn to patent-eligible subject matter.").

^{286.} Id. at *8 (quoting Diamond v. Diehr, 450 U.S. 175, 191-92 (1981)).

^{287.} Comiskey, 499 F.3d at 1370 (PTO rejected claims as obvious).

^{288.} Part IV discusses why particular subject matter bars do not fall under reasonable statutory interpretation. However, interpretation of "process" to exclude claims where every step can *only* be performed in the mind or with pencil and paper (and faithful application of that interpretation, which was missing in *Comiskey*) might be a reasonable reading of 35 U.S.C. §100(b). Such an interpretation would also exclude "pure" mathematical algorithms divorced from any other steps. The "machine or transformation" test of *Bilski* does not provide a similarly grounded test.

^{289.} In re Nuijten, 500 F.3d 1346, 1348 (Fed. Cir. 2007).

medium.²⁹¹ The reason the applicant cared about patentability of the signal was so that the patent owner could sue not only on the senders of such signals for infringement, but also the carriers of such signals, such as internet service providers, even though they might unknowingly carry the signal.²⁹²

Some have commented that signals should be yet another specific unpatentable subject matter exception.²⁹³ A problem with this approach is that many patent claims are in some sense related to ordered information.²⁹⁴ Others have focused on the statutory requirements for patentable categories.²⁹⁵ This is how the *Nuijten* Court proceeded, ruling that a signal does not fit one of the statutory categories.²⁹⁶

Nuijten's rigorous categorical analysis is more in line with this paper but is still difficult to apply to abstract ordered information, such as signals.²⁹⁷ In *O'Reilly v. Morse*, the Supreme Court upheld a claim for "the system of signs ... in combination with machinery for recording them, as signals for telegraphic purposes."²⁹⁸ The *Nuijten* signal could very well fall in the category of dots and

292. See Nujiten, 500 F.3d at 1353 (stating that "any tangible means of information carriage will suffice for all of the claims at issue"). It is not clear that such a theory would work in practice, as one must "use[]" the invention to be liable. 35 U.S.C § 271(a).

293. Cotter, *supra* note 266, at 872 n.100 (describing *Nuijten* as pushing the limits of Federal Circuit subject matter jurisprudence).

294. Kevin Emerson Collins, *Claims to Information Qua Information and a Structural Theory of Section 101*, 4 I/S: A JOURNAL OF LAW AND POLICY 11, 26–29 (2008) (discussing the difficulty of determining what is and is not information, and the further difficulty of determining which information is patentable and which is not).

295. John F. Duffy, *Nuijten: Patentable Subject Matter, Textualism and the Supreme Court*, PATENTLY-O (Feb. 5, 2007) http://patentlyo.com/patent/2007/02/in_re_nuijten_p.html (discussing statutory categories and applying historical meaning of terms to determine whether signals are "compositions of matter"); Han, *supra* note 291, at 56 (embodiment of a signal in a tangible medium creates patentable subject matter).

296. Nuijten, 500 F.3d at 1357.

297. See, e.g., Han, supra note 291, at 65–67 (arguing that signals fall within statutory category of § 101 and that patentability should be determined by other patentability criteria). Han relies only on *method* claims that *use* signals to support his argument that a signal, standing alone, is statutory subject matter; he does not rely on any case holding that a signal is actually a composition of matter, for example. *Id.*; see also Osenga, supra note 5, at 1111–12 (noting the same confusion).

298. O'Reilly v. Morse, 56 U.S. 62, 86 (1853); see also Nuijten, 500 F.3d at 1353 (signals are

watermarking is a technique by which an original signal (such as a digital audio file) is manipulated so as to embed within it additional data.").

^{291.} Id. at 1350–51. In broadest terms, a signal like Nuijten's is a quantum of information organized in a specific way but separated from any physical medium. In re Foster, 438 F.2d 1011, 1016 (C.C.P.A. 1971) (explaining that a signal is "[a] visual, aural, or other indication used to convey information" or "[a]n event or occurrence that transmits information from one location to another.") (citations omitted); see, e.g., Sam S. Han, Analyzing the Patentability of "Intangible" Yet "Physical" Subject Matter, 3 COLUM. SCI. & TECH. L. REV. 2, 55 (2002) ("Webster's dictionary provides that a 'signal' is: in radio, etc. the electrical impulses transmitted or received. Although that definition only provides for 'electrical impulses,' other types of signals may be encompassed in our analysis (e.g., magnetic impulses, continuous waves, etc.)." (footnote omitted).

dashes claimed by Morse. On the other hand, the claim at issue in *Morse* covered a system of signals combined with specific machinery.²⁹⁹ In other words, Morse's claim was for a particular method of using a signal and not for the signals themselves transmitted by other media.³⁰⁰

Another way to consider signals is through the application of requirements for patentability other than category. Fundamentally, a signal is information. The question, then, is whether a particular combination of information can be novel and nonobvious; the apparent answer is no. Under the rationale of *Funk Brothers*, the combination of known elements into something that is not more than the sum of parts cannot be novel and nonobvious.³⁰¹ Further, such signals—in the abstract at least—have no practical utility; they fail to "do" anything until coupled with a storage medium or process.³⁰² Under this analysis, a signal should not be patentable on grounds unrelated to subject matter.

H. Books, Art, and Music

Books, art, music, and pictures are extensions of signals: they are other forms of "ordered information." Such works are generally not patentable for a variety of reasons.³⁰³

First, books, art, and music are not processes, compositions of matter, or machines.³⁰⁴ Books are a manufacture, but art and music stretch the interpretation of manufacturing, which requires raw materials to take a new form.³⁰⁵ Further, even though art takes a new form when paint is combined on a canvas, and

299. See Morse, 56 U.S. at 86.

302. In re Nuijten, 500 F.3d 1346, 1365 (Fed. Cir. 2007) (Linn, J., dissenting) (unless abstract information is applied, such information is not useful).

physical); Arrhythmia Research Tech., Inc. v. Corazonix Corp., 958 F.2d 1053, 1059 (Fed. Cir. 1992) ("The view that 'there is nothing necessarily physical about 'signals' is incorrect." (quoting *In re* Taner, 681 F.2d 787, 790 (C.C.P.A. 1982))); U.S. Patent No. 5,568,202 (filed Sept. 22, 1992) (in which inventor Koo claimed "[a]n electronic reference signal in a system for minimizing the effects of ghosts occurring during the transmission and reception of a television signal over a communications path . . ."). Both Morse and Koo claimed signals as part of a specific system that used the signals in a particular way rather than the signals themselves. *Morse*, 56 U.S. at 86; U.S. Patent No. 5,568,202 (filed Sept. 22, 1992).

^{300.} See id.

^{301.} Funk Bros. Seed Co. v. Kalo Inoculant Co., 332 U.S. 755 (1947).

^{303.} In addition to the reasons discussed below, constitutional limitations may limit the patenting of such "writings." *See infra* Part IV.

^{304.} MANUAL OF PATENT EXAMINING PROCEDURE, § 2106.01 (2007) ("Certain types of descriptive material, such as music, literature, art, photographs, and mere arrangements or compilations of facts or data, without any functional interrelationship is not a process, machine, manufacture, or composition of matter."). Of course, "performing music" or "showing art" might be a method for entertaining. Similarly, "blowing into a flute" might be a method for making sounds.

^{305.} Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11–12 (1931) (fruit dipped in borax does not take a new form).

photographs are printed from film, only the *first* piece of art and the *first* photograph were novel manufactures.³⁰⁶

Second, such copyrightable subject matter would often be obvious under *Funk Brothers* because it is made of preexisting materials and information without any new effects based on the combination.³⁰⁷ Under this analysis, textual writing in the abstract, no matter how creative, is not patentable because it is a combination of known letters and words and thus, obvious.³⁰⁸ Furthermore, ordered information can be viewed as a set of instructions and finding defendants liable for transmission of such instructions would make little sense³⁰⁹—it would be infringement to read, copy, or transmit the patent document itself.³¹⁰

Third, such works would not be "practically useful" under *Brenner v. Manson* because their sole use would be for visual or auditory examination.³¹¹ In *Brenner*, the Court determined that a process for making steroids lacked utility because the resulting steroid had no known practical use beyond further study.³¹² Like the steroid in *Brenner*, visual and auditory art does not *do* anything and is only useful for static viewing.³¹³ It may be that the first book was a novel, nonobvious, and useful medium used to convey information, but successors that

308. A new language, however, might be patentable as a communication method if the symbols therein are nonobvious. Morse code is an example of such a language, though such symbols were tied to the particular telegraph hardware.

309. Collins, *supra* note 244, at 318 (patent law makes instructions part of public domain).

310. *Cf.* Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746, 1755 (2007) ("[Software] abstracted from a tangible copy no doubt is information—a detailed set of instructions—and thus might be compared to a blueprint (or anything containing design information, e.g., a schematic, template, or prototype). A blueprint may contain precise instructions for the construction and combination of the components of a patented device, but it is not itself a combinable component of that device."); Pellegrini v. Analog Devices, Inc., 375 F.3d 1113, 1117–19 (Fed. Cir. 2004) (transmission of instructions is not the same thing as transmission of the object the instructions describe).

311. Brenner v. Manson, 383 U.S. 519, 534–35 (1966); *see In re* Nuijten, 500 F.3d 1346, 1365 (Fed. Cir. 2007) (Linn, J. dissenting) (unless abstract information is applied, it is not useful).

312. Brenner, 383 U.S. at 520.

313. *Ngai*, 367 F.3d at 1339 (printed matter must have some functional relationship to whatever the information is printed on in order to create a "new" product); Kreiss, *supra* note 62, at 79 (arguing for a "functional" requirement for printed matter). Of course, some forms of art may be mechanical and thus have such practical utility, but the use would be the mechanical structure and not the non-practical viewing value.

^{306.} *See In re* Gulack, 703 F.2d 1381, 1384 (Fed. Cir. 1983) (affirming ruling that a hatband with material printed on it was statutory subject matter as a manufacture, but only patentable if writing made it novel and nonobvious).

^{307.} Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948); Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152–153 (1950); *see also In re* Ngai, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (printed matter must have some functional relationship to whatever the information is printed on in order to create a "new" product); *Gulack*, 703 F.2d at 1385 ("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.").

change only the information contained therein would not be patentable due to the failure to create a new use.³¹⁴

Art, music, and other copyrightable subject matter, however, could be patentable if they otherwise met the criteria for patentability. Examples include a rain dance that actually produced rain, a method for consistently inducing sleep through the singing of a particular lullaby, a new medium for artistic expression (e.g. holographic technology), a compact disc with novel sounds that could operate a machine, or other useful forms of copyrightable subject matter. Such examples, however, would not bar ordinary, unpatented art and music and thus floodgate concerns are not significant.

IV. Potential Criticism and Concerns

Discarding specialized subject matter restrictions will undoubtedly raise concerns. First, some might argue that subject matter restrictions are constitutionally warranted, or alternatively, might argue that there is no reason to question judicial statutory interpretation of patentable subject matter categories. Second, some might be concerned about the competitive or ethical harm that broadly construed patentable subject matter might create, and as a fallback might argue that there is no good reason to reject the status quo. Third, some might argue that the proposal is unworkable in practice because the statutory criteria do not coincide with the rigorous patentability criteria discussed previously.

A. Constitutional and Statutory Concerns

1. Potential Constitutional Bar

Some concerned with this Article's proposal might contend that allowing patents on all subject matter is unconstitutional.³¹⁵ For example, in *Graham v. John Deere Co.*, the Supreme Court stated, "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available."³¹⁶ Even if one accepts the statement as a normatively appropriate reading of the constitution,³¹⁷ *Graham* does not necessarily apply to patentable subject

^{314.} Signals differ from books in that a signal in a medium can have nonobvious effects that render the end product as something different. For the same reason, the first "electronic book" might be patentable.

^{315.} *See, e.g.*, Kreiss, *supra* note 62, at 58–66 (describing constitutional limits on subject matter); Liivak, *supra* note 159, at 273–74 (U.S. Constitution requires "originality").

^{316.} Graham v. John Deere Co., 383 U.S. 1, 6 (1966).

^{317.} *See, e.g.*, Special Equip. Co. v. Coe, 324 U.S. 370, 378 (1945) (stating that Congress has wide latitude in determining just how to promote the progress); Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1544–45 (Fed. Cir. 1995) (stating that Congress has broad damages authority under constitutional mandate). Indeed, removing pre-existing knowledge from the public domain could

matter.³¹⁸ Instead, this quote reads much more like a constitutional requirement for novelty and nonobviousness: that which is in the public domain should not be protected because it does not "promote the progress of [the] useful arts."³¹⁹

In any event, this Article's focus on rigorous patentability complies with *Graham*: if something sought to be patented preexists and is publicly known, then it will not be novel or nonobvious, and a patent should not issue.³²⁰ Even under a theory that every patentability prerequisite must separately "promote the progress,"³²¹ it is not at all clear that absolute bars to a particular subject matter will separately promote progress.³²²

Finally, one might argue that any protection that is unrelated to the "technological arts" is unconstitutional.³²³ The PTO has recently used the "technological arts" limitation as a justification of patentable subject matter rejections.³²⁴ However, no clear precedential consensus mandates that "useful arts"—under which "technological arts" would fall—be so narrowly construed.³²⁵

318. *See, e.g.,* Merges, *supra* note 127, at 587 ("Given a constitutional provision rooted in a blind faith in 'progress,' we cannot read in historically contingent limitations on patentable subject matter. Put simply, there are no plausible subject matter limits, express or implied, in this broad, enabling clause."); *cf.* Chisum, *supra* note 215, at 1011 (arguing that opponents of the particular subject matter have burden of proving that the subject matter falls outside the constitutional mandate).

319. U.S. CONST. art. I, § 8, cl. 8. However, to the extent a product of nature does not qualify as prior art under § 102, something that is not new might be patentable. Such a rule may not necessarily be contrary to promoting progress.

320. *Graham*, 383 U.S. at 6; *see* McKenna, *supra* note 145, at 1253 ("Today, the Patent Act's requirements of utility, novelty, and nonobviousness ensure that the constitutional purpose is met. A narrow reading of the statutory classes of subject matter is unnecessary to meet this constitutional purpose.").

321. U.S. CONST. art. I, § 8, cl. 8. *But see* Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 422–23 (1908) (rejecting constitutional argument that failure to exploit patented invention does not promote the progress of useful arts).

322. *See, e.g.*, Chisum, *supra* note 215, at 1015–16 (describing how protection for algorithms might create incentives for innovation); *see also* Parts II, III for examples of innovation despite supposed subject matter bars.

323. See In re Musgrave, 431 F.2d 882, 893 (C.C.P.A. 1970) ("All that is necessary, in our view, to make a sequence of operational steps a statutory 'process' within 35 USC 101 is that it be in the technological arts so as to be in consonance with the Constitutional purpose to promote the progress of 'useful arts.'" (citations omitted)).

324. Steven M. Greenberg, *The Inconsistent Treatment of Computer Software as Patentable Subject Matter*, 11 J. TECH. L. POL'Y 77, 88 (2006) (basis for rejections are mental steps and technological arts rejections rather than rejections based on other patentability criteria).

325. Cf. Corning v. Burden, 56 U.S. 252, 267 (1854) ("useful art" is a general term). But see

promote the progress of the "useful arts" depending on the terms of such removal. For example, patents are granted on inventions that others have used only secretly. 35 U.S.C. § 102(g)(2) (2000). The patent grant removes this knowledge from the public domain (even as to the prior users), but the corresponding public disclosure of the invention may very well promote progress generally. Similarly, patenting of natural phenomena might provide an incentive to fund basic research, which would in turn promote the "useful arts."

For example, in *Jacobs v. Baker*, the Court assumed a broad meaning of "art" as anything that did not fall into the other subject matter categories.³²⁶ In another case, the Court implied that the goals of the constitution are adaptable.³²⁷ Finally, the Court included bookkeeping in the categories of useful arts, along with use of medicine, construction of ploughs, and mixing paints, implying that "useful art" in the constitutional sense is not necessarily "mechanical" or "technological."³²⁸ The brief congressional authorization in the Intellectual Property Clause does not warrant subject matter limits.³²⁹

2. Statutory Concerns

Even if this Article's proposal passes constitutional muster, another potential criticism is that judicial common law limitations on patentable subject matter are simply a matter of statutory interpretation. For example, critics might wonder why the mental steps exclusion under "process" is improper statutory interpretation,³³⁰ but the "practical utility" interpretation of "useful"³³¹ is acceptable.

The statutory interpretation concern, however, assumes that courts limiting patentable subject matter are actually performing statutory interpretation. While the *Brenner* Court explicitly noted that it was interpreting the statute,³³² many

327. Kendall v. Winsor, 62 U.S. 322, 328 (1858) ("The true policy and ends of the patent laws enacted under this Government are disclosed in [Article I] of the Constitution, the source of all these laws, viz: 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society." (quoting U.S. CONST., art. I, § 8, cl. 8)).

328. Baker v. Selden, 101 U.S. 99, 102 (1879) (ruling that copyright cannot protect bookkeeping forms); *cf*. Bleistein v. Donaldson Lithographing Co., 188 U.S. 239, 249 (1903) ("We shall do no more than mention the suggestion that painting and engraving unless for a mechanical end are not among the useful arts, the progress of which Congress is empowered by the Constitution to promote. The Constitution does not limit the useful to that which satisfies immediate bodily needs.").

329. U.S. CONST. art. 1, § 8, cl. 8.

330. *Compare* 35 U.S.C. § 101 (2000) ("any . . . process"), *with In re* Comiskey, 499 F.3d 1365, 1375 (Fed. Cir. 2007) ("Specifically, Supreme Court decisions after the 1952 Patent Act have rejected a 'purely literal reading' of the process provision and emphasized that not every 'process' is patentable.").

331. *Compare* 35 U.S.C. § 101 (2000) ("any ... useful"), *with* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (specific and substantial utility required).

332. Brenner, 383 U.S. at 532 ("Since we find no specific assistance in the legislative

Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (en banc) ("The exclusive right, constitutionally derived, was for the national purpose of advancing the useful arts – the process today called technological innovation.").

^{326.} Jacobs v. Baker, 74 U.S. 295, 298 (1868) ("But waiving all these difficulties as hypercritical, and assuming the correctness of the positions taken, that whatever is neither a machine, nor a manufacture, nor a composition of matter, must (*ex necessitate*) be 'an art;' that a jail is a thing 'made;' and that the patent is for the '*process* of making it'....').

patentable subject matter opinions simply assume that certain subject matter should not be patentable.³³³ Of course, courts do sometimes interpret the statute. In *Brogdex*, the Supreme Court determined that dipping an orange in borax did not create a new manufacture.³³⁴ Similarly, in *Nuijten*, the Federal Circuit considered whether a signal fell into any of the particular categories set forth in § 101 and, in doing so, considered the meanings of each.³³⁵ Such analysis, however, is not the norm; as discussed in Parts II and III, most patentable subject matter decisions were based in large part on the parroting of dicta from prior cases with little or no actual statutory interpretation.³³⁶

The most recent example is the Federal Circuit's en banc *In re Bilski* decision.³³⁷ The court gives lip service to the notion of statutory interpretation, but then it discards the actual words of the statute in a footnote, with almost no analysis.³³⁸ The court then goes on to apply what it sees as Supreme Court precedent about "fundamental principles" when neither *Benson, Flook*, nor *Diehr* used that terminology, and certainly not in the context at issue.³³⁹ Even if those cases had used that terminology, the discussion in Parts II and III shows that Supreme Court pronouncements are not statutorily based either. Finally, the court settled on the "machine or transformation" test as the *only* test, despite the fact that *Benson* and *Flook* explicitly state that the Court was not ruling on that question and no other decision has so held.³⁴⁰ This is not what statutory

334. Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11–12 (1931) (considering the meaning of the word "manufacture" in the dictionary and in other statutory contexts).

335. *In re* Nuijten, 500 F.3d 1346, 1354–57 (Fed. Cir. 2007) (considering the meaning of each term and applying to the proposed claim).

336. See, e.g., In re Comiskey, 499 F.3d 1365, 1377 (Fed. Cir. 2007) (stating that "mental processes" are not patentable based on list of dicta categories from *Gottschalk v. Benson*); In re Bilski, No. 2007-1130, 2008 WL 4757110, at *13 (Fed. Cir. Oct. 30, 2008) ("Thus, while we agree with Applicants that the only limit to patent-eligibility imposed by Congress is that the invention fall within one of the four categories enumerated in § 101, we must apply the Supreme Court's test to determine whether a claim to a process is drawn to a statutory 'process' within the meaning of § 101.").

337. No. 2007-1130, 2008 WL 4757110 (Fed. Cir. Oct. 30, 2008).

338. *Id.* at *62 n.3; *see also id.* at *25 (Newman, J., dissenting) ("The definition of 'process' provided at 35 U.S.C. §100(b) is not 'unhelpful,' as this court now states . . . but rather points up the errors in the court's new statutory interpretation. Section 100(b) incorporates the prior usage 'art' and the term 'method,' and places no restriction on the definition. This court's redefinition of 'process' as limiting access to the patent system to those processes that use specific machinery or that transform matter, is contrary to two centuries of statutory definition.").

339. *Id.* at *3 (majority opinion).

340. Id. at *6-7.

materials underlying § 101, we are remitted to an analysis of the problem in light of the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other.").

^{333.} *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130–31 (1948) (waxing poetically about how certain natural phenomena cannot be patented, without any explicit interpretation of the statute).

interpretation, or even faithful interpretation of Supreme Court precedent, is made of.

Instead, application of basic statutory interpretation principles calls into question interpreted limits on patentable subject matter. The section at issue is short:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.³⁴¹

To start, a plain language reading of the statute³⁴² yields a few insights that support this Article's proposal. First, the term "any" is unambiguous: virtually every definition of the word states that it denotes a quantity without limitation.³⁴³ Thus, any limitation must come from the remainder of the section.³⁴⁴ The first limitation is "new" and the second limitation is "useful," both of which are described in more detail in Parts II and III.³⁴⁵

The next limitations are of category.³⁴⁶ These terms might very well be vague or ambiguous; as discussed above, some of the category terms have been interpreted and others might need interpretation with respect to specific claims.³⁴⁷

However, ambiguity does not mean that the term should be interpreted without reference to possible meanings, statutory definitions, congressional intent, historical precedent, and other bases for statutory interpretation. For example, "process" has an extremely broad statutory definition.³⁴⁸ Further, "process" generally means a series of definite steps taken to achieve some end.³⁴⁹ The term "process" was inserted into the statute in replacement of the term "art."³⁵⁰ As discussed above, "art" was historically considered anything that did

^{341. 35} U.S.C. § 101 (2000).

^{342.} Plain language is a preferred method of statutory interpretation where terms are not ambiguous. Randall v. Loftsgaarden, 478 U.S. 647, 656 (1986) ("Here, as in other contexts, the starting point in construing a statute is the language of the statute itself.").

^{343. 1} OXFORD ENGLISH DICTIONARY 538–39 (1989) (defining "any" as "[a]n indeterminate derivative of *one*").

^{344.} *See, e.g.*, Roth v. United States, 354 U.S. 476, 479, 484 (1957) (finding that obscenity is exempted from "no law" language of First Amendment because it is not protected speech under the amendment).

^{345. 35} U.S.C. § 101 (2000).

^{346.} Id. (i.e. process, machine, manufacture, or composition of matter).

^{347.} For example, because the constitution separates protection of writings from protection of discoveries, any ambiguities in the categories of § 101 might exclude writings. *Cf.* Baker v. Selden, 101 U.S. 99, 102–03 (1879) (separating writings from the "useful arts" that the writings describe).

^{348. 35} U.S.C. § 100(b) ("The term "process" means process, art, or method and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

^{349. 12} OXFORD ENGLISH DICTIONARY 545–48 (1989) (defining "process" as "an action or series of actions; progress, course").

^{350.} In re Schrader, 22 F.3d 290, 295 n.11 (Fed. Cir. 1994).

not fit into one of the other categories.³⁵¹ It is true that early case law discussed a process in terms of the physical, but none of the cases examined any dictionaries, statutory definitions, congressional intentions, patent policies, or other principled bases for interpretation.³⁵² Unlike the interpretation of "manufacture" in *Brogdex*, sweeping limiting interpretations of "process" and other statutory categories have generally parroted dicta.³⁵³ However, close analysis shows that "process" was never intended to be limited to physical processes.³⁵⁴

No apparent statutory basis exists, therefore, to exclude a business method or even a mathematical algorithm from the process category based on an arbitrary test. The Supreme Court recognized this even as it struck down patents on mathematical algorithms; it did so on grounds other than a narrow interpretation of "process."³⁵⁵ As discussed in Part II, most nominal subject matter decisions were not really about patentable subject matter; however, to the extent that courts

^{351.} Jacobs v. Baker, 74 U.S. 295, 298 (1868). *But see* Sean M. O'Connor, *Using Insights From the History of Science to Redefine Patentable Subject Matter under the IP Clause* 14 (Oct. 8, 2007), *available at* http://ssrn.com/abstract=1104899 ("art" historically considered broad in history of science, but ultimately arguing that "useful" arts should be understood much more narrowly).

^{352.} Cochrane v. Deener, 94 U.S. 780, 788 (1877) ("A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.").

^{353.} See, e.g., In re Comiskey, 499 F.3d 1365, 1376 (Fed. Cir. 2007) ("In that context, the Supreme Court has held that a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter.").

^{354.} *Schrader*, 22 F.3d at 295 n.12 ("subject matter" in *Cochrane* was not limited to physical transformation, and transformation of "intangibles" is also statutory subject matter, or else the method used by the telephone would not have been patentable). *Comiskey* does not discuss this aspect of *Schrader*. *See Comiskey*, 499 F.3d 1365; *see also In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *11 (Fed. Cir. Oct. 30, 2008) (transformation of data about physical objects is sufficient transformation).

^{355.} Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) ("The statutory definition of 'process' is broad. An argument can be made, however, that this Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing.' ... [W] eassume that a valid process patent may issue even if it does not meet one of these qualifications of our earlier precedents." (citations omitted)); *see also* Gottschalk v. Benson, 409 U.S. 63, 71 (1972) ("It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a 'different state or thing.' We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents. It is said that the decision precludes a patent for any program servicing a computer. We do not so hold. It is said that we have before us a program for a digital computer but extend our holding to programs for analog computers. We have, however, made clear from the start that we deal with a program only for digital computers. It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. Such is not our purpose.").

rendered such decisions on the basis of subject matter limitations, the courts did not conduct statutory interpretation of the § 101 categories.

The final limitation, "subject to the conditions and requirements of this title,"³⁵⁶ supports this Article's proposal. If *any* claimed invention falls into one of the categories, it is patentable, but *only if* it meets the rigorous criteria set forth in the Patent Act. To exclude inventions that otherwise fall into a category and satisfy the criteria of the Patent Act essentially reads those provisions out of the statute, something to be avoided in statutory interpretation.³⁵⁷

B. Competitive and Ethical Harm

One potential criticism of this Article's *laissez-faire* approach to patentable subject matter is the risk that more patents will issue that bar the use of "fundamental truths," and that such patents will lead to anti-competitive or unethical results. However, these concerns can be addressed. First, evidence shows that competition would not be harmed, and the judiciary is not in a position to avoid harm in any event. Second, there are strong policy reasons to adopt the proposal.

1. Competition Would Not be Harmed

Concern about the effect of broad subject matter patentability can be allayed in two ways: (a) such concern is empirically unsupported, and (b) the judiciary is poorly equipped to address subject matter policy.

First, whether unwarranted growth in the number of patents will occur is unclear.³⁵⁸ Careful claims drafting can avoid many subject matter limitations, which means that focus on subject matter rather than on the underlying invention should have little effect on unwarranted patent claims.³⁵⁹ Not surprising, then, is the fact that evidence does not indicate excessive growth in patenting of "suspect" subject matter.³⁶⁰ For example, in the eight years since *State Street Bank*.³⁶¹ condoned business method patents, only 4% of business method patent applications actually issued as patents.³⁶² Similarly, in computer software, only

2008]

^{356. 35} U.S.C. § 101 (2000).

^{357.} Robinson v. United States, 324 U.S. 282, 285 (1945).

^{358.} *See, e.g.*, Gruner, *supra* note 91, at 429 (arguing that even if subject matter is not considered, patents must still overcome several hurdles before being granted); Lemley & Sampat, *supra* note 126, at 32, 34, 41 (stating that only 13% of patent applications are in software and that only 3% are in business methods).

^{359.} There are exceptions. In *In re* Nuijten, 500 F.3d 1346 (Fed. Cir. 2007), the PTO allowed a patent on a signal in a "storage medium," and the focus on whether a signal in the abstract was patentable subject matter was critical because the patentee wanted to assert patent infringement against those who transmitted, but did not store, the signal. *Id*. at 1351.

^{360.} Lemley & Sampat, *supra* note 126, at 31, 41.

^{361.} State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368 (1998).

^{362.} Lemley & Sampat, supra note 126, at 31, 41 (additionally, 52% of business method

51% of applications matured into patents, compared to an overall 69% grant rate.³⁶³ Even these statistics do not address whether the allowed claims are broad or narrow.

While the grant rate in biotechnological and chemical subject matter is 60%,³⁶⁴ only 4% of all applications are in biotechnology and organic chemistry.³⁶⁵ Studies have found that biotechnology patents have resulted in few "anticommons."³⁶⁶ Applicants in these areas may be cognizant of the prior art—which is more easily discernable than software and business method patents—resulting in patent applications that are filed on specific and discrete inventions that carefully avoid the prior art. Furthermore, as discussed above, a rigorous application of the patent rules should lead to fewer issued patents in the biotechnology area.³⁶⁷

Of course, the contrary concern may apply—rigorous patentability may result in too few patents issuing, especially in biotechnology research, which might be costly even if such research does not yield patentable results.³⁶⁸ This question is commercially important.³⁶⁹ For example, isolating a protein from its natural

366. Timothy Caulfield et al., Evidence and Anecdotes: an Analysis of Human Gene Patenting Controversies, 24 NATURE BIOTECHNOLOGY 1091, 1092-93 (2006) (summarizing studies and arguing that lack of access is more related to market price and terms other than exclusion: "The empirical research suggests that the fears of widespread anticommon effects that block the use of upstream discoveries have largely not materialized."); Christopher M. Holman, The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation, 76 UMKC L. REV. 295, 318, 352 (2007) (noting that many "gene" patents do not actually claim genes per se, and finding that, to date, enforcement of human gene patents does not appear to have a had substantial negative impact on innovation or access to gene-based technologies); see also Caulfield, supra note 366, at 1092. Caulfield noted that gene patents relating to diagnostic testing have been more exclusive. Id. Whether "sole source" availability of genetic testing is harmful is unclear. Id. at 1092–93. So long as new therapies are being researched, Congress and not the courts should evaluate the evidence and legislate accordingly. John P. Walsh et al., Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research, 36 RESEARCH POLICY 1184, 1199–1201 (2007) (concluding that despite the existence of patents, intellectual property rights have little effect on research and finding the inability to obtain physical materials is a bigger hindrance to research).

367. *Ex parte* Kubin, Appeal 2007-0819, 83 U.S.P.Q.2D (BNA) 1377 (B.P.A.I. May 31, 2007) (rejecting patent claim as "obvious to try").

368. To the extent that a process is expensive to discover and implement, it is less likely to be found obvious.

369. But see In re Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) ("Congress did not intend for these practical implications to affect the determination of whether an invention satisfies the

applications are abandoned); *see also* John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 BERKELEY TECH. L.J. 987, 1081 (2003) (finding that business method patents show indicators of high quality, such as several prior art references).

^{363.} Lemley & Sampat, *supra* note 126, at 32. *But see* Greenberg, *supra* note 324, at 88 (asserting that basis for rejections are mental steps and technological arts rejections rather than rejections based on other patentability criteria).

^{364.} Lemley & Sampat, *supra* note 126, at 30.

^{365.} *Id.* at 27.

source can be far more expensive than replicating the protein from a derived cDNA sample.³⁷⁰ However, this too should not be the province of judicially mandated subject matter rules: patentability is based on invention, not expense.³⁷¹ For example, many manufacturing methods may be cheaper than the alternatives, but unless such methods meet the patentability criteria they are not entitled to a patent.³⁷² A court considering a specific patent cannot consider such facts. Perhaps biotechnology research should be incentivized by one means or another, but such incentives should be narrowly tailored and legislatively mandated.³⁷³

To generalize, judicial attempts to create subject matter policy in a particular industry would likely be doomed by focus on the trees rather than the forest. First, such attempts would likely not take into account variations within that industry. Second, focus on the subject matter of any particular invention can cause unintended effects in that and related industries.

Thus, neither competitiveness nor ethics should be the province of patentable subject matter determinations by courts³⁷⁴ or the PTO without an express legislative bar.³⁷⁵ In addition to recognizing and protecting certain biotechnology patents,³⁷⁶ Congress has also passed laws that countenance business method

373. See, e.g., 35 U.S.C. § 103(b) (2000) (providing for special protection for biotechnology processes). See also supra Part III.

374. Parker v. Flook, 437 U.S. 584, 595 (1978) ("Difficult questions of policy concerning the kinds of programs that may be appropriate for patent protection and the form and duration of such protection can be answered by Congress on the basis of current empirical data not equally available to this tribunal."). The *Flook* Court, however, opted for *not* allowing patentability unless Congress took such action. *Id* at 596. *But see* Burk & Lemley, *Policy Levers*, supra note 17, at 1669 (arguing against judicial minimalism: "we think the solution is for the courts to get their decisions right, rather than for them to wash their hands of involvement in the calibration of policy."). This Article argues that courts cannot "get their decisions right" if those decisions are based on broad subject matter rules.

375. Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980) ("Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. . . . The subject-matter provisions of the patent law have been cast in broad terms. . . ."); Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("Of course, Congress is free to declare particular types of inventions unpatentable for a variety of reasons"); *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) ("public policy considerations . . . are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law."); Chisum, *supra* note 215, at 1011 (opponents of the broad statutory construction have burden of proving that exclusions are necessary); Kiley, *supra* note 7, at 474 ("It is not the job of the patent system to regulate new technologies, but rather to bring them into being, and into view.").

376. 35 U.S.C. § 103(b) (2000) (protecting biotechnological processes, including genetic processes, if the resulting composition, including DNA, is novel and nonobvious).

requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112.").

^{370.} Davis, supra note 144, at 336.

^{371. 35} U.S.C. §§ 101–103, 112 (2000).

^{372.} See State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F. 3d 1368, 1376 (1998).

patents³⁷⁷ as patentable subject matter. The Court's caution in *Flook* that "[i]t is our duty to construe the patent statutes as they now read, in light of our prior precedents, and we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress," ³⁷⁸ is belied by congressional action that has implicitly accepted that controversial subject matter may be patented.³⁷⁹ Instead, because Congress has at least acquiesced to broad subject matter patentability of two controversial technologies, courts should be wary of imposing restrictions on the otherwise broad statutory language.³⁸⁰

Rather, Congress and other policymakers should study all the evidence,³⁸¹ and devise whatever reasonable and narrowly tailored limits³⁸² to the enforcement of patents are warranted by public policy.³⁸³ Congress may address problematic areas in a variety of creative ways.³⁸⁴ For example, patents on nuclear weapons

382. Burk & Lemley, *Policy Levers, supra* note 17, at 1634–35 ("Even if industry-specific patent legislation is legal, we are not persuaded that it is a good idea [W]e are skeptical of the ability of a statute to dictate in detail the right patent rules for each industry. Many of the predictions of economic theory are fact-specific – they suggest different factors that should bear on the outcome of particular cases, but that require case-by-case application that cannot easily be captured in a statute.").

383. Kreiss, *supra* note 62, at 67 ("[T]he Court seems to have foreclosed [congressional investigation and legislation into the effect of subject matter rules on progress] through its pronouncements that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter."); Kiley, *supra* note 7, at 473 (arguing that denial of patents on "products of nature" would be "without regard to the positive good resulting from [such products'] isolation. Patentees profit in general relation to the extent the public profits by their labors. Will there no longer be any profit in sifting the cornucopia of nature?").

384. See, e.g., Drennan, supra note 139, at 329 (suggesting that tax patents be allowed, but limiting the types of damages that can be obtained). But see Rai, supra note 170, at 841–42 (legislature is a poor choice because problems are associated with poor judicial opinions, not the rules themselves). If it is true that the problem is caused by poor judicial implementation of existing law, it is unclear why one might expect the courts to correct themselves while the legislature could

^{377.} Id. § 273 (limiting damages for pre-existing users of patented business methods).

^{378.} Parker v. Flook, 437 U.S. 584, 596 (1978).

^{379.} *Id.* In fact, as discussed in note 6, *Flook*'s methodology relied on the narrow statutory reading in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972), which was also overturned by Congress.

^{380.} Part IV.A discusses why the statutory interpretation should be broad.

^{381.} *Cf.* Caulfield et al., *supra* note 366, at 1093 ("The survey of policy reports reveals that the Myriad Genetics [breast cancer gene] controversy was used as primary tool for justifying patent reform – thus highlighting the potential of a single high-profile controversy to mobilize . . . policy makers."); Hearing, *supra* note 139 (statement of James Toupin) (discussing tax methods: "So, in terms of whether a patent would make a strategy more available or less available, it is a bit of a trade-off between whether the cost of the license that might be requested outweighs the cost of each tax adviser inventing the same strategy for each client. The second issue is if members of the tax advice community want to establish that certain strategies are well known, they will begin to publish the information about those strategies that they may not have published previously. So, the net effect – it is possible that the net effect of patenting is to make strategies more readily available to the public rather than less.").

are banned outright,³⁸⁵ patents that may harm national defense may be kept secret or banned,³⁸⁶ doctors may not be sued for infringement of certain types of patents,³⁸⁷ and certain prior users of business methods are exempt from suit.³⁸⁸ These are all different and reasonable solutions, only one of which includes a specialized subject matter ban.³⁸⁹

Further, Congress is not the only authoritative body that can act. For example, the Internal Revenue Service could issue rules relating to the use of patented tax strategies.³⁹⁰ Also, technology consortiums routinely mandate cross-licensing of issued patents.³⁹¹ Additionally, rather than complex judicial rules about the patentability of sports methods, any sports league concerned with "anticompetitive" patents may make rules either banning or mandating compulsory free licensing in order to use a patent method.³⁹² This is no different than generally accepted sports league rules, such as the rule regulating the size and shape of goaltender gear by the National Hockey League.³⁹³ Regardless of whether such rules are normatively justified, the interested regulatory authority is in a better position to implement the rules it considers best in a way more tailored to the authority's needs than a court would be.

2. Policy Supports Broad Subject Matter Eligibility

Even if potential harm is not an issue, another possible concern is that there is no policy reason to shift from the current system. However, policy dictates the opposite course: limited judicial bars on patentable subject matter because of the current system's costly failure of purpose.

not do so through clarifying amendments. Rai does discuss how special interest groups might impede congressional reform. *Id.* Industry capture is a more relevant concern. *See, e.g.*, John Boehner & Roy Blunt, Letter to House Speaker Nancy Pelosi (Aug. 20, 2007) (describing opposition to patent reform bill), *available at* http://www.patentlyo.com/patent/law/RepublicanReform.pdf.

^{385. 42} U.S.C. § 2181(a) (2000).

^{386.} Id. § 181.

^{387.} Id. § 287(c).

^{388.} Id. § 273.

^{389.} The above provisions may or may not have followed careful study. Of course, such study will lead to better policy outcomes. In all events, courts are not engaged in such study.

^{390.} See, e.g., Dennis Crouch, Tax Strategy Patents, PATENTLY-O (Nov. 13, 2007) http://www.patentlyo.com/patent/2007/11/tax-strategy-pa.html.

^{391.} Mark A. Lemley, *Intellectual Property Rights and Standard-Setting Organizations*, 90 CAL. L. REV. 1889, 1904 (2002) (discussing standards setting organizations that require IP disclosure and/or licensing).

^{392.} See generally MAJOR LEAGUE BASEBALL, OFFICIAL BASEBALL RULES (2008), http://mlb.mlb.com/mlb/official_info/official_rules/foreword.jsp; NATIONAL HOCKEY LEAGUE, OFFICIAL RULES 2006–07 (2006), available at http://cdn.nhl.com/rules/20062007rulebook.pdf.

^{393.} NATIONAL HOCKEY LEAGUE, OFFICIAL RULES 2006–07 25 (2006) *available at* http://cdn.nhl.com/rules/20062007rulebook.pdf (stating rule 11 which limits the size of the goalie's equipment).

Changing the standards required to obtain a patent generally should be disfavored due to settled expectations.³⁹⁴ Historically, this was not a problem; despite lip service to subject matter limitations, very few patent applications were actually rejected based solely on their subject matter.³⁹⁵

Now, however, patentable subject matter is as uncertain as ever. Consider, for example, *Metabolite*.³⁹⁶ Patentable subject matter was not in dispute: the issue was never explicitly raised until the case reached the Supreme Court.³⁹⁷ When the Supreme Court granted certiorari on a previously dormant subject matter issue, it injected uncertainty into the analysis and debate began.³⁹⁸ Indeed, even if the dissent were the majority decision in *Metabolite*, the case would not have settled prospective questions about other new technological subject matter is extremely difficult.³⁹⁹ The dissent "decision" would have likely created more uncertainty because it would have invalidated the patent as a so-called "phenomenon of nature" without providing any guidance about how such phenomena should be identified and analyzed.

The Federal Circuit recently attempted to identify natural phenomena with little success by attempting to reconcile *Benson*, *Flook*, and *Diehr* in a new "machine or transformation" test.⁴⁰¹ In doing so, it explicitly disapproved of the "useful, concrete and tangible result" test that had been used in the ten years since *State Street*.⁴⁰² Indeed, the court did not even address if or how the patent in *State Street* would have been valid under the new test; under the new *Bilski* test, a process is patentable if it is tied to a machine, but not if the machine is "insignificant post-solution activity."⁴⁰³ Every attempt to create a new subject matter test has the opposite effect of destabilizing the patentability landscape and unsettling expectations.⁴⁰⁴

400. Id. at 2922.

- 402. *Id.* at *9.
- 403. Id. at *8.

404. *Id.* at *42 (Newman, J. dissenting) ("Not only past expectations, but future hopes, are disrupted by uncertainty as to application of the new restrictions on patent eligibility. For example, the court states that even if a process is 'tied to' a machine or transforms matter, the machine or transformation must impose 'meaningful limits' and cannot constitute 'insignificant extra-solution activity.' We are advised that transformation must be 'central to the purpose of the claimed process,' . . . although we are not told what kinds of transformations may qualify These concepts raise new conflicts with precedent.").

^{394.} LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW § 9-1 (2d ed. 1988) ("We deal here with the idea that government must respect 'vested rights' in property and contract – that certain settled expectations of a focused and crystallized sort should be secure against governmental disruption, at least without appropriate compensation.").

^{395.} See supra Parts II & III.

^{396.} Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006).

^{397.} *Id.* at 2925.

^{398.} Id. at 2926.

^{399.} Id. at 2926-27.

^{401.} In re Bilski, No. 2007-1130, 2008 WL 4757110, at *11 (Fed. Cir. Oct. 30, 2008).

Further, *Bilski* raises more questions than it answers: What is a fundamental principle? What is a machine? What does it mean to transform something to a different state? What about processes tied to compositions of matter or manufactures, or even other processes? What about low-tech processes that do not involve machines? How is one to determine whether a claim element is postsolution or insignificant? This last question—that of insignificant post-solution activity—swallows the entire test. The machine or transformation prong becomes irrelevant if it is impossible to determine whether such machine or transformation is significant.

Finally, even if barring preemption of "fundamental principles" were the optimal subject matter rule, the machine or transformation test fails to achieve a systematic resolution of that question. For example, *Bilski* cites to *Mackay Radio* & *Telegraph Co. v. Radio Corp. of America* for the proposition that an application of a natural principle is patentable.⁴⁰⁵ This citation implies that the *Bilski* court approved of the patent in *Mackay Radio* case. The claim at issue in *Mackay Radio* was a radio antenna that implemented wire lengths that identically matched angles and lengths predicted by a well-known equation.⁴⁰⁶ The Supreme Court found that this could be patentable because the equation was applied to a structure.⁴⁰⁷ This was an apparent triumph of the machine or transformation test because the formula was tied to the antenna.

However, the result is not so clear. First, under *Bilski*, the antenna is a physical item rather than a process, so the court would have to determine whether the physical item is really just a pretext for the mathematical equation such that the test is implicated in the first place. Second, it is not clear that the antenna is a machine—it has no moving parts and performs no actions. *Bilski* implies that *only* a machine may satisfy the test.⁴⁰⁸ Third, there could not be a more simple and direct application of this fundamental principle—it is certainly no more complex than the calculations performed by a machine in *Benson*, and there is little question that the antenna at issue pre-empted the fundamental principle associated with the antenna's dimensions.

As such, the machine or transformation test is unclear even in this simple case, and might very well call the implementation of the formula into an antenna

^{405.} *Id.* at *4 (majority opinion) (citing Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939)).

^{406.} Mackay Radio, 306 U.S. at 92-93.

^{407.} *Id.* at 94 ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.").

^{408.} *Bilski*, 2008 WL 4757110, at *62 n24 (Rader, J., dissenting) ("Our statement in *Comiskey* that 'a claim reciting an algorithm or abstract idea can state statutory subject matter only if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, i.e., a machine, manufacture, or composition of matter,'... was simply a summarization of the Supreme Court's machine-or-transformation test and should not be understood as altering that test."). It is unclear whether *Bilski* is disapproving of the inclusion of manufactures or compositions of matter or not.

"insignificant postsolution activity"⁴⁰⁹ despite the fact that the Supreme Court ruled that the antenna could be patented. *Bilski's* announcement of a new test that might (or might not) invalidate a patent claim explicitly allowed by the Supreme Court shows that judicial attempts to shape subject matter tests outside the statutory categories are uncertain and unhelpful.⁴¹⁰

Because current patentable subject matter standards are in flux,⁴¹¹ especially given cases like *Bilski* and *Metabolite*, the movement toward more subject matter limitations will impose unwarranted private and social costs⁴¹² without producing any corresponding benefits by allowing fewer "bad" patents.

Like any bright line rule, fixed subject matter rules will lead to both over and under-allowance of bad or good patents respectively.⁴¹³ For example, where a subject matter is barred, the incentive to research and invent in a particular area, such as biotechnology, can be significantly reduced.⁴¹⁴ On the other hand, some

411. See, e.g., In re Warmerdam, 33 F.3d 1354, 1359 (Fed. Cir. 1994) ("The difficulty is that there is no clear agreement as to what is a 'mathematical algorithm,' which makes rather dicey the determination of whether the claim as a whole is no more than that. An alternative to creating these arbitrary definitional terms which deviate from those used in the statute may lie simply in returning to the language of the statute and the Supreme Court's basic principles") (citation omitted); *In re* Musgrave, 431 F.2d 882, 891 (C.C.P.A. 1970) (describing how mental steps doctrine is a "morass"); Eisenberg, *Re-examining, supra* note 169, at 784 (noting persistent lack of clarity about patenting of DNA); Osenga, *supra* note 5, at 1093–1103 (describing inconsistent decisions).

412. But see Gruner, supra note 91, at 398 ("Disputes that still rage over the minimum physical features of patentable inventions . . . miss the point of keeping our patent system general and ensuring that this system encourages the broadest possible range of innovations of benefit to the public."). Rather than adopting the approach of this Article, Gruner later argues that subject matter rules should be determined on a case by case basis using a three-pronged test to maximize patent benefits for that type of technology. *Id*.

413. Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 857 (2006) (discussing the effect of patent scope on incentives); Gruner, supra note 91, at 428 ("The consequences of finding that a particular type of advance falls outside of patentable subject matter are particularly severe. These sorts of advances are never subject to patent rewards and incentives no matter how new and advantageous to society the advances might be.").

414. Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 868–69 (1990) (discussing effect of patent scope on incentives); Gruner, *supra* note 91, at 428 ("The consequences of finding that a particular type of advance falls outside of patentable subject matter are particularly severe. These sorts of advances are never subject to patent rewards and incentives no matter how new and advantageous to society the advances might

^{409.} *Id.* at *8 (majority opinion) ("Therefore, even if a claim recites a specific machine or a particular transformation of a specific article, the recited machine or transformation must not constitute mere 'insignificant postsolution activity.'" (quoting *Flook*, 437 U.S. at 590 ('The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance."))).

^{410.} *Id.* at *60 (Rader, J., dissenting) ("An abstract idea must be applied to (transformed into) a practical use before it qualifies for protection. The fine print of Supreme Court opinions conveys nothing more than these basic principles. Yet this court expands (transforms?) some Supreme Court language into rules that defy the Supreme Court's own rule.").

might argue that no additional incentives are needed to encourage the development of business methods patents, leading to over-production of such patents if such patents are not barred. However, society might be better off barring certain biotechnology claims despite the negative effect on research. Similarly, society might fare better allowing certain business method claims despite the "positive" effect on future applications for such patents.⁴¹⁵

In other words, although subject matter restriction can be a "policy lever,"⁴¹⁶ it is not a very effective lever because the rules cannot be applied narrowly or consistently.⁴¹⁷ Because poorly defined and mis-targeted subject matter exclusions cannot effectively answer fine-grained policy questions, resources should instead focus on the statutory patentability criteria. These criteria form a set of requirements developed over time that,⁴¹⁸ in combination, work more like a standard designed to grant only those patents deserving of protection.⁴¹⁹

To be sure, standards are more costly to implement than rules, but the PTO is already engaged in applying such standards. Indeed, most PTO resources appear to be focused on the statutory patentability criteria because very few rejections are currently based on patentable subject matter.⁴²⁰

However, the institution of new rules, like that in *Bilski*, that would cause more subject matter rejections, or even more subject matter analysis,⁴²¹ may have

416. *Id.* at 1642–44 (discussing "abstract ideas" as a potential area for judicial patent policy).

420. Kane, supra note 39, at 519 (noting decrease in rejections based on subject matter).

421. In re Comiskey, 499 F.3d 1365, 1371 (Fed. Cir. 2007) ("[T]he *obligation* to determine what type of discovery is sought to be patented [so as to determine whether it is 'the kind of "discoveries" that the statute was enacted to protect'] *must precede* the determination of whether that discovery is, in fact, new or obvious." (quoting Parker v. Flook, 437 U.S. 584, 593 (1978)). *But see In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *62 n.1 (Fed. Cir. Oct. 30, 2008) (Rader, J., dissenting) (stating that *Comiskey* does not actually hold that subject matter

2008]

be.").

^{415.} Burk & Lemley, *Policy Levers, supra* note 17 at 1634–35 (arguing that policy concerns are best handled on a case by case basis rather than through industry specific legislation).

^{417.} Carroll, *supra* note 413, at 893 ("The courts have resisted using discretion to sustain categorical exclusions from patentable subject matter, finding this to be too crude a filter.").

^{418.} *Cf.* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW § 2.2 (4th ed. 1992) (common law rules developed over time are efficiency maximizing).

^{419.} John A. Squires & Thomas S. Biemer, *Patent Law 101: Does a Grudging* Lundgren *Panel Decision Mean That the USPTO Is Finally Getting the Statutory Subject Matter Question Right?*, 46 IDEA 561, 582 (2006) ("Instead, the PTO should shift its focus to ensuring that only quality patents are granted. In order to do that, the PTO needs to better utilize the tools already at its disposal [O]nce the focus is properly placed on the quality of the patents it issues . . . it becomes clear that different tools, 35 U.S.C §§ 102 and 103, readily exist for the PTO to ensure such quality."); Burk & Lemley, *Policy Levers, supra* note 17, at 1639 (noting that standards "allow courts flexibility to accommodate different technologies within the general framework of patent law"); Carroll, *supra* note 413, at 893–94 (discussing rigorous patentability standards as reducing uniformity costs). *But see* Drennan, *supra* note 139, at 252–53 (arguing that applying patentability standards to tax patents is "messy" (quoting DONALD S. CHISUM, ET AL., PRINCIPLES OF PATENT LAW 847 (3d ed. 2004))); Burk & Lemley, *Policy Levers, supra* note 17, at 1639 (arguing that courts should sometimes implement bright-line rules).

the effect of diverting examination resources away from statutory patentability requirements and toward judicial subject matter limitations.⁴²² Examination resources should instead be focused on whether inventions meet each of the relatively well-settled statutory patentability criteria.⁴²³

One cost of *ad hoc* patentable subject matter definition⁴²⁴ is uncertainty and confusion in litigation and patent prosecution,⁴²⁵ and cases like *Bilski* and *Metabolite* that encourage unpatentable subject matter defenses in litigation serve to increase this cost.⁴²⁶ If courts impose further subject matter limits, uncertainty costs will continue to grow⁴²⁷ due to more extensive and prioritized subject matter inquiries in the PTO examination process.⁴²⁸ If nebulous subject matter requirements were actively enforced, then much more uncertainty would be injected into the patent system.⁴²⁹ The PTO's subject matter guidelines have already hopelessly confused subject matter with other patentability criteria,⁴³⁰ and

determinations must be done first).

423. *In re* Bergy 596 F.2d 952, 959–64 (C.C.P.A. 1979) (describing how most rigorous patentability standards are already in place).

424. That is, defining the rules themselves on a case by case basis.

425. Bergy, 596 F.2d at 961 ("The PTO, in administering the patent laws, has, for the most part, consistently applied § 102 in making rejections for lack of novelty. To provide the option of making such a rejection under either § 101 or § 102 is confusing and therefore bad law."); Conley & Makowski, *supra* note 41, at 378–79 ("The line between a product of nature, which does not constitute statutory subject matter, and a manmade machine, manufacture, or composition of matter, which does, has not been well defined The lower courts have been even less helpful in delineating the boundary between products of nature and patentable inventions. In the first place, courts have been inconsistent in deciding whether the product of nature problem is a section 101 subject matter issue, a section 102 novelty issue, a section 103 nonobviousness issue, or some combination of the three.").

426. See, Rochelle Cooper Dreyfuss, In Search of Institutional Identity, 23 BERKELEY TECH. L.J. 787, 789 (2008) ("[O]bservers of the patent system have voiced increasingly vociferous complaints about the state of patent jurisprudence . . . subjective elements in patent doctrine . . . increase costs and discourage inventors").

427. Kane, *supra* note 39, at 545–46 ("Yet, the prohibition on patenting laws of nature can result in an absurd kind of legal reductionism if a distinction is not made between the embodiments of physical laws and the laws themselves, such that all entities are judged to be the unpatentable expression of underlying natural laws.").

428. *In re* Comiskey, 499 F.3d at 1371 (subject matter to be determined *first*). *But see In re* Bilski, No. 2007-1130, 2008 WL 4757110, at *62, n.1 (Fed. Cir. Oct. 30, 2008) (Rader, J., dissenting) (arguing that *Comiskey* does not require such initial determination).

429. Bergy, 596 F.2d at 961.

430. See generally United States Patent and Trademark Office, Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Nov. 22 2005),

^{422.} Burk & Lemley, *Policy Levers, supra* note 17, at 1635 (noting administrative costs of industry specific rules); Cohen, *supra* note 16, at 1168 ("However, the intense focus on statutory subject matter ignores the existence of other statutory requirements for patentability."); Squires & Bierner, *supra* note 419, at 582 ("Special rules create special problems, particularly when a more general fix is required." (citing ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 203–05 (2004))).

more restrictions will only cause more confusion. Further, prioritizing the subject matter inquiry means that the PTO and courts would be forced to adjudicate difficult and poorly defined subject matter questions in patent applications that could otherwise be quickly disposed of on other grounds.⁴³¹ If § 101 determinations are to be made first, then such determinations should be straightforward and categorical.

A corollary concern also applies: given limited resources, excessive scholarly and popular focus on patentable subject matter detracts from focus on rigorous analysis of the other patentability criteria. A simple count of law review articles relating to the *Metabolite* opinion illuminates the attention given to uncertain patentable subject matter.⁴³² The time and effort spent thinking about and analyzing patentable subject matter could be better applied to the statutory requirements of patentability with more fruitful results in developing how statutory standards should apply to new technology.⁴³³

A further problem with broad, non-statutory subject matter restrictions is that such restrictions defeat the purpose of patent law.⁴³⁴ The constitutional authorization of patent law is to "promote the progress" of useful arts.⁴³⁵ The primary application of patent law is to determine whether a new technology is useful, novel, and nonobvious—even when the technology was not foreseen when the patent examination system was formed more than 150 years ago.⁴³⁶ If the

432. Cotter, *supra* note 266, at 872 ("But perhaps the most anticipated development in the law of patent eligibility in recent years turned out to be something of a non-event."). Database searches show approximately 100 articles predismissal, and more than 500 secondary source/law journal references to the dissent.

433. Ironically, the time spent in this Article as well.

435. U.S. CONST. art. I, § 8, cl. 8.

436. Gruner, *supra* note 91, at 396 ("The difficulty in defining patentable subject matter standards lies in describing a future range of potentially patentable technologies of value to the public, but which we cannot understand nor even remotely appreciate in concrete terms now.");

available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf; Osenga, *supra* note 5, at 1111 n.176 ("[I]t is unclear to me (and the 2005 Guidelines do not explain) why the examiner would need to conduct a thorough search of the prior art before determining subject matter eligibility under § 101."). *But see Bilski*, 2008 WL 4757110, at *8 ("whether a claimed process is novel or non-obvious is irrelevant to the § 101 analysis").

^{431.} *See, e.g.*, Dann v. Johnston, 425 U.S. 219, 223–25 (1976). In *Dann*, the Supreme Court granted certiorari on both subject matter and obviousness issues, but only ruled on the obviousness issue, which was much more easily disposed of. *Id*.

^{434.} The Supreme Court, lower courts, and commentators often rely on language from the Congressional Report related to the 1952 Patent Act stating that "anything under the sun made by man" is patentable subject matter. *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 309 (1979). However, the actual report only applies to two categories, "machine or manufacture." S. Rep. No. 82-1979 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H. R. Rep. No. 82-1923 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399. As such, the importance of this phrase on a policy basis may be overstated as to compositions of matter (*e.g.* biotech) and/or processes. In any event, the Report does support the rule proposed in this Article: "Section 101 sets forth the subject matter that can be patented, 'subject to the conditions and requirements of this title.'" *Id*.

patentability of a new art is in doubt until the Supreme Court rules on such art's subject matter appropriateness, then the patent system cannot foster progress in that art. Instead, technology would have to thrive despite the patent system rather than because of it. As a result, there is little reason to maintain the *status quo* and even less reason to expand or prioritize subject matter bars.

C. Potential Novelty Problems in Practice

A final concern with this Article's proposed rule is that the practical application of rigorous patentability standards will not invalidate particular patents that would otherwise be barred by subject matter rules. Part III addressed some of these concerns with respect to particular subject matter areas. This part discusses how one particular issue—preexisting materials and their effect on naturally derived products—might be affected if there were no judicial subject matter limitations.

1. Foreign and Unchanged Prior Art

One concern with reliance on novelty in natural product patents is that preexisting materials unknown in the U.S. or derived from materials located only in foreign countries ordinarily would not be included in prior art under § 102(a), which only bars patents for inventions "known or used" in the United States.⁴³⁷ This rule may lead to the patenting of derivatives of natural products such as a previously unknown plant or DNA that would not otherwise be patentable under this Article's proposal. However, to the extent that the natural product is truly unknown or available only overseas, then creating an incentive for inventors to seek out and disclose the utility of such compositions may be desirable.⁴³⁸ Those who would rather see such materials remain in the public domain could bring them to the United States or publish materials about them in order to defeat the novelty claims of others.⁴³⁹

Additionally, rigorous patentability could extend to bar patenting of such substances. One alternative is to use $\$ 102(f)^{440}$ to bar patents derived from

Kreiss, *supra* note 62, at 66; Kiley, *supra* note 7, at 474 (noting that if patents are limited to what Congress knows at any given time, then there can be few new patents because current technologies would be obvious).

^{437. 35} U.S.C. § 102(a) (2000). Note, however, that § 102(a) does include foreign prior art if it is published or patented. *Id*.

^{438.} *Cf.* The Incandescent Lamp Patent, 159 U.S. 465, 475–76 (1895) (use of Japanese bamboo in a light bulb).

^{439.} This is a partial answer to the protection (or non-protection) of traditional knowledge. Under this Article's proposal, traditional U.S. knowledge could never be patentable, and those wanting to stop patents on foreign knowledge would seek that knowledge out and publicize it.

^{440.} No patent may be granted if inventor "did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f) (2000).

preexisting materials wherever located.⁴⁴¹ An unchanged natural product is not invented by anyone.⁴⁴² Even if the material is modified, materials derived from another under § 102(f) could be considered prior art for obviousness consideration.⁴⁴³ Rigorous patentability implies that the literal terms of § 102(f) could apply to substances that are naturally occurring.

2. The Inherency Problem

One problem with the rigorous view of novelty proposed in this Article is that many patented or indisputably patentable inventions were merely extensions of preexisting natural phenomena.⁴⁴⁴ Many "natural" inventions throughout history were discovered both through ingenuity and by accident; this alone should not be a bar to patentability.⁴⁴⁵ For example, Pasteur invented germ-free yeast through the process of making beer.⁴⁴⁶ Even Edison's light bulb was an extension of the discovery that a certain type of bamboo would glow brightly conducting an electrical current without burning out of existence.⁴⁴⁷ Critics may then ask why these inventions should be considered novel while an isolated gene or test for a vitamin deficiency should not be patentable. As a result, gene patenting and *Metabolite* style cases are far more difficult from a policy standpoint than they may appear. Determining just what should and should not anticipate claims can be very difficult.

The answer lies in the inherency doctrine. Inherency is the "unintended, 'accidental' anticipation of an invention. [It] involve[s] the inherent, unintended production of a particular physical product." ⁴⁴⁸ In *Schering Corp. v. Geneva Pharmaceuticals*, the Federal Circuit ruled that the patent for Loratadine⁴⁴⁹

443. OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1403–04 (Fed. Cir. 1997).

^{441.} Liivak, *supra* note 159, at 265 ("The patent applicant cannot simply patent something they find even if they can prove that another *person* did not create it. Thus, secondly, originality also requires that the patent applicant did not copy or take the subject matter of the patent from *somewhere* else.") (emphasis in original).

^{442.} See 35 U.S.C. § 102 (2000). Indeed, such a substance might fail § 101 scrutiny as not being "new" – this is an argument for giving that term independent meaning. See text accompanying note 74 *supra*.

^{444.} *Cf.* Conley & Makowski, *supra* note 41, at 391 ("[T]he fact that an invention possesses novelty does not prove that it is not a product of nature, since new products of nature are discovered every day.").

^{445. 35} U.S.C. § 103(a) (2000) ("Patentability shall not be negatived by the manner in which the invention was made.").

^{446.} U.S. Patent No. 141,072, at [3] (filed May 9, 1873) (claiming "[y]east, free from organic germs of disease, as an article of manufacture").

^{447.} See The Incandescent Lamp Patent, 159 U.S. 465, 475–76 (1895).

^{448.} ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 190 (rev. 4th ed. 2007). "Anticipation" means that pre-existing knowledge deprives a patent claim of novelty under 35 U.S.C. § 102. *Id.* at 188.

^{449.} THOMPSON HEALTHCARE, INC., PHYSICIAN'S DESK REFERENCE: GUIDE TO INTERACTIONS, SIDE EFFECTS AND INDICATIONS 659 (2008) (stating that Loratadine is the generic name for

inherently anticipated a proposed patent claim for a composition generated by the human body while metabolizing Loratadine.⁴⁵⁰ The court ruled that Loratadine necessarily caused the production of the metabolized composition, and thus the composition was not novel.⁴⁵¹

Few cases have expressly invalidated a claim for inherent anticipation. Determining why is one of the problems with applying inherency doctrine.⁴⁵² In *Tilghman v. Proctor*, the Court considered the patentability of a process to separate component parts of fat by the use of "water at high temperature and pressure."⁴⁵³ Unexpectedly, the normal operation of known steam engines necessarily ("inherently") created the same compound due to the application of steam to the tallow fat used to lubricate parts.⁴⁵⁴ However, the Court did not invalidate the patent based on the steam engine; it held that a process not understood by ones skilled in the art could not bar a patent.⁴⁵⁵

However, the "lack of understanding" argument does not always hold true.⁴⁵⁶ In *In re Seaborg*, the Court of Customs and Patent Appeals considered the patentability of a new element, called "Element 95."⁴⁵⁷ Seaborg was the first to isolate the element. The patent specification discloses that the process for creating the element required a specific mix of raw materials, as well as a lengthy process for extracting the element from those materials.⁴⁵⁸ The inventor's method for extracting the element thus appears to have created something different not just in degree, but in kind.

However, the PTO objected because the same element was believed to exist as part of prior particle acceleration experiments.⁴⁵⁹ Seaborg argued that the theoretical existence of the element was less than one one-hundred millionth of a gram distributed among forty tons of uranium.⁴⁶⁰ The Court ruled that even if scientists *understood* that Element 95 had in theory been previously created, the amount was undetectable.⁴⁶¹ Seaborg does not apply the "understanding" rule of

453. Tilghman v. Proctor, 102 U.S. 707, 709 (1881) (quoting U.S. Patent No. 11,766 (filed Oct. 3, 1854)).

457. *In re* Seaborg, 328 F.2d 996 (C.C.P.A. 1964). Element 95 is now known as Americium. U.S. Patent No. 3,156,523, col.1, l.11-13 (filed Nov. 10, 1964).

Claritin®).

^{450.} Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1380 (Fed. Cir. 2003).

^{451.} *Id*.

^{452.} See generally Burk & Lemley, Inherency, supra note 39.

^{454.} *Tilghman*, 102 U.S. at 711–12.

^{455.} *Id.* Note, though, that this was a process patent; it may very well be that the steam process would bar patenting of the product if it was not already known. There was also a real question about whether the process actually separated the fat. *Id.* (*"if* the scum which rose on the water issuing from the ejection pipe was fat acid . . .") (emphasis added).

^{456.} Burk and Lemley argue that "lack of understanding" is not a dispositive factor in any inherency case. Burk & Lemley, *Inherency, supra* note 39, at 376–77.

^{458.} U.S. Patent No. 3,156,523 (filed Aug. 23, 1946).

^{459.} Seaborg, 328 F.2d at 997.

^{460.} Id.

^{461.} *Id.* at 998–99.

Tilghman, does not address isolation and purification, and does not provide a useful alternative framework for determining inherency.⁴⁶²

Furthermore, the "point of novelty" implications of *Parker v. Flook*, where scientific principles are treated as prior art, are difficult to square with *Tilghman's* "understanding" requirement. The difficulty with interpreting *Flook* as a novelty case is that the mathematical algorithm may not have been understood by those skilled in the art.⁴⁶³ Thus, the existence of the algorithm in nature should not have constituted inherent anticipation that would have barred patentability of the catalytic converter at issue.⁴⁶⁴

How then, should novelty and inherent anticipation be applied to the use of natural products and phenomena such as genes and medical tests? One potential solution is to apply the general rule suggested by Professors Lemley and Burk: if the public enjoys the "benefits" of a natural product, whether or not known, then no inventor can claim novelty in that product.⁴⁶⁵ The "benefits" analysis is consistent with the "known or used" bar to novelty.⁴⁶⁶ If the public is not obtaining a benefit, then a product is not used. This means that genes which only express proteins that already exist might not be novel, but spliced genes that express new proteins might be novel.⁴⁶⁷ "Benefits" should be expanded to include "benefits or detriments" or perhaps even "effects." As a result, a detrimental product of nature (say, poison ivy) might still inherently anticipate an extract of poison ivy. The "known or used" the prior product in any way, whether positive or negative.

Another potential reconciliation is to apply the general rule that unmodified preexisting materials or knowledge are not novel, but their use in unnatural ways

^{462.} *See generally Seaborg*, 328 F.2d 996. Professors Burk and Lemley attribute this ruling to a general notion that prior "inherent" creation of a product will not bar a patent where the public does not get the benefit of the inherent product. Burk & Lemley, *Inherency, supra* note 39, at 382–83.

^{463.} *See* Burk & Lemley, *Inherency, supra* note 39, at 407–08 (stating that the better test is whether the public obtained any benefit).

^{464.} Id.

^{465.} Burk & Lemley, *Inherency, supra* note 39, at 407; *see, e.g.*, Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 161 (4th Cir. 1958) ("As found in 'natural' fermentates, [vitamin B12] has no utility, therapeutically or commercially, until converted into compositions comparable to the patented products."); *see also* N. Scott Pierce, *A New Day Yesterday: Benefit as the Foundation and Limit of Exclusive Rights in Patent Law*, 6 J. MARSHALL REV. INTELL. PROP. L. 373, 416 (2007); *cf.* Foley v. United States 260 U.S. 667, 676–77 (1923) ("The assertions [that a non-infringing method inherently practices the patent] prove too much If the asserted result was inevitable in the method of the patents, it was inevitable in the method in use prior to the patents, and, we repeat, the patents are left without justification.").

^{466. 35} U.S.C. § 102(a) (2000) (emphasis added).

^{467.} *See, e.g.*, Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003) (metabolite of loratadine that is formed in the human body inherently anticipated by loratadine patent, which "enabled" one to ingest loratadine).

may be novel.⁴⁶⁸ For example, Edison's light bulb used a particular type of bamboo that had high electrical resistance.⁴⁶⁹ This was an unnatural use for a natural product.⁴⁷⁰ This rule could be considered a subset of the "benefits" test because the public might not benefit from a natural use.

This analysis confirms why *Metabolite* was a difficult case. Whether the public enjoyed the "benefit" of the natural relationship between homocysteine and vitamin deficiencies is not clear.⁴⁷¹ Thus, discovery and application of the relationship and disclosure of the benefit for the first time may very well have been novel.

3. The Anticipation/Infringement Dichotomy

Seaborg illustrates one additional potential problem with the novelty analysis discussed in Part III and in the previous subsections. The law of novelty follows the maxim, "that which would *literally* infringe if later in time anticipates if earlier than the date of the invention."⁴⁷² Applied to DNA, this means that if *in vivo* DNA would infringe a purified gene patent, then *in vivo* DNA would anticipate the gene patent. Those who support gene patents attempt to garner support by arguing that *in vivo* DNA would not infringe a gene patent.⁴⁷⁵

^{468.} *See, e.g.*, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."); Mackay Co. v. Radio Corp., 306 U.S. 86, 94 (1939) ("[W]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."); Tilghman v. Proctor, 102 U.S. 707, 729 (1880) ("The chemical principle or scientific fact upon which it is founded is, 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. This chemical fact was not discovered by Tilghman. He only claims to have invented a particular mode of bringing about the desired chemical union between the fatty elements and water.").

^{469.} The Incandescent Lamp Patent, 159 U.S. 465, 475–76 (1895).

^{470.} See id.

^{471.} Pierce, *supra* note 465, at 450–51 (arguing that the public did not benefit from the "natural" relationship, and thus the discovery was novel); LeRoy v. Tatham, 55 U.S. 156, 175 (1853) ("A patent will be good, though the subject of the patent consists in the discovery of a great, general, and most comprehensive principle in science or law of nature, if that principle is by the specification applied to any special purpose, so as thereby to effectuate a practical result and benefit not previously attained.") (citation omitted).

^{472.} Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis in original).

^{473.} See, e.g., Kevin Noonan, Science Fiction in the New York Times (Feb. 13, 2007) ("[A]nyone familiar with this space or any other truthful description of DNA patenting knows that patented DNA must be 'isolated' or 'isolated and purified.' In short, no one has ownership rights over 'your' DNA"), available at http://patentdocs.typepad.com/patent_docs/ 2007/02/science_fiction.html.

The problem thus lies in the logical contrapositive of the maxim: if *in vivo* DNA cannot infringe a gene patent, then *in vivo* DNA cannot anticipate a gene patent. In *Seaborg*, for example, the contrapositive appears to hold true—the prior experiments would not have infringed the "isolated" Element 95, and thus they did not anticipate the claim.⁴⁷⁴ Following this logic, *in vivo* DNA cannot deprive isolated gene claims of their novelty.⁴⁷⁵

Two potential answers exist that will allow the maxim and its contrapositive to hold true with the "benefits" view of inherency.⁴⁷⁶ The first approach is to accept that a gene patent would be infringed by *in vivo* DNA. This is called "inherent infringement,"⁴⁷⁷ and it is not unheard of.⁴⁷⁸ However, this does not mean that the maxim would cause infringement of every natural extract. If the test for novelty is whether the new composition is different in kind, then there is no need to worry about *in vivo* infringement because the composition will be different in fact. Patentees would be very unlikely to argue for *in vivo* infringement, because doing so would be tantamount to admitting that the composition is not novel.

The second answer is to apply an obviousness test instead of a novelty test. To the extent that an isolated composition is different from the natural prior art such that *in vivo* DNA neither anticipates nor infringes such a claim,⁴⁸⁰ it may still be obvious and unpatentable in light of the *in vivo* DNA.⁴⁸¹ Each of these two answers is consistent with the application of rigorous patentability in accordance with historical analytic principles in patent law.

CONCLUSION

Abandoning judicial subject matter restrictions will not answer all of the difficult patentability questions that have arisen and may yet arise as our nation's inventors and researchers continue to discover new technologies. Those difficult questions, however, should be answered by the general criteria that Congress has established—criteria that have worked for over 150 years—to determine whether a particular patent claim should be allowed.

^{474.} In re Seaborg, 328 F.2d 996, 997 (1964); Merges & Duffy, supra note 162, at 189, 374.

^{475.} *Cf.* Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381 (Fed. Cir. 2003) (holding that a nonisolated composition claim is anticipated by chemicals in the body, but stating in dicta that isolated composition would not be anticipated). *Schering* cites the anticipation/infringement maxim with approval. *Id.* at 1379.

^{476.} A third, more simple answer is to accept that the contrapositive need not be true, but that solution has not been borne out over time, nor is it logically satisfying.

^{477.} Burk & Lemley, Inherency, supra note 39, at 401 (discussing inherent infringement).

^{478.} *Id.* (discussing Smithkline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004)).

^{479.} *See, e.g., id.* at 401 n.152 (noting that a patent that was "inherently infringed" was ultimately invalidated based on inherent anticipation).

^{480.} Thus, it would be novel.

^{481.} *But see* Cohesive Tech, Inc. v. Waters Corp., 543 F.3d 1351, 1364–65 (Fed. Cir. 2008) (inherent prior art need not lead to obviousness).

The exact contour of the trade-offs between innovation and patent protection are largely unknown. Therefore, the PTO and courts should focus on answering specific questions about how to best apply rigorous standards of novelty, nonobviousness, utility, and specification with a scalpel rather than simply eliminating broad swaths of innovation with a machete.